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Deadline: December 4, 2020

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ABIM Board Certified physicians need to complete their MOC activities by December 31, 2020 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2021 for this activity.
MOC QUESTION

If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

Include specific strategies or changes that you plan to implement. THESE ANSWERS WILL BE REVIEWED.

ACG Virtual Grand Rounds

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Week 29: The Pain of Chronic Pancreatitis: Never Lose Infinite Hope
Darwin L. Conwell, MD, MS, FACG
October 8, 2020 at Noon EDT

Week 30: Pouch or True “Ouch”?- Avoid Common Mistakes in the Diagnosis and Management of Ileal Pouch Disorders
Bo Shen, MD, FACG
October 15, 2020 at Noon EDT

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**Disclosures:**

Allison R. Schulman, MD, MPH
Apollo Endosurgery (Consultant); Boston Scientific (Consultant); MicroTech (Consultant); GI Dynamics (Grant/Research Support)

Violeta B. Popov, MD, PhD, FACG
No conflicts of interest.
Endoscopic Management of Obesity and Complications of Bariatric Surgery

Allison R. Schulman, MD, MPH
Assistant Professor
Director of Bariatric Endoscopy
Michigan Medicine

Trends in the United States

American College of Gastroenterology
Trends in the United States

Obesity (BMI ≥30 kg/m²)

1994

2000

2014

Diabetes

1994

2000

2014

Virtual Grand Rounds

American College of Gastroenterology
Outline

• Review bariatric surgical procedures
  – Recent trends
  – Common surgical complications
  – Endoscopic and medical management of each

• Primary endoscopic bariatric and metabolic therapy
  – What is here
  – What is coming

Bariatric Surgical Procedures
Virtual Grand Rounds

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MBSC Trends

American College of Gastroenterology
Complications Following RYGB

Roux-en-Y gastric bypass (RYGB)

- Gastric pouch
- Gastric remnant
- Roux limb
Roux-en-Y gastric bypass (RYGB)

Complications of RYGB

- Marginal ulceration
- Stenosis of gastrojejunal anastomosis
- Dilation of gastrojejunal anastomosis
- Gastrogastric fistula
- Surgical leaks
- Choledocholithiasis
Complications of RYGB

- Marginal ulceration
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Marginal ulceration

- Ulcer at the gastrojejunal anastomosis (GJA)
- Jejunal > gastric
- Occurs in up to 16% of patients; incidence likely much higher
- Symptoms: epigastric pain, obstruction, GI bleeding

Azagury, D. et al., Endoscopy, 2011
Marginal ulceration - etiology

- Acidity
- Poor local tissue perfusion
- Smoking
- Diabetes
- Medications
- Surgical technique
- *H. pylori*
- Foreign material

Marginal ulceration - treatment

- High dose proton pump inhibitors
  - Soluble or open capsule form
  - +/- sucralfate solution
- Smoking cessation
- Discontinuation of NSAIDs
- Removal of foreign material
- *H. Pylori* testing
- Endoscopic suturing, surgery

American College of Gastroenterology
Complications of RYGB

- Marginal ulceration
- Stenosis of gastrojejunal anastomosis
- Dilation of gastrojejunal anastomosis
- Gastrogastric fistula
- Surgical leaks
- Choledocholithiasis
Stenosis

• No precise definition for stenosis
  – Symptomatic + upper endoscope cannot pass through GJA

• Management: endoscopic balloon dilation
  – GJA is end-to-side anastomosis
  – Must be careful of jejunal wall

• Goal: symptom improvement (not >15 mm)
Complications of RYGB

- Marginal ulceration
- Stenosis of gastrojejunal anastomosis
- Dilation of gastrojejunal anastomosis
- Gastrogastric fistula
- Surgical leaks
- Choledocholithiasis
Dilated GJA

• 15–35% failure; 1/3 of maximum weight lost is regained at 10 yrs
• Dilation of the GJA has a linear relationship with weight recidivism

