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Gastric Embolization as Treatment for Overweight Patients; Efficacy and Safety

S. Elens[1] · T. Roger[2] · M. Elens[3] · J. Rommens[2] · A. Sarafidis[2] · E. Capelluto[2] · C. Delcour[4]

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Abstract

Objectives The aim of this study was to evaluate the efficacy and safety of left gastric artery (LGA) embolization for the treatment of overweight patients who weren't candidates for bariatric surgery.

Materials and Methods We retrospectively collected data of 16 patients who underwent a selective embolization of the LGA. The mean body mass index (BMI) before intervention was 28.9 kg/m^2 ± 2.5, and therefore, patients were not candidates for bariatric surgery in Belgium. The embolization was realized with 500–700 µm particles via the right common femoral artery approach. Before and following the intervention, an upper endoscopy was performed. Patient demographics, weight loss, hunger sensation and a satisfactory scale were reviewed.

Results Between February 2015 and May 2017, 16 overweight patients were treated, one embolization was unsuccessful. Four (25%) patients were lost in follow-up. Nine (56%) patients showed early weight loss, one (6%) maintained his bodyweight and one (6%) patient underwent bariatric surgery 2 years after consultation. Only one (6%) patient had a gastric ulceration on control endoscopy. One (6%) patient ended in the intensive care unit for pancreatitis and gastric perforation. The mean weight loss was 8 kg ± 5.12, reducing their mean BMI to 25.5 ± 3.5. The hunger sensation was decreased, and patients were satisfied.

Conclusion This is a preliminary study in an overweight population that appears to induce weight loss and appetite suppression. Larger studies are needed to confirm these preliminary findings.

Keywords Bariatric · Embolization · Overweight · Endovascular

✉ S. Elens
stephanieelens@gmail.com

T. Roger
thierry.roger@skynet.be

M. Elens
elensmaxime@gmail.com

J. Rommens
jacques.rommens@chirec.be

A. Sarafidis
asarafidis@skynet.be

E. Capelluto
capellutoelie@yahoo.fr

C. Delcour
christian.delcour@chu-charleroi.be

[1] Hopital Erasme, Route de Lennik 808, 1070 Brussels, Belgium

[2] CHIREC Site Delta, Boulevard du Triomphe 201, 1160 Brussels, Belgium

[3] Hôpital Universitaire de Saint-luc, Avenue Hippocrate 10, 1200 Woluwe-Saint-Lambert, Belgium

[4] Hôpital Marie Curie, Chaussée de Bruxelles 140, 6042 Charleroi, Belgium

Introduction

In October 2017, the World Health Organization updated the numbers on obesity and overweight. Since 1975, obesity has nearly tripled worldwide. In the adult population,

39% were overweight in 2016 and 13% were obese. Raised body mass index (BMI) is linked to various comorbidities including diabetes type II, cardiovascular diseases, musculoskeletal disorders, cancers, etc. The risk for these comorbidities increases, with increasing BMI.

A normal BMI is between 18.5 and 24.9, so we speak about overweight when the BMI is more than 24.9 but less than 30. Once above 29.9 we speak about obesity.

Traditional management of overweight and obesity with exercise, low-calorie diet, behavior modification and pharmacotherapy can lead to a net energy deficit although the limited effectiveness had driven the need to more sustainable therapies like bariatric surgery [1]. Surgery is momentarily the best-known option for sustained and clinically meaningful weight loss in obese patients. The high morbidity rate due to the invasiveness of the technique and the cost are limiting factors to surgery [2]. Therefore, less invasive therapies that could also target earlier stages of obesity are warranted [3].

Gastric embolization for weight loss has been introduced in a porcine model by Arepally et al. [4]. Since the successful animal model, human studies are ongoing in the USA on obese patients with BMI > 40, but these studies have still a restricted number of patients [5–9].

The rationale for left gastric artery (LGA) embolization is based on the hormonal role played by the stomach in hunger and satiety. Ghrelin is an orexigenic hormone that is produced primarily and secreted at 99% by the gastric fundus [10]. A selective embolization of the LGA responsible for the fundic blood supply with embolic microspheres causes an ischemic insult of the ghrelin-producing cells [11].

