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Bariatric Arterial Embolization: Position Statement by the Pan Arab Interventional Radiology and the Saudi Interventional Radiology Societies

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Preface

These guidelines are developed based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system.[1] Grading strength of recommendations and quality of evidence is based on the UpToDate classification [Appendix A].[2] The scientific committees of the Pan Arab Interventional Radiology Society (PAIRS) and the Saudi Interventional Radiology Society (SIRS) nominated the guidelines development group (GDG) based on their expertise in the field of vascular interventional radiology and bariatric surgery from both private and academic institutions. Members are selected from different countries to further represent wide geographic distribution and institutional variations in practice within the Middle East and North Africa (MENA) region.

Definitions and Abbreviations

1. Obesity: The World Health Organization (WHO) defines obesity as a body mass index (BMI) ≥30 kg/m^2
   a. Obesity Class I: BMI of 30.0–34.9 kg/m^2
   b. Obesity Class II: BMI 35.0–39.9 kg/m^2
   c. Obesity Class III: BMI Above 40 kg/m^2.
2. Overweight: BMI ≥25 kg/m^2
3. Ideal body weight (IBW): There are several methods for calculating IBW. Based on Lorentz formula,[3] IBW is calculated as follows:
   a. Males: IBW = (height [cm]−100)−([height (cm)−150])/4
   b. Females: IBW = (height [cm]−100)−([height (cm)−150])/2.
4. Excess body weight: Current weight − ideal weight
5. Weight changes are expressed in the literature using several parameters including:
   a. Percentage total weight loss = ([Pretreatment total weight − post treatment total weight]/ Pretreatment total weight)
   b. Percentage excess weight loss (EWL) = ([Pretreatment excess weight − Posttreatment excess weight]/Pretreatment excess weight) × 100
   c. Percentage BMI reduction: ([Pretreatment BMI − Posttreatment BMI]/pretreatment BMI) × 100
   d. Waist circumference change[4]
   e. Weight-to-height ratio change[4]
   f. Total body fat area = Subcutaneous + visceral + intramuscular fat areas[3]
   g. Total abdominal adipose tissue = Subcutaneous + visceral fat areas[4]
   h. Subcutaneous fat area: Determined on computerized tomography/ magnetic resonance imaging (CT/ MRI) using the outer boundary of the abdominal wall muscles and paraspinal muscles[3,4]
   i. Visceral fat area: Determined on CT/MRI using the inner boundary of the abdominal wall muscles and paraspinal muscles[3,4]
   j. Intramuscular fat: Determined on CT using the threshold attenuation values for fat (between − 190 and − 30 HU) within the skeletal muscle compartments.[3]
6. Ghrelin: A neuropeptide predominantly produced in the gastric fundus, which

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stimulates growth hormone secretion and food intake, and is considered a primary regulator of appetite.[5] Other hormones (cholecystokinin, leptin, peptide YY3-36, and glucagon-like peptide-1) involved in satiety control are discussed in depth in literature[5]

7. Bariatric arterial embolization (BAE): This technique entails transarterial embolization of the arterial supply to the gastric fundus using various embolic agents for bariatric indications. BAE term encompasses embolization of vessels other than the left gastric artery, such as the right gastroepiploic artery
8. Left gastric artery embolization (LGAE): This refers specifically to isolated left gastric artery transcatheter embolization
9. Gastric artery chemical embolization: Refers to LGAE using chemical liquid embolics such as morrhuate sodium[6,7]
10. BEAT Obesity trial: Bariatric Embolization of Arteries for the Treatment of Obesity[8,9]
11. GET-LEAN trial: Gastric Artery Embolization Trial for the Lessening of Appetite Nonsurgically[10]
12. EMBARGO trial: Embolization of arterial gastric supply in obesity.[11]

Methods

A comprehensive literature review was conducted using the medical subheading (MESH) terms and Boolean operators searching "bariatric" AND "embolization," then "LGAE" AND "bariatric." After eliminating the irrelevant titles, a total of 34 records were retrieved including reviews, commentaries, preclinical, retrospective, prospective studies, and case series/reports. Literature search was updated on October 24, 2019 before the final release of the document. The articles were distributed to all members before drafting the guidelines and recommendations. Initial draft was circulated between the GDG members and underwent several rounds of discussion and review using online platforms. The document was then refereed for external expert review for further evaluation and comments (A. J. Gunn). The final document was reviewed and endorsed by the scientific committees and received final approval by the executive boards of both PAIRS and SIRS.

