Left Gastric Artery Embolization for the Treatment of Obesity

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Disclosure

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Disclosures

Consultant/Medical Advisory Board

- Abbott
- BSCI
- Cardinal Health/Cordis
- Cook Medical
- CR BARD/Becton Dickinson
- CSI
- Endologix
- Inari
- Medtronic
- Micro Medical Solutions
- Philips/Volcano/Spectranetics
- Penumbra
- Terumo/Bolton
- WL Gore
Gastric Artery Embolization

Worldwide Epidemic

USA, China and India

High Health system costs

Bariatric Surgery - High Morbidity

Lack of alternatives
Medical Complications of Obesity

US Obesity-related healthcare costs:

$147 billion – $210 billion per year

https://stateofobesity.org/adult-obesity/
Treatment Modalities

Pharmacotherapy

- Lorcaserin
- Phentermine
- Phentermine / Topiramate
- Bupropion / Naltrexone
- Orlistat
- Liraglutide

Endoscopic Weight Loss

- Space-occupying
- Restrictive
- Bypass Line
- Aspiration Device
- Stimulator
Bariatric Surgery

https://www.news-medical.net/health/Bariatric-Surgery-Types.aspx
Gastric Artery Embolization: GAE

LEFT GASTRIC ARTERY EMBOLIZATION

http://pardisnoor.com/clinics%20detail?id=-505071861
GAE: How does it work?

All bariatric surgeries effectively isolate fundal Ghrelin-producing cells

Two patients who underwent left gastric artery (LGA) embolization. (Presented in poster format at Image-Guided Intervention: 50th Anniversary meeting in Portland, OR, July 23–24, 2014)
GAE: Early human data

- Retrospective
- UGIB patients
- LGA embolized (fundus)
  - N = 19
- Non-LGA embolized
  - N = 28

3 month TWL:
- LGA embo = 7.3%
- Controls = 2% TWL
GAE: Clinical trial evidence

Letter to the Editor
Endovascular Bariatrics: First in Humans Study of Gastric Artery Embolization for Weight Loss

Nickolas Kipshidze MD, PhD, Akaki Archadze MD, Stefan Bertog MD, Martin B. Leon MD, Horst Sievert MD

Original Research
Vascular and Interventional Radiology

Clinical Safety of Bariatric Arterial Embolization: Preliminary Results of the BEAT Obesity Trial

Clifford R. Weiss, MD, Olagueoke Akinwande, MD, Kaylan Paudel, MD, Lawrence J. Cheskin, MD, Brian Holty, MD, Kelvin Hong, MD, Aaron M. Fischman, MD, Rahul S. Patel, MD, Eun J. Shin, MD, Kimberley E. Steele, MD, PhD, Timothy H. Moran, PhD, Kristen Kaiser, Amie Park, BS, David M. Shade, JD, Dara L. Kraitchman, VMD, PhD, Aravind Arepally, MD

Original Contributions

Bariatric Embolization of the Left Gastric Arteries for the Treatment of Obesity: 9-Month Data in 5 Patients

Zhi-Bin Bai, Yong-Lin Qin, Gang Deng, Guo-Feng Zhao, Bin-Yan Zhong, Gao-Jun Teng
## GAE: The Clinical Trial Evidence

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Embolic Agent</th>
<th>Embolic Size (μm)</th>
<th>Follow-Up (mo)</th>
<th>Primary Endpoint</th>
<th>Adverse Events</th>
<th>Mean Baseline BMI (kg/m²)</th>
<th>Absolute Weight Loss</th>
<th>Excess Weight Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kipshidze et al&lt;sup&gt;34&lt;/sup&gt;</td>
<td>5</td>
<td>Bead Block particles</td>
<td>300–500</td>
<td>24</td>
<td>Weight loss</td>
<td>Mild transient epigastric discomfort</td>
<td>42.2</td>
<td>17.2%</td>
<td>Unknown</td>
</tr>
<tr>
<td>Syed et al&lt;sup&gt;35&lt;/sup&gt;</td>
<td>4</td>
<td>Bead Block particles</td>
<td>300–500</td>
<td>6</td>
<td>Safety</td>
<td>Mild nausea, occasional vomiting, mild epigastric discomfort</td>
<td>42.4</td>
<td>7.8%</td>
<td>17.2%</td>
</tr>
<tr>
<td>Weiss et al&lt;sup&gt;36&lt;/sup&gt;</td>
<td>5</td>
<td>Embosphere microspheres</td>
<td>300–500</td>
<td>3</td>
<td>30-day adverse events</td>
<td>Transient pancreatitis, asymptomatic superficial ulcer</td>
<td>43.8</td>
<td>4.7%</td>
<td>9%</td>
</tr>
<tr>
<td>Bai et al&lt;sup&gt;37&lt;/sup&gt;</td>
<td>5</td>
<td>PVA particles</td>
<td>500–710</td>
<td>9</td>
<td>Safety</td>
<td>Superficial linear ulceration, hematoma at puncture site</td>
<td>38.1</td>
<td>Unknown</td>
<td>12.64%</td>
</tr>
</tbody>
</table>