To help patients with a BMI not high enough for bariatric surgery and after a multidisciplinary board decision, the novel treatment by embolization of the LGA could be offered as a minimal invasive alternative. The effects of bariatric embolization have never been studied in an overweight population (BMI between 25 and 30 kg/m^2) before.

The purpose of this study was to evaluate the feasibility, safety and the short-term efficacy of LGA embolization on overweight patients.

Materials and Methods

The present study complies with the principles outlined in the Declaration of Helsinki. Approval for this retrospective data analyses with retrospectively and prospectively gathered data in a monocenter setup was obtained from the ethic committee (EC 332 (OM 157)).

Table 1 shows the complete list of inclusion and exclusion criteria.

Study Population

Between February 2015 and May 2017, 26 patients over the age of 18, with a BMI between 25 and 30 kg/m^2, were sent by a bariatric surgeon to our interventional radiology consultation. All patients sought help because they failed to lose weight with diet and advice. They all underwent a comprehensive medical examination that included a history, physical examination and blood tests. An upper endoscopy was performed by the gastroenterologist as part of the screening process to exclude gastric ulcers or polyps. After an extended explanation of the procedure, 10 patients refused the endovascular treatment, and thus 16 patients were enrolled in the study.

The 16 remaining patients underwent LGA embolization in our institution by an experienced interventional radiologist. Patient demographics are listed in Table 2. Bariatric embolization was performed in sixteen overweight adults: 14 women (87.5%) and two men (12.5%) with a mean BMI of 28.9 $\pm$ 2.5 kg/m^2.

The pre-interventional upper endoscopy revealed peptic esophagitis in 11(78.7%) patients.

Embolization Procedure

Standard microcatheters, guidewires, and embolic agents that are commonly utilized in visceral interventions were also used for the LGA embolization. All procedures took place under local anesthesia, and percutaneous approach was performed by a retrograde puncture of the common femoral artery and a 5F sheath (Cordis, Miami, FL) was then inserted. Selective catheterization of the celiac trunk was achieved with a 5F cobra catheter (COOK, Bloomington, Indiana), and selective catheterization of the LGA was realized with a 5F multipurpose (MP) catheter. In 3 patients, a 5F van Schie catheter (Cook, Bloomington, Indiana) was used to catheterize although this was taken out of the market and till now the 5F MP catheter is still used to perform the catheterization. Digital subtraction angiography (DSA) of the celiac trunk and the superior mesenteric artery (SMA) was performed to identify all arteries supplying the gastric fundus including the LGA and other potential accessory gastric arteries Once understanding the angio-architecture of the LGA and his distal branches, a coaxial Progreat 2.7F (Terumo, Tokyo, Japan) microcatheter and his guidewire was advanced approximately three to four cm distally from the origin of the LGA. Selective angiography was performed to ensure proper catheter position and allow definition of the anatomy and course of the LGA.

In two (12.5%) patients, a retrograde catheterization via the SMA and the gastroduodenal artery was needed to reach the LGA due to an early origin of the LGA on the

Table 1 Inclusion and exclusion criteria

Type and no. of criteria	Criterion
Inclusion	
1	Willing, able, and mentally competent to provide written informed consent
2	BMI between 25 and 35 kg/m^2
3	Age > 18 years
4	Suitable for protocol therapy, as determined by the interventional radiology investigator
Exclusion	
1	Prior gastric pancreatic, hepatic, and/or splenic surgery in the year before potential embolization
2	Prior radiation to the upper abdomen
3	Prior embolization of the stomach, spleen, or liver
4	Portal venous hypertension
5	Current peptic ulcer disease
6	Daily nonsteroidal anti-inflammatory drug, steroids or anti-coagulants use
7	Substantial risk factors for peptic ulcer disease, including daily nonsteroidal anti-inflammatory drug use
8	Known disease with secondary obesity
9	Psychiatric disorder
10	Known aortic disease (e.g., aneurysm, dissection) and renal insufficiency as evidenced by an estimated glomerular filtration rate of, 60 mL/min
11	Enrolled in other studies
12	Pregnancy
13	Preexisting chronic abdominal pain
14	Cirrhosis
15	History of allergy to iodinated contrast media