Dilated GJA

• 15–35% failure; 1/3 of maximum weight lost is regained at 10 yrs
• Dilation of the GJA has a linear relationship with weight recidivism
• TORe
  – Endoscopic suturing
  – Thermal therapy
    • APC, RFA, Cryotherapy
  – Cap-mounted clips (OTSC)
  – Plication (IOP)
Dilated GJA
- 15–35% failure; 1/3 of maximum weight lost is regained at 10 yrs
- Dilation of the GJA has a linear relationship with weight recidivism
- TORe
  - Endoscopic suturing
  - Thermal therapy
    * APC, RFA, Cryotherapy
  - Cap-mounted clips (OTSC)
  - Plication (IOP)

Schulman, AR, Kumar, N, Thompson, CC. GIE 2017
Abu Dayyeh, Thompson, CC. Gastro 2011
Interrupted stitch

Purse-string suture

TORe

<table>
<thead>
<tr>
<th></th>
<th>Interrupted (n=48)</th>
<th>Purse-string (n=164)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>%Total weight loss (TWL)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>8.0 [6.5, 9.4]</td>
<td>8.6 [6.8, 9.4]</td>
<td>0.41</td>
</tr>
<tr>
<td>12 months</td>
<td>6.4 [4.7, 8.1]</td>
<td>8.6 [7.3, 9.4]</td>
<td>0.02*</td>
</tr>
<tr>
<td><strong>%Excess weight loss (EWL)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>16.7 [11.0, 21.3]</td>
<td>20.5 [18.0, 23.0]</td>
<td>0.39</td>
</tr>
<tr>
<td>12 months</td>
<td>11.7 [5.8, 20.0]</td>
<td>19.8 [16.4, 23.0]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td><strong>Total weight loss (kg)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>11.3 [6.7, 17.7]</td>
<td>9.5 [8.6, 10.5]</td>
<td>0.32</td>
</tr>
<tr>
<td>12 months</td>
<td>7.8 [5.5, 9.3]</td>
<td>9.5 [7.7, 11.2]</td>
<td>0.04*</td>
</tr>
<tr>
<td><strong>%Regained weight lost (RWL)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>33.3 [23.5, 56.0]</td>
<td>44.7 [24.5, 65.1]</td>
<td>0.56</td>
</tr>
<tr>
<td>12 months</td>
<td>27.8 [11.4, 60.0]</td>
<td>40.2 [31.9, 48.5]</td>
<td>0.02*</td>
</tr>
</tbody>
</table>
TORe – 5 year data

- N = 331; at 5 yrs (n = 123)
- All purse-string pattern
- TORe prevented weight gain in 77% of patients
- NNT = 1.3
- Mean TWL = 10.3 ± 14.6 kg
- 62% experienced > 5% TWL

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Thermal therapy (APC)

- Circumferential scarring and/or mucosal devitalization
- Contact or non-contact ablation
- Multiple sessions

Dilated GJA

- Multicenter (n=8) study (N=558)
  - 70W and 2 L/min
  - %TWL of 6-10% at 12 months

- GJA size may play a role
  - No difference between TORe and APC when GJA size ≤18 mm
  - TORe may be more effective at a GJA size of >18 mm
Complications of RYGB

• Marginal ulceration
• Stenosis of gastrojejunal anastomosis
• Dilation of gastrojejunal anastomosis
• Gastrogastric fistula
• Surgical leaks
• Choledocholithiasis
Virtual Grand Rounds

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RYGB Anatomy

- Gastric pouch
- Gastric remnant
- Roux limb
- Gastrojejunal anastomosis (GJA)

Virtual Grand Rounds

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Gastrogastric fistula

- Symptoms: weight regain, pain, reflux, nausea
- Diagnosis: EGD or UGI series, cross-sectional imaging
- Treatment: high dose PPI and closure if patient symptomatic
  - ≤1 cm: endoscopic closure often successful
  - >1 cm: consider therapy on remnant stomach

American College of Gastroenterology
Gastrogastric fistula

Complications of RYGB

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Complications of RYGB

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Surgical leaks

- Leaks can occur at several points along any staple line
- Location and chronicity dictate endoscopic management
- Treat downstream obstruction
Complications of RYGB