Aim

The prevalence of obesity is increasing in the MENA over the past several decades.[12] For example, more than 30% of the adult population are considered obese in Kuwait, Jordan, Saudi Arabia, Qatar, Libya, Turkey, Lebanon, Egypt, United Arab Emirates, and Iraq.[12] As such, dietary, surgical, and endoscopic bariatric interventions are on the rise in the Arab World and Gulf countries in attempt to contain this epidemic.[13] Recently, bariatric arterial embolization (BAE) has been introduced as a minimally invasive procedure for appetite control and weight loss. However, the scarcity of evidence and lack of standardized protocols for this intervention necessitate careful evaluation. The aim of this document is to provide a position statement on BAE by PAIRS and the SIRS and to propose a protocol for future research studies on BAE.

Background

The endocrine function of the gastric fundus in regulating satiety and body weight is predominantly controlled by Ghrelin, which stimulates growth hormone secretion and food intake. Several other hormones produced by the gastrointestinal (GI) tract are involved in metabolic homeostasis.[5] Early preclinical animal studies have identified a link between suppression of plasma concentrations of Ghrelin and devascularization of the gastric fundus by occlusion of the left gastric artery by means of chemical embolization,[6,7] particulate embolics,[11,14-19] surgical clipping,[20] or radioembolization with Y90.[21] This results in decreased appetite and weight Modulation as a result of reducing Ghrelin-expressing cells in the gastric fundus.[6,7,11,14-18,20-22]

Early weight loss was reported in patients with GI bleeding who underwent LGAE compared to those who had embolization of different mesenteric vessels.[23-25] Body composition analysis following LGAE for gastric bleeding indicated significant decrease in subcutaneous and total body fat as well as skeletal muscle index leading to significant decrease in body weight and BMI.[3]

Effects of BAE on weight

The currently reported retrospective studies and prospective trials included obese patients with mean BMI range between 38 and 52 kg/m^2 and reported short-term clinical outcomes.

In a retrospective study on patients who underwent LGAE for GI bleeding indications, the LGAE group lost an average of 7.3% of initial body weight at 3 months after embolization, which was significantly greater than the 2% weight loss observed in the control group of other mesenteric embolization.[24] Kim *et al*. reported a median of 16.3 kg weight loss over a median time of 12 months (range, 2–72 month) following LGAE in cancer naïve patients with upper GI bleeding.[23] Similarly, Kevin Anton *et al*. reported significant early (1 and 4 month) weight loss after LGAE for bleeding indications; however, weight change was not significant at 8 and 12 month compared to the control group of other mesenteric arterial embolization.[25]

The GET-LEAN trial reported average EWL at 6 months of 17.2%.[10] Bai *et al*. demonstrated significant average weight loss of 10.4 kg at 6 month following BAE.[4] The BEAT trial, which enrolled 20 participants with mean BMI of 45 kg/m^2, showed that BAE resulted in significant weight loss of 11.5% at 6 months, which was maintained until 12 months of follow-up. Kipshidze *et al*. reported that all 5 patients maintained significant weight loss of

17% at 20–24 months post BAE.[26] Zaitoun *et al*. reported significant BMI reduction of 8.8% at 6 months following the procedure.[27] Elens *et al*. evaluated BAE in overweight patients with mean baseline BMI of 28.9 kg/m^2. The mean early weight loss in 9 patients at 6 months was 8 kg, which corresponded to 10% of their baseline weight. One-year follow-up was available in 3 patients who maintained mean weight loss of 9.66 kg.[28] In a recent pooled analysis[29] of 47 patients in 6 studies,[4,8,10,26,28,30] BAE resulted in statistically significant mean absolute weight loss of 8.85 kg (7.6–22 kg) correlating to mean percentage weight loss of 8.1% (4.7%–17%) at 12-month follow-up. Male sex was associated with greater weight loss compared to females.[29]

Effects of BAE on glycemic control and lipid profile

The HgbA1c-lowering effect of BAE is demonstrated in few reports.[8,10,27] Zaitoun *et al*. evaluated the effect of BAE on 10 obese prediabetic patients with baseline BMI of 37.4 kg/m^2 and mean HgbA1c of 6. There was statistically significant reduction in mean BMI and HbA1c of 8.8% and 21.4%, respectively. In the BEAT study, the mean total cholesterol and low-density lipoprotein levels were lower at 12 months compared to their respective means at baseline. Conversely, the high-density lipoprotein was significantly higher at 12-month follow-up. Mean triglycerides initially decreased at 1 month, then increased back to baseline levels at 3, 6, and 12 months. Hemoglobin A1c at 12 months was significantly lower than baseline but did not correlate with weight change.[8] Although there is a favorable signal to improved lipid profile and glycemic control during the 1st month after BAE, these changes require careful evaluation in future studies.