Table 2 Patient demographic data

Patient no.	Age (y)	Sex	Weight (kg)	Height (m)	BMI (kg/m:
1	19	F			
2	38	F	72	1.58	28.842
3	37	M	100	1.89	27.995
4	40	F	72.5	1.52	31.380
5	35	F	84	1.65	30.854
6	49	F	73	1.65	26.814
7	48	F	81	1.78	25.565
8	34	F	71	1.59	28.084
9	36	M	89	1.75	29.061
10	18	F	80	1.56	32.873
11	52	F	66	1.49	29.728
12	38	F	82	1.69	28.710
13	39	F	94	1.68	33.305
14	29	F	63	1.62	24.005
15	54	F	78	1.66	28.306
16	40	F	82	1.7	28.374

celiac trunk, and thus this would cause a difficult and time-consuming catheterization of the LGA. In two (12.5%) cases, Embospheres (Merit medical, Jordan, Utah) of 300–500 μm were used to embolize the LGA, and in the other cases, microspheres of 500–700 μm were used. Repeated injections of small amounts of Embospheres alternated with contrast were performed to assess flow characteristics. Injections of Embospheres were continued until the distal branches of the LGA were no longer visible during contrast injection. We never exceeded the amount of 2 cc. To prevent reflux and the associated complications as splenic infarct and pancreatitis, gelfoam (Pfizer, Zurich, Switzerland) was used as a liquid suspension after fragmenting the gelfoam and mixing it with contrast in a 3 cc syringe. Figure 1 shows representative images from a bariatric embolization procedure.

We used 300–500 μm particles in the first patient because this was the size used in ongoing human studies but due to severe pain and for safety reason we switched to 500–700 μm.

An intravenous antiemetic and pain medication protocol was applied after the first patient with 100 mg of Chlorhydrate d'alizapride and tramadol 100 mg 3 times a day during one or 2 days. Additional paracetamol could be given on demand of the patient (maximum 1 g, 4 times a day).

