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LETTER TO THE EDITOR

# Response to Letter to the Editor: Left Gastric Artery Embolization for Weight Loss—a Dead-End Procedure

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To the Editor,

We have been following, with great interest, the continued and balanced discussion surrounding the results published by Bai et al., "Bariatric embolization of the left gastric artery for the treatment of obesity: 9-month data in 5 patients."

Our interest was piqued by two key points.

Firstly, Bai and colleagues reported their first experience with a new approach to treat obesity, bariatric embolization [1]. There may be a treatment potential with this method that should not be hastily disqualified [2]. In fact, it could fit into an existing treatment gap between those who qualify for pharma/conservative treatment of obesity and those who qualify for established bariatric/metabolic procedures [3].

Secondly, our interest in this discussion is amplified by our own ongoing prospective, randomized, sham-controlled, single-blind trial involving 40 patients (BMI 35–50 kg/m$^2$) whom consented for left gastric artery embolization (LGAE) using 300–500-μm microspheres through the Lamina™ Infusion System (EndoBar, Orangeburg, NY, USA). All patients were followed-up for 12 months and the study was approved by the IRB as well as by SUKL (State Institution equivalent of FDA in the USA).

Among other objectives, the main goals of the study were, but not limited to, assess the safety of the embolization procedure, changes in weight loss (%TBWL and %EWL), and changes in incretin levels (Ghrelin, GIP, GLP-1, Resistin, PAI-1, and others) up to 12 months after embolization.

Patients (mean BMI 39.6 kg/m$^2$ ± 3.77 kg) were recruited and randomized to either undergo LGAE or an equitable sham procedure. They were blinded to their group assignment and were unable to identify which group they were assigned to as both groups received sedation, local anesthesia in the groin, and at a minimum their skin was punctured with a needle. Both groups also followed comprehensive lifestyle therapy.

After 6 months, the sham group was unblinded and crossed over to undergo LGAE. Twelve months study results are indeed encouraging, as there is a statistically significant and clinically meaningful difference between the Treatment and sham groups.

Preliminary results of our RCT demonstrated that the majority of treated subjects sustained ≥ 5% TBWL out to 12 months, with a statistical superiority over the sham group at 6 months. With regard to safety, no serious adverse events were reported, while a small minority ($n = 7$) of subjects demonstrated superficial, small ulcers. Final safety and efficacy data from our RCT are forthcoming.

Some critics of LGAE cited concerns with the possibility of a second procedure. With our own RCT, despite the fact that patients achieved weight loss during the study, two of the study patients asked for an additional bariatric/metabolic operation in order to further leverage the weight loss they already experienced within the study.

Sleeve gastrectomy was performed in one of them, the second patient was subjected to laparoscopic gastric plication. The entire stomach was perfectly vital during both operations as well as the blood supply of the remaining stomach tube was not compromised. At the beginning of both operations, laparoscopies did not reveal any signs of adhesions or any alteration of serosal layer of the stomach wall in the left gastric artery region. However, the only finding different from non-embolized patients was more pronounced (serpentine type curved /coiled) appearance of small arteries within the serosal stomach layer at the lesser curvature compared to non-embolized patients Fig. 1. Both of our patients recovered without any perioperative or postoperative complications, and their postoperative course

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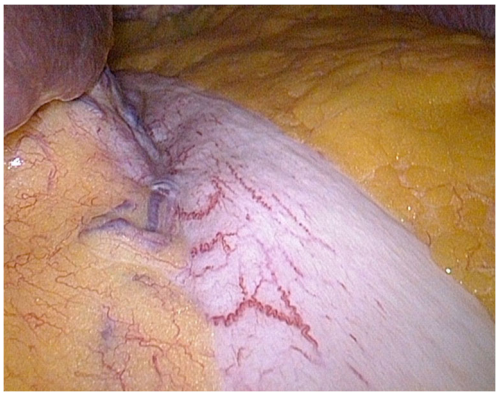

**Fig. 1** Small arteries within the serosal stomach layer at the lesser curvature

was uneventful. They were discharged home as per our institutional guidelines, and sent home no different if they had received these procedures naïve (i.e., not embolized previously).

Our recent RCT supports those observations of Bai and colleagues, in regard to the promising effect of left gastric artery embolization on weight loss and Ghrelin lowering [1]. Preliminary findings from Weiss and colleagues on Phase I of the BEAT Obesity trial (prospective, single-arm) also show promising clinical results with bariatric embolization. Both Bai et al. and Weiss et al. reported no major adverse events, and our RCT findings demonstrated a similar safety profile. Of course, long-term durability of the intervention should be further investigated (i.e., 2 + years), as no data currently exists at this point [1, 4].

However, given our own experience, we respectfully disagree with several of the concerns raised by Fink and colleagues [2].

They state that in general there's no need for other, non-invasive procedures, and that the current array of treatment options is sufficient (established laparoscopic bariatric/metabolic operations on one side and intragastric balloons together with pharmacotherapy (Liraglutide) on the other side) [2]. In our opinion, there's an opportunity to fill in the existing gap and unmet needs in the underserved area between those therapeutic modalities, both from an economical perspective as well as the opportunity to have a low-invasive treatment for those who may not qualify for a more invasive surgery. Additionally, we must not forget the perspective of the patient and to provide them with evidence-based treatment options. There's a large group of patients (and some medical specialties) to whom the currently available surgical interventions seem too aggressive/invasive to seek the treatment, or to refer the patients to surgeries. At the same time, balloons and pharmacotherapy are not considered as effective for this subset and/or may be perceived as inconvenient.

Fink and colleagues postulated that embolizing the left gastric artery leaves almost no room for a second, established bariatric procedure. In our experience with 40 patients, this is just a hypothetic speculation. With our knowledge and clinical experience, there is no evidence to support this concern. On the contrary, two of our own LGAE patients recently underwent successful re-operation. We found that there were still options available to these patients to receive a secondary, established bariatric/metabolic procedure.

New technologies and emerging treatment possibilities naturally warrant caution, as was witnessed in the past with many other surgical procedures of which many are considered a standard nowadays. In our opinion, gastric artery embolization at this stage does not exhibit any major, threatening complications, or drawbacks to deem it as a Dead-End Procedure [5–9). On contrary, results of our own study suggest that there may be a potential in treating obesity and metabolic disorders. These findings encourage the need for more studies and research on bariatric embolization.

## Compliance with Ethical Standards

**Conflict of Interest** Martin Fried was Principal Investigator of the RCT and Nodar Kipshidze was Endobar Solutions LLC Part-time consultant for statistical analysis.

**Ethical Approval Statement** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed Consent Statement** Informed consent was obtained from all individual participants included in the study.

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