• Marginal ulceration
• Stenosis of gastrojejunal anastomosis
• Dilation of gastrojejunal anastomosis
• Gastrogastric fistula
• Surgical leaks
• Choledocholithiasis
Choledocholithiasis

- Gallstone disease common after RYGB
- Rapid weight loss
- ERCP is very arduous
  - Balloon-assisted enteroscopy
  - Laparoscopic-assisted enteroscopy
  - EUS-guided gastrostomy
  - EUS-directed transgastric ERCP (EDGE)
EDGE

- Size of stent (10 mm, 15 mm, 20 mm)
- Use of a wire
- GG fistula vs. JG fistula
- Secure/fix the stent (suturing/clip)
- Drive through the stent same day or wait until epithelialization
- When to remove the stent, pigtail placement
- Closure technique
- Confirmation of closure

Complications Following Sleeve Gastrectomy
Sleeve Gastrectomy (SG)

Complications following SG

- Sleeve stenosis
- Sleeve leaks
- Reflux/Barrett’s
- Weight regain
Complications following SG

- Sleeve stenosis
- Sleeve leaks
  - Reflux/Barrett’s
  - Weight regain
Sleeve stenosis

- Incidence 0.1-3.9%
- n/v, dysphagia, weight loss, regurgitation, reflux
- Types of strictures:
  - Early: <4 weeks following surgery
    - Post-surgical edema/hematoma
  - Late: >4 weeks following surgery, “true” strictures
    - Ischemia, scarring, misalignment/rotation during stapling, use of small bougie


Sleeve stenosis

Jirapinyo et al. DDW 2018
Sleeve stenosis

• Diagnosis
  – No clear descriptive criteria
  – UGI series high PPV, low NPV
  – EndoFLIP* pilot study (N = 10)

<table>
<thead>
<tr>
<th>Response</th>
<th>Non-response</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-dilation</td>
<td>Diameter (mm)</td>
<td>11.4 ± 4.2</td>
</tr>
<tr>
<td>DI (mmHg)</td>
<td>13.8 ± 8.5</td>
<td>3.3 ± 4.3</td>
</tr>
<tr>
<td>Post-dilation</td>
<td>Diameter (mm)</td>
<td>19.9 ± 2.0</td>
</tr>
<tr>
<td>DI (mmHg)</td>
<td>21.3 ± 1.6</td>
<td>4.9 ± 3.4</td>
</tr>
<tr>
<td>Change in diameter (mm) following RBD</td>
<td>0.5 ± 6.1</td>
<td>4.4 ± 3.8</td>
</tr>
<tr>
<td>Change in DI following RBD (mmHg)</td>
<td>7.5 ± 7.1</td>
<td>0.7 ± 0.9</td>
</tr>
</tbody>
</table>

Virtual Grand Rounds

*Endoluminal functional impedance planimetry, Medtronic

Sleeve stenosis

• Treatment is controversial

• Management strategies:
  – Endoscopic balloon dilation
  – Self-expanding metal stents (SEMS)
  – Endoscopic tunneled strictuloplasty
  – Surgical conversion to Roux-en-Y gastric bypass

universe.gi.org
Sleeve stenosis – balloon dilation algorithm

• Dilation of incisura with 20 mm hydrostatic
• Progress to pneumatic balloon
  – Start with a 30 mm balloon, attempt to attain PSI 20
  – Depending on resistance, maximal PSI may not be reached
  – In 2-4 weeks, the procedure is repeated
    • Use same size balloon if maximum PSI not reached
    • Use a balloon 5 mm greater in size if maximum PSI is reached
• Success ranges from 41.4-86.6%
• Bleeding (3%) and perforation (3%)

Sleeve stenosis

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Sleeve stenosis - SEMS

• Self-expanding metal stents (SEMS) play a role in resistant cases
• High risk of migration (28.2%)
• Recommend fixation of proximal end of stent