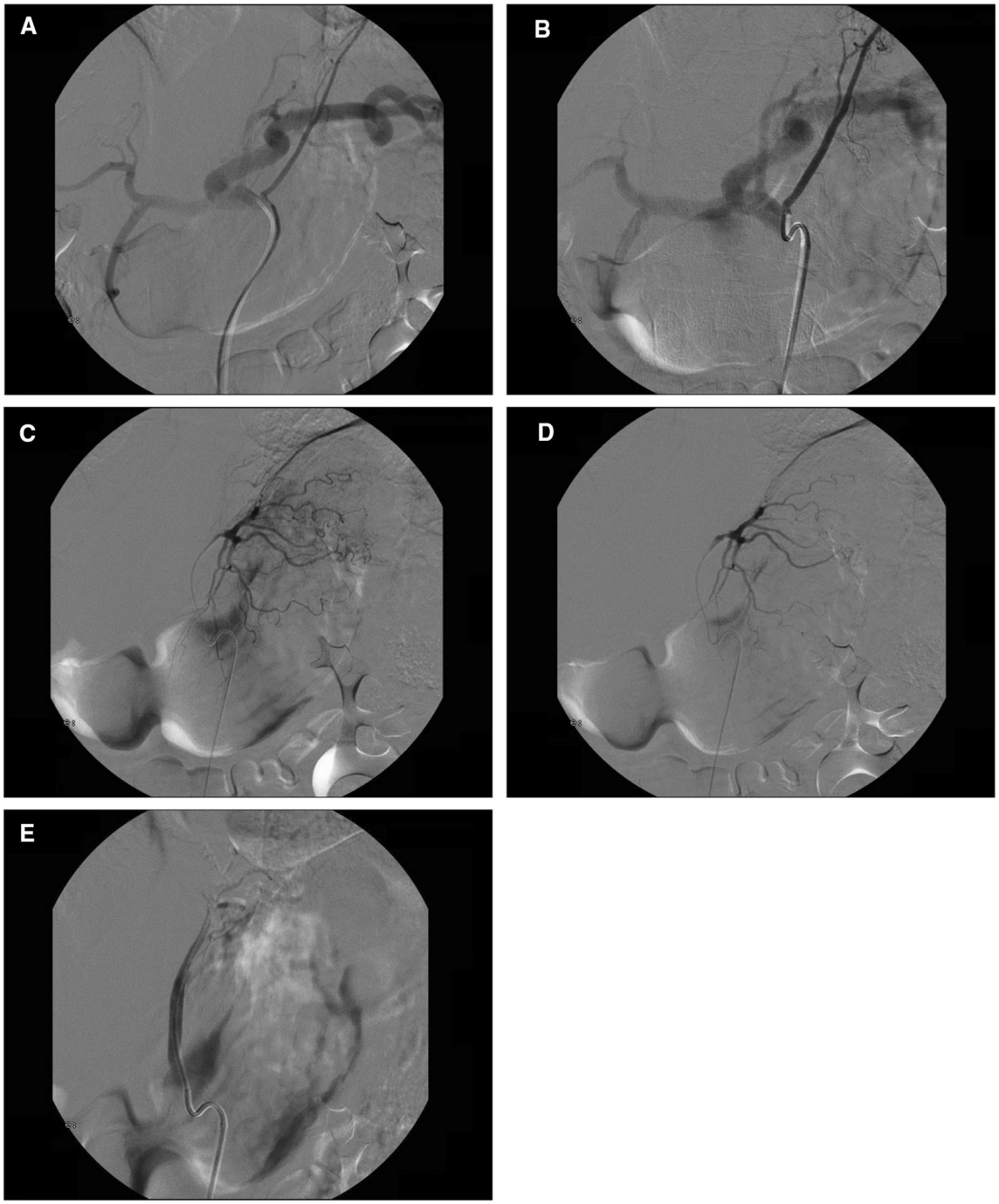

Fig. 1 Example of a bariatric embolization in a 40-year-old man. **A** Celiac angiogram obtained before bariatric embolization shows classic LGA anatomy, with the LGA arising from the proximal celiac artery. **B** Selective catheterization and angiogram of the LGA with a Van Schie catheter before bariatric embolization. **C** LGA angiogram obtained after distal catheterization with a Progreat 2.7 microcatheter and before bariatric embolization shows perfusion of the fundus. **D** Control LGA angiogram after injection of 500–700 μm Embospheres shows partial devascularization of the fundal vascular territory. **E** Final control LGA angiogram after injection of 500–700 μm Embospheres

All patients received 40 mg of pantoprazole daily during a month periprocedural to prevent gastric complications.

In one patient, 300–500 μm particles were used because the unavailability of 500–700 μm particles and the 900 μm particles occluded the microcatheter on the first embolization attempt the same day. After the procedure, a closing device was used to obtain hemostasis.

Outcome Measurements and Definitions

The primary outcome measurements of this study were to evaluate the efficacy of the therapy assessed as the weight loss, and was defined as a percentage relative to the initial body weight and was assessed at 3, 6 and 12 months. A 5–10% weight loss was considered as significant.

Secondary outcome measurements were the satisfactory scale, the appetite assessment and the safety of the procedure, classified as minor and major adverse events. The major adverse event was defined as a complication causing a longer hospital stay or hospitalization in the intensive care unit (ICU). The minor adverse event was defined as a complication causing discomfort and medicational need after the hospitalization. Postprocedural superficial gastric ulcerations that healed on control upper endoscopy were considered as a minor adverse event.

The appetite has been measured as a percentage diminishment on daily meal size. The patients had to consider their meal size before the intervention and compare it with their actual meal quantities.

The satisfactory scale is a scale classified from 0 till 10 ranging from very bad to very good, and patients had to put the number corresponding on their global satisfaction.

Technical feasibility was defined as the ability to embolize the LGA.

The early weight loss was defined as the weight loss at 3 and 6 months follow-up. The weight loss observed at 12 months and later was considered late weight loss.

No specific instructions were given to improve dietary habits and/or the level of physical activity.