**Abbreviations:** BMI, body mass index; PVA, polyvinyl alcohol.
Systematic Review of articles through 2017

→ 62 patients
   → 53 Obese (BMI >= 30)
   → 9 Morbidly Obese (BMI >= 40)
Followup

BMI ↓ (1-3 Months)
• 7% Obese
• 11% Morbidly Obese

BMI ↓ (1 Year)
2% BMI decrease in both groups
Results

Ghrelin (⅘)

↓ 36% in 3 Months

Hemoglobin A1c

↓ 7.4% - 6.3% at 6 months

Improved Quality of Life (SF-36)
New Developments

One year results published online April 2, 2019.

Original Research
Vascular and Interventional Radiology

Clinical Safety of Bariatric Arterial Embolization: Preliminary Results of the BEAT Obesity Trial

Author List
Clifford R. Weiss, MD, Olagwoke Akinwande, MD, Kaylan Paudel, MD, Lawrence J. Cheskin, MD, Brian Holly, MD, Kelvin Hong, MD, Aaron M. Fischman, MD, Rahul S. Patel, MD, Eun J. Shin, MD, Kimberley E. Steele, MD, PhD, Timothy H. Moran, PhD, Kristen Kaiser, Amie Park, BS, David M. Shade, JD, Dara L. Kraitman, VMD, PhD, Aravind Arepally, MD

Additional Information
BEAT Obesity Trial

• Prospective Study with 2 sites (June ‘14 – Feb ‘18)
• 20 participants aged 27 - 68 (16 women)
• Mean body mass index of 45 ± 4.1
• Transarterial embolization of gastric fundus
• 300-500 micron embolic microspheres
BEAT Obesity Trial

• Primary endpoints
  – 30-day adverse events
  – Weight loss at 12 months

• Secondary endpoints
  – Technical feasibility
  – Health-related QOL
  – Impact of weight on QOL
  – Hunger/appetite using visual scale
BEAT Obesity Trial

• Bariatric embolization - 100% technically successful
• No major adverse events
• 11 minor adverse events
  – 8 participants 11 events
    • Subclinical pancreatitis with transient elevation of lipase (1 patient)
    • Nausea, vomiting, epigastric pain - - supportive care
• All participants discharged home 24-48 hours after admission (resolution of all symptoms)
BEAT Obesity Trial

- Mean excess weight loss / weight loss in lbs
  - 1 month: 8.2% (-12.1 lbs)
  - 3 months: 11.5% (-16.8 lbs)
  - 6 months: 12.8% (-19.4 lbs)
  - 12 months: 11.5% (-17.2 lbs)

- All Quality of Life Secondary Endpoints improved at 1 year.
- Hunger/appetite decreased for 4 weeks after embolization
  - increased thereafter but didn’t reach pre-embolization levels.
Bariatric Embolization

Key Points

• Feasible with 100% technical success in 20 adults with severe obesity
• Well tolerated with NO major complications
• Substantial weight loss – 11.5% at 12 months
• Participants showed evidence of metabolic change
  – Decrease in hemoglobin A1C and total cholesterol
  – Increase in high density lipoproteins (HDL)
BEAT Obesity Trial

Summary

Bariatric Embolization is feasible and well tolerated in severely obese patients, inducing appetite suppression and weight loss up to 12 months.
GAE: Summary

• Gastric Embolization with 300-500micron spheres in severely obese patients
  – Appears Safe + Effective in short and intermediate term

• Moving Forward
  – Need placebo-controlled trial
  – Need longer term follow up
  – Ancillary Effects:
    • Effect on future bypass?

https://www.medicalnewstoday.com/articles/317442.php
Conclusions

➔ LGA embolization therapy has insufficient data to alter practice (Grade C, Level 3 of evidence according to Kordzadeh, et al.).

➔ Obesity treatment must have a multidisciplinary approach

➔ Psychologist, dietician and physical therapist must work together to sustain and enhance the results of any procedure

➔ Bariatric alternatives may have a place in the Interventionalist Practice if done as part of an integrative approach
Where do we go from here?

- Development of clinical trials with multidisciplinary approach and long-term follow up
- Placebo-controlled trials
- Possibly combine with antiobesity medication treatment.
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