Sleeve stenosis - strictuloplasty

• Endoscopic tunneling (strictuloplasty)
• May be ideal:
  – Length of stenosis and length of gastric sleeve prohibit pneumatic dilation
  – Does not desire multiple sessions
Complications following SG

- Sleeve stenosis
- Sleeve leaks
  - Reflux/Barrett’s
  - Weight regain
Sleeve leaks

• Most feared adverse event
• Tachycardia, leukocytosis, ↑CRP, fulminant peritonitis/sepsis,
• Occur when intragastric pressure exceeds burst pressure
  – Often precipitated by distal sleeve stricture
• Majority develop at the proximal staple line below angle of His
  – Area of relative ischemia (take-down of short gastric arteries)
  – Zone of increased pressure
Sleeve leaks
• Timing and chronicity affect management strategy
  – Acute (<1 week) or early (1-6 weeks) leaks
  – Late (6-12 weeks) or chronic (>12 weeks) leaks
• The size of the leak plays a role
• Endoscopic armamentarium:
  – SEMS, plastic pigtail stents, thermal devices, mechanical devices, tissue sealants
  – Dilation distal to the sleeve leak is imperative

Sleeve leaks - SEMS
• Ideally used in acute/early leaks
• Should span from the distal esophagus to duodenal bulb
  – Consider overlapping SEMS to achieve extension/coaptation
  – Provides anterograde flow of secretions
  – Fixate proximal end
• Stents specifically designed for bariatric use
  – MEGA™ and BETA Stents, TaeWoong Medical
  – Hanaro Bariatric Seal Stent, M.I. Tech, S. Korea
Sleeve leaks - SEMS

- Reported success rates of 73-83%; high migration rates
- Multi-center retrospective study (n=110)
  - Probability of success decreased with leak chronicity (76% at 1 mo decreased to 48.5% at 6 mo)
  - Stent migration occurred in 74 of 169 (44%) SEMS, resulting in 8 perforations and 1 death

- Meta-analysis (14 studies; N = 212)
  - Investigated strategy of endoscopic suture fixation
  - Pooled migration rate of 15.9%
Sleeve leaks - pigtail stents

- Ideally used in late leaks, walled off cavity
- Facilitate drainage of the cavity into the gastric lumen
- Technique used is similar to necrosectomy
- High technical success, fewer required procedures, and lower morbidity/mortality than SEMS
- Single-center retrospective study (n=67)
  - Average time of leak: 52 days (range 1-1450)
  - 98.5% technical success; 78.2% clinical success
Sleeve leaks - septotomy

- Late or chronic leaks
- Requires a fibrotic septum and contained leak
- The staple line (septum) separating the cavity and the gastric lumen is incised and divided
- Exposes the cavity; equalizes pressures
- Needle knives, APC, insulated cutting knives; may require multiple sessions

Sleeve leaks – other devices

- OTSCs
- Suturing
- Sponges
  - Endoscopic vacuum therapy
- Fibrin sealants
- Cyanoacrylates
- Tissue scaffolds / mesh
- Cardiac septal defect occluders

Summary

- Bariatric surgery is effective, with the prevalence of sleeve gastrectomy rapidly rising
- Despite improvement in the performance of these procedures, complications are not uncommon
- Endoscopists should be familiar with the anatomy and complication management strategies
- Should be performed in the context of a comprehensive, multidisciplinary center
Primary Therapy for Obesity

Surgery is effective

- Significant weight loss
- Improvement in obesity-related comorbidities

However...