Candidates for bariatric artery embolization

- Patients with severe or morbid obesity (WHO grade 3, BMI >40 kg/m^2), or with complications of obesity should be offered surgical interventions first. BAE may be offered as alternative option for nonsurgical candidates or those who refuse surgical procedure (Grade 2C)
- We suggest limiting BAE to individuals with WHO grade ≥2 obesity to achieve clinically meaningful weight loss (Grade 2C)
- There is limited evidence studying the metabolic effects of BAE, such as improvements in glycemic control. Therefore, BAE should not replace proven medical or surgical therapies for patients with diabetes or prediabetes
- Nutritional consultation is vital for all patients before and following BAE. Patients with a known history of eating disorders should not undergo BAE
- Patients with active or a history of peptic ulcer disease should not undergo BAE
- Patients with prior surgery to the stomach or small intestine should not undergo BAE.

Effects on quality of life

Weight changes after BAE are correlated with decreased hunger scores and improved QoL as demonstrated by the GET-LEAN and BEAT trials.[8,10] The psychological impact of weight changes, waist circumference decrease, and improvement in mental and physical scores may help in maintaining appetite control and lifestyle modifications. Nonetheless, QoL and other mental scores need to be carefully evaluated in future studies and compared to other methods of weight reduction.

Effects of BAE on gastric mucosa

One of the main concerns in BAE is the sequelae of gastric ischemia and the histologic changes induced by BAE. Initial animal studies demonstrated reduction in Ghrelin-expressing cells in the gastric fundus with preservation of the overall architecture and parietal cells,[7,16] with a trend toward increased fibrosis in the gastric fundus[16] Although mucosal gastric ulcers are reported post gastric artery embolization in both animal[16,19,21] and human studies,[4,8,9,23,28,31] majority of ulcers healed spontaneously with no major complications. Only single case of gastric perforation and splenic infarction was reported following BAE with 500–700 polyvinyl alcohol (PVA) particles.[28] The use of smaller particles (100–300 μ) appears to induce greater weight loss, but with more gastric ulcerations.[19] The administration of gastroprotective agents and embolization of fewer arteries to the gastric fundus did not prevent gastric ulceration in porcine models.[15]

Gastrointestinal protection

- We recommend the use of gastroprotective agents (oral omeprazole 40 mg twice daily and sucralfate 1 g four times daily) 2 weeks before BAE and 6 weeks after (Grade 2C)
- It is advised to perform upper endoscopy prior to BAE and within 4 weeks after procedure to further document the impact of gastric embolization on gastric mucosa (Grade 2C)
- We suggest a single dose of pre procedure prophylactic antibiotics.

Effects of BAE on fundal vascularity and future bariatric surgery

Diana *et al*. performed surgical clipping of the gastric artery in porcine models and demonstrated increased vascular anastomotic network in the fundus in 2 of pigs with no noticeable change in the remaining 3 animals.[20] The EMBARGO trial, which investigated the possibility of sleeve gastrectomy after LGAE, suggested that embolization may enhance the vascular supply to the gastroesophageal junction in preparation for sleeve procedure.[11]

Although some authors caution that BAE may preclude future bariatric surgery due to potential compromise of

fundal vascularity,[32,33] the evidence to support or refute this concern remains not investigated. In human subjects, there is a single reported case of bariatric surgery 2 years after bariatric embolization.[28] None of the existing human studies evaluated fundal vascularity by catheter or CT angiography following BAE.

BAE and future bariatric surgery

- Due to concerns about the safety of bariatric surgery following BAE, the GDG recommends careful multidisciplinary patient selection and counseling of patients who may require future bariatric surgery
- Patients who will undergo bariatric surgery after BAE may require evaluation of the gastric arterial supply by catheter or CT angiography to determine the patency of fundal supply.

Proposed BAE technique

Access

Avoiding puncture site complications is of particular importance in morbidly obese patients. Femoral artery access in morbidly obese patients is shown to be associated with greater risk for bleeding and access site complications after coronary interventions.[34-36] Therefore, transradial approach has become the standard access for coronary interventions particularly in this subset of patients. Adopting transradial access (TRA) for visceral interventions is gaining increasing popularity[34-36] as it is associated with improved patient experience and shorter recovery times; however, it can be more technically challenging and may require longer procedure/fluoroscopy times.[37,38] Pirlet *et al*. performed a pilot study to evaluate the feasibility, safety, and efficacy of LGAE using TRA.[30] The mean fluoroscopy time in their study was 10 min, which appears shorter than what is reported in the GET-LEAN study (26 min)[10] and the BEAT study (31 min).[8] No puncture site complications were reported in neither femoral nor radial access BAE interventions.