Follow-Up Evaluation

Patients were scheduled for a postprocedural contact at 3, 6 and 12 months. A physical examination, hunger scaling, weight assessment and laboratory control were performed. Ten out of the 15 successful embolized patients underwent upper endoscopy after one or 2 months postprocedural. One patient had an active ulcus, one patient had a gastric perforation with pancreatitis, and the 8 remaining patients had a normal endoscopy.

We contacted the patients by phone to assess their actual weight at 3, 6 and 12 months and the satisfactory score at 6 and 12 months.

Data Analysis

Continuous variables are presented as mean ± standard deviation for normally distributed variables, while categorical data are given as the counts (percentages). Analyses were performed using (Excel; Microsoft, Redmond, Wash).

Results

Over the studied period, 16 patients accepted the bariatric endovascular treatment. Technical success, defined as the ability to embolize the gastric fundus, was achieved in 94% of the cases. One unsuccessful embolization was due to the difficult anatomy and selective catheterization failure. Four (26%) patients have been lost in follow-up.

Weight Loss

Nine (56%) patients showed early weight loss, one (6%) patient didn't succeed to decrease his body mass, and one (6%) patient underwent bariatric surgery 2 years after embolization. The weight loss at three and 6 month was considered as early weight loss. The mean early weight loss was 8 kg ± 5.12 and corresponds to 10% of their initial body mass. We have a follow-up of 1 year or more in only 3 patients. In those restricted number of patients, the weight loss was 9.66 kg ± 3.21.

Adverse Events and Safety Profile

Only one patient (6%) had a superficial gastric ulceration observed on endoscopy after the intervention. He was treated with 40 mg of pantoprazole daily for 6 weeks, on control endoscopy 3 months later, the ulcer was resolved.

One (6%) postprocedural major adverse event occurred, a severe pancreatitis with splenic infarction and late gastric perforation was diagnosed and the patient ended in intensive care unit. Since then, a postprocedural computed tomodensitometry scan (CT-scan) was performed and showed splenic infarction. Approximately, 66% of the patients remained one night in the hospital and 33% stayed two nights. The patient (6%) with the major adverse event had a total hospital stay of a month.

Appetite and Satisfactory Assessments

At 6 and 12 months, we asked the patients whether they would recommend this intervention on others and whether they were satisfied with the intervention. The mean satisfactory score in 7 patients was 7.7 ± 1.6. Two patients (12.5%) considered the intervention very painful and would not repeat it.

Four patients had a 30% meal size reduction after the LGA embolization that persisted even after 6-month follow-up.

Discussion

The hormonal regulation of hunger is complex and is primarily governed by hunger-inhibiting hormones. Short-term hunger modulation in response to meals is largely due to cholecystokinin. Long-term regulation of energy balance and weight is controlled largely by the effects of insulin and leptin. Although over 40 hormones have been shown to inhibit appetite, only ghrelin has been shown to stimulate appetite.

Individuals often choose diets when seeking to lose weight, but this approach generally fails because many of these diets encourage unnatural eating habits that cannot be sustained. Counting calories sounds ideal, but may not be practical and realistic for many patients [12]. Wadden et al. report that behavioral treatment can result in short-term weight loss of approximately 5–10% of initial weight, but couldn't demonstrate long-term success of these treatments [13].

Bariatric surgery gives faster and proven results with weight loss that ranges between 50 and 75% of excess body weight [1]. After the radical weight loss, it makes it easier for the patient to follow a diet to maintain the weight loss [12].

Despite its effectiveness, bariatric surgery carries some serious complications that are associated with severe morbidity and mortality [10].

Nowadays, a major gap exists between non-operative treatments and surgery in terms of results and complication ratio. As part of a therapeutic continuum from lifestyle modifications to surgery, new therapies such as percutaneous interventional procedures have been developed [10].

In surgery as in diets, there will be no long-term success if there is no commitment of the patient to healthier eating [12].