- Surgery alone cannot contain an epidemic
- <1% of eligible patients undergo surgery
- High risk profile

Adapted from Chris Thompson
Spectrum of obesity management

Benefits of EBMT

- Less invasive
- Potential to appeal to patients who do not qualify for or want bariatric surgery
- Could bridge a critical gap in the treatment of obesity; reaches patients earlier (BMI 30-35)
- Repeatable, used in combination; perhaps better for a chronic condition as weight can be regained even after the most successful bariatric surgical programs
Endoscopic Bariatric and Metabolic Therapy

WHAT IS HERE
Primary Therapy for Obesity (Gastric)

WHAT IS COMING
Primary Therapy for Obesity + Diabetes (Small bowel)
Endoscopic Bariatric and Metabolic Therapy (EBMT)

Primary Therapy for Obesity (Gastric)

Primary Therapy for Obesity + Diabetes (Small bowel)

WHAT IS HERE

WHAT IS COMING

American College of Gastroenterology
## EBMT procedures

<table>
<thead>
<tr>
<th>Gastric Devices</th>
<th>FDA-approved</th>
<th>RCT data</th>
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<tbody>
<tr>
<td><strong>Space-occupying</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orbera IGB</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Reshape IGB</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Obalon IGB</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Spatz III IGB</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Transpyloric Shuttle</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Full Sense Device</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td><strong>Gastric remodeling</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESG (Apollo)</td>
<td>Y*</td>
<td>N</td>
</tr>
<tr>
<td>POSE</td>
<td>N**</td>
<td>Y</td>
</tr>
<tr>
<td><strong>Aspiration therapy</strong></td>
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<td></td>
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<tr>
<td>AspireAssist</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

*Device FDA-approved
**POSE in current configuration did not meet endpoints in pivotal trial*

---

## Candidates for EBMT

<table>
<thead>
<tr>
<th><strong>Indications</strong></th>
<th><strong>Contraindications</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI &gt; 30 kg/m²*</td>
<td>Prior bariatric, gastric, or esophageal surgery</td>
</tr>
<tr>
<td>Not successful at losing weight through non surgical methods</td>
<td>Large hiatal hernia</td>
</tr>
<tr>
<td>Do not desire surgical intervention</td>
<td>Esophageal motility disorder, strictures</td>
</tr>
<tr>
<td>Require bridge therapy to other surgical interventions</td>
<td>Inflammatory bowel disease of the upper GI tract</td>
</tr>
<tr>
<td></td>
<td>Pregnancy</td>
</tr>
<tr>
<td></td>
<td>High risk of upper GI bleeding (AVMs, varices)</td>
</tr>
<tr>
<td></td>
<td>Concurrent use of anticoagulation or NSAIDs</td>
</tr>
<tr>
<td></td>
<td>Inability to use a proton pump inhibitor</td>
</tr>
<tr>
<td></td>
<td>Coagulopathy</td>
</tr>
<tr>
<td>* Procedure dependent</td>
<td>Psychiatric or drug/alcohol use disorder</td>
</tr>
</tbody>
</table>

*Procedure dependent*
Intragastric balloons (IGBs)

Space occupying therapy

IGBs

- FDA approved for BMI 30-40 kg/m²
- ASGE considers patients with BMI > 40 kg/m² reasonable candidates for use as bridge therapy to any surgery
IGBs

- Fluid filled
- Silicone spheres
- Placed / removed endoscopically
- Remain in the stomach for 6 mo

Orbera
Apollon Endosurgery

Reshape
Removable by Apollon

Obalon
Obalon Therapeutics

Virtual Grand Rounds
IGBs

- Orbera
  - Apollo Endosurgery
  - Silicone spheres
  - Fluid filled
  - Placed / removed endoscopically
  - Remain in the stomach for 6 mo

- ReShape
  - ReShape Medical; recently purchased by Apollo
  - Gas (nitrogen) filled balloon
  - Thin polymer ellipses
  - Sequentially swallowed every 2-3 wk
  - Removed endoscopically 6 mo after 1st balloon placed

- Obalon
  - Obalon Therapeutics
  - 400-700
  - 375-450
  - 250

Comparison of IGBs

<table>
<thead>
<tr>
<th>Type</th>
<th>Study Design</th>
<th># Subjects (Active)</th>
<th>%TBWL (6 mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbera (Apollo Endosurgery)</td>
<td>Open label Pivotal RCT, 12 visits</td>
<td>125</td>
<td>10.2 ± 6.6</td>
</tr>
<tr>
<td>ReShape (ReShape Medical)</td>
<td>Sham-controlled Pivotal RCT, 6 visits</td>
<td>187</td>
<td>8.4</td>
</tr>
<tr>
<td>Obalon (Obalon Therapeutics)</td>
<td>Sham-controlled Pivotal RCT, 7 visits</td>
<td>198</td>
<td>6.8 ± 5.1</td>
</tr>
</tbody>
</table>

- Achieve more weight loss in clinical practice (%TBWL~13-15%)
  - Bazerbachi et al, Obes surg, 2018
    - Fluid filled balloons more likely to lead to weight loss
    - More likely to be removed early for intolerance
  - Moore et al, Surg Obes Relat Dis, 2019
    - Gas filled balloons may be equally as effective, especially in BMI > 40

*Knowledge of subject assignment
Space occupying therapy

Transpyloric Shuttle (TPS)
Transpyloric shuttle

- Large spherical bulb attached to smaller cylindrical bulb by a flexible tether
- Placed and removed endoscopically at 12 mo
- Intermittently occludes pylorus; delays gastric emptying

Transpyloric shuttle

- ENDObesity II trial (N = 302)
  - A 12 month multicenter, randomized, double-blind, sham-controlled study
  - BMI 30-40 kg/m²

- Results:
  - Mean weight loss 9.5% vs 2.8% in TPS vs sham (p<0.0001)
  - 67% in the TPS group achieved ≥5% TWL
  - Improvement in blood pressure, lipids, insulin
Gastric remodeling

Endoscopic Sleeve Gastroplasty (ESG)
Primary Obesity Surgery Endoluminal (POSE)

ESG

- Full-thickness sutures placed to invaginate the greater curvature of the stomach
- Extend from incisura to the GEJ Creates a narrow luminal sleeve with small fundic pouch
- Decreases gastric volume by up to 70%
ESG

• Multicenter retrospective study
• 248 consecutive patients
  – Antibiotics, anti-emetics, PPIs
  – Diet: 2-3 weeks of liquid protein shakes, 2 weeks of pureed food, resume regular diet (1,000-1,200 calories, 70g protein/day)
  – Discharged same day (USA) or following day (Spain)
• Outcome: % TBWL at 6 mo and 24 mo
### ESG

<table>
<thead>
<tr>
<th>N total</th>
<th>Lost to follow-up</th>
<th>%TBWL at 6 months</th>
<th>%TBWL at 24 months</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 month</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>248</td>
<td></td>
<td>15.17 [14.2–16.25]</td>
<td>0.25</td>
<td></td>
</tr>
<tr>
<td>18-24 month</td>
<td></td>
<td>18.6 [15.7–21.5]</td>
<td>0.7</td>
<td></td>
</tr>
</tbody>
</table>


---

### ESG - safety profile

- **Algahtani et al (GIE, 2018)**
  - Prospective, single center study (N=1000)
  - 24 (2.4%) readmitted

- **Fayad et al (GIE, 2020)**
  - 2:1 (83 SG: 54 ESG) matched control
  - ESG:
    - ↓ GERD (17.1% ± 6.5% vs 23.6% ± 7.6%, *P* < .01)
    - ↓ adverse events (5.2% vs 16.9%, *P* < .05)
Re-do ESG

Redo endoscopic sleeve gastroplasty: technical aspects and short-term outcomes
Ivo Beškoski, Valerio Pontecorvi, Camilla Gallo, Vincenzo Bove, Lucrezia Laterza and Guido Costamagna

Re-suturing after primary endoscopic sleeve gastroplasty (ESG) for obesity
Gontrand Lopez-Nava, Ravishankar Asokkumar, Anuradha Negi, Enrique Normand and Immaculada Bautista

Received: 25 February 2020 / Accepted: 20 May 2020
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POSE

Virtual Grand Rounds
Aspiration

Aspiration Therapy (AT)

AT

- AspireAssist® (Aspire Bariatrics)
  - Approved for BMI 35-55 kg/m²
  - Similar to endoscopic gastrostomy (PEG) tube
  - Facilitates removal of ~30% of calories after a meal
  - Aspirate 20-30 minutes after a meal; 2-3 times/day
AT device

Virtual Grand Rounds

Thompson et al., Am. J. Gastroenterol. 2016

AT – Pathway study

Overall Satisfaction

Co-Primary Endpoint #1
Mean %EWL at 52 Weeks of AT Group at least 10% greater than Control Group

Co-Primary Endpoint #2
At least 50% of AT group achieves 25% %EWL or more at 52 Weeks

Willingness to Recommend

If the AspireAssist were available, how likely would you be to recommend it to a close friend or relative who was interested in losing weight?

Virtual Grand Rounds

Thompson et al., Am. J. Gastroenterol. 2016

Courtesy of Shelby Sullivan
## AT impact on comorbidities

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%EWL</th>
<th>%TBL</th>
<th>IWQOL</th>
<th>HDL (mg/dl)</th>
<th>TRIG (mg/dl)</th>
<th>%HbA1C</th>
<th>ALT (IU/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td>63.8±17.9</td>
<td>52.2±14.4</td>
<td>141.4±81.6</td>
<td>5.69±0.60</td>
<td>24.0±14.4</td>
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<tr>
<td>Year 1</td>
<td>82</td>
<td>37.1±27.6</td>
<td>14.2±9.8</td>
<td>16.3±17.7</td>
<td>3.6±8.8</td>
<td>-24.3±62.2</td>
<td>-0.36±0.45</td>
<td>-7.6±12.9</td>
</tr>
<tr>
<td>Year 2</td>
<td>42</td>
<td>40.8±25.3</td>
<td>15.3±8.8</td>
<td>17.7±14.3</td>
<td>6.1±10.5</td>
<td>-24.7±81.3</td>
<td>-0.32±0.26</td>
<td>-7.2±14.7</td>
</tr>
<tr>
<td>Year 3</td>
<td>22</td>
<td>44.7±29.7</td>
<td>16.6±10.5</td>
<td>20.6±14.7</td>
<td>6.3±7.2</td>
<td>-28.6±78.5</td>
<td>-0.30±0.46</td>
<td>-5.6±12.3</td>
</tr>
<tr>
<td>Year 4</td>
<td>12</td>
<td>49.9±33.1</td>
<td>18.4±12.1</td>
<td>26.0±14.4</td>
<td>8.1±9.0</td>
<td>-31.7±75.4</td>
<td>-0.34±0.56</td>
<td>-11.9±12.7</td>
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</tbody>
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### Virtual Grand Rounds

**Endoscopic Bariatric and Metabolic Therapy (EBMT)**

- **EBMT**
  - **Primary Therapy for Obesity** (Gastric)
  - **Primary Therapy for Obesity + Diabetes** (Small bowel)

**WHAT IS HERE**

**WHAT IS COMING**

---

American College of Gastroenterology
Endoscopic Bariatric and Metabolic Therapy (EBMT)

Primary Therapy for Obesity (Gastric)

Primary Therapy for Obesity + Diabetes (Small bowel)

WHAT IS HERE

WHAT IS COMING

Small bowel EBMTs

<table>
<thead>
<tr>
<th>Gastric Devices</th>
<th>FDA-approved</th>
<th>RCT data</th>
</tr>
</thead>
<tbody>
<tr>
<td>EndobARRIER Sleeve</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Duodenal mucosal surfacing</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>ValenTx Sleeve</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Incisionless anastomosis</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>

Jiraponyo, Thompson, CGH 2018
Sullivan, Edmundowicz, Thompson, Gastro 2017
Conclusion

• EBMT is aimed at addressing the obesity epidemic and obesity-related comorbidities
• Fills gap between medications and surgery
• Reversible, repeatable, cost-effective, and can used in combination
• Several devices are currently available, devices to treat the complications of obesity are evolving
• Should be performed in the context of a comprehensive, multidisciplinary center

Thank you

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Questions:

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Apollo Endosurgery (Consultant); Boston Scientific (Consultant); MicroTech (