- The choice of arterial access should be at the discretion of the operator's expertise. However, it is advised to use radial access for BAE interventions whenever possible to improve patient satisfaction and minimize vascular complications associated with morbid obesity. Availability of TRA expertise and equipment is paramount to ensure shorter fluoroscopy times and lower radiation exposures (Grade 1A).

Choice of embolic agent

Various methods have been reported for left gastric artery occlusion for bariatric or bleeding intentions including surgical clipping, chemical sclerosants, gelfoam, coils, Y90 radioembolization, and most commonly particulate embolics. Bariatric embolization should achieve sufficient devascularization of the gastric fundus and Ghrelin-producing cells without resulting in mucosal ischemia and ulcerations. Larger particles may aggregate in the proximal vessel and may result in less devascularization of the target cells due to collateral filling from other arterial anastomosis. On the other hand, smaller particles may lead to more gastric ulcers but associated with greater weight loss as demonstrated in animal study by Fu *et al*.[19]

In the clinical studies on BAE, particulate size was 300–500 μ[8-10,26,27,30,31] or 500–700 μ.[4,28] Only single case of gastric perforation is reported with the use of 500–700 μ PVA particles, without details on the embolization procedure.

- Comparative safety and efficacy data on the choice of embolic agent and particulate size remain lacking and require further research
- We suggest to use particulate size of 100–300 or 300–500 μ until further evidence is available (Grade 2C)
- Proximal embolization with coils or vascular plugs should be avoided as it may preclude future embolization and may not be sufficient for fundal devascularization due to collateral anastomosis (Grade 2C)

Number of embolized vessels

LGAE was performed in all previously reported studies.[4,8-10,26-28,30,31] The gastroepiploic artery was embolized in 3 patients in the BEAT study.[9]

- We recommend careful evaluation and mapping of the fundal arterial supply before bariatric embolization (Grade 1A). It is advised to perform pre procedure CT angiography to assess the vascular anatomy and determine the arterial access
- Identification of left gastric artery variants is essential to achieve proper embolization of the fundus
- Gastroepiploic artery embolization may be considered if fundal blush is deemed incomplete on the left gastric artery angiography
- It is advised to perform selective cannulation of the fundal branches to minimize the risk of mucosal ulceration and non-target embolization such as to the pancreas or spleen.

Postprocedure care and follow-up

- We recommend the use of gastroprotective agents 2 weeks before BAE and 6 weeks after
- We recommend close monitoring of weight changes to determine the effectiveness of BAE. Long-term outcomes are needed to determine the durability of BAE
- We recommend strict adherence to dietary regimens to further augment the benefits of BAE
- Ghrelin monitoring is advised, particularly in the context of research protocols
- Periodic HgbA1c and lipid profile monitoring is recommended in prediabetic and diabetic patients

- It is advised to perform upper endoscopy before BAE and within 4 weeks after procedure to further document the impact of gastric embolization on gastric mucosa (Grade 2C).

Conclusion

There is scarce evidence that indicates the safety and effectiveness of BAE in achieving early weight reduction and possibly glycemic control. The intermediate and long-term effects of BAE in maintaining Ghrelin levels and weight loss are unknown yet. The ideal BMI of candidates remains unclear, and additional studies are still required. The GDG concludes that BAE should only be conducted in the context of clinical trials and proposes the aforementioned protocol recommendations based on the existing preclinical and clinical evidence as well as authors' expertise in the field.

Disclaimer

These guidelines serve as an educational resource to help practicing physicians in their approach to candidates for bariatric arterial embolization and to promote high-quality clinical practice and research. These guidelines are drafted based on currently available evidence, and recommendations may change over time as new evidence emerges. This document is not intended to be a legal standard of care and its use should be at the discretion of the practicing physicians. PAIRS and SIRS are not responsible for any clinical actions taken based on these guidelines.

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Conflicts of interest

There are no conflicts of interest.

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Appendix A: UpToDate grading recommendations

Grade of recommendation	Clarity of risk/benefit	Quality of supporting evidence	Implications
1A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Strong recommendations: can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present
1B. Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Strong recommendation: applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present
1C. Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain	Strong recommendation: applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Weak recommendation: best action may differ depending on circumstances or patients or societal values
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens, some uncertainly in the estimates of benefits, risks, and burdens	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Weak recommendation: alternative approaches likely to be better for some patients under some circumstances
2C. Weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain	Very weak recommendation: other alternatives may be equally reasonable