Multiple animal studies using distally penetrating embolic agents showed up to 60% decrease in serum ghrelin levels, with decreased weight gain in growing swine compared to the control groups. Bawudun et al. [10] also showed suppressed ghrelin and weight gain after gastric artery embolization in a canine model. Significant ghrelin serum level reduction could be obtained by Diana et al. in pigs that underwent gastric artery embolization with 100–300 μm beads followed by coil embolization, compared to the group treated with 500–700 μm beads alone. A retrospective analysis of 19 patients who underwent LGA embolization for gastrointestinal bleeding showed a 7.3% weight reduction compared to patients who had a different blood vessel embolized for upper gastrointestinal bleeding [10].

Kipshidze et al. [8.] performed the first prospective human trial in which embolization of the LGA via a femoral approach was performed in 5 patients using 300–500 μm particles (BeadBlock, Biocompatibles UK Ltd., Surrey, UK). The study reported a mean weight loss of 20 kg at 6 months after the procedure with no adverse events. Mean body weight was reduced by 10%, 13%, 16%, 17%, and 17% at 1, 3, 6, 12, and 24 months of follow-up, respectively [8].

In the ongoing clinical trial of GET LEAN, four morbidly obese (BMI > 40 kg/m^2) patients underwent an LGA embolization with 300-500-μm Bead Block particles. The mean body weight change at 6 months was 8.5% (range, 2.2% to 19.1%) [7].

Our study is the first retrospective human study performed on overweight patients who are not candidates for bariatric surgery. We report a mean weight reduction of 10% at 3 and 6 months follow-up. This is comparable with the short-term result of the ongoing GET LEAN trial and the behavioral treatment described in Wadden et al. article. We report a 3% extra weight loss compared to the 19 patients with LGA embolization for upper gastrointestinal bleeding, in the retrospective study of Gunn and Oklu.

As said by Gunn and Oklu [14], the weight loss was modest and less sustained when compared to that seen in bariatric surgery which may be due to recanalization of the embolized LGA, the development of collateral flow to the fundus reestablishing ghrelin production, and/or compensatory ghrelin production from other sites in the body [14].

The ongoing trials and some of the animal studies used 300–500 μm particles. No significant ghrelin reduction was obtained in the EMBARGO trial using the 500–700 μm particles when compared to baseline [6]. The canine model of Bawudun et al. used 500–700 μm for embolization of only one artery, that is, the LGA, supplying the gastric fundus [11]. We preferred to use 500–700 μm particles after severe pain was reported by the first patients embolized with 300–500 μm particles. The pain could be explained by the hypothesis that larger microspheres could cause less pain due to less penetration into the gastric mucosa but as said before, the splenic infarcts could also be the cause of pain in our study. Although there were concerns about the efficacy of larger bead as mentioned in multiple studies, we preferred to play it initially safe but with the acknowledgment of the splenic infarcts, we will use the 300–500 μm particles during the next LGA embolization.

The appetite assessment and satisfactory scale could be more systematic and objective, by using a visual analog scale (VAS) and measuring it before the meals.

Several limitations of our study should be noted. First, the analysis was retrospective in nature. Second, we were unable to correlate serum ghrelin levels due to the absence of a scheduled diet and timed blood sample. Third, we did not assess the effect of bariatric embolization on gastric

motility, since ghrelin has been shown to control gastric motility. Fourth, there was no systematic interval between the body weight, satisfactory scale or appetite reduction scale measurements. In spite of these limitations, the data are suggesting that LGA embolization has the potential to reduce weight in overweight patients and to limit their food intake. Randomized, prospective studies are certainly needed to confirm its safety and efficacy.

Conclusion

Overweight and obesity is a worsening global epidemic that presents a major burden for health care systems. The current approach to treat overweight is the modification of diet and exercise, followed by referral for bariatric surgery in obese patients. Though bariatric surgery has shown positive outcomes regarding weight loss, our patients were not candidates for surgery and this have led to less invasive therapies such as LGA embolization. The primary results on safety and efficacy are promising in our retrospective study. More importantly, the duration of any effects will be a crucial factor in determining the future potential of this promising therapy. Additionally, long-term confirmation of safety and efficacy will be necessary.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval 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 Declaration of Helsinki and its later amendments or comparable ethical standards.

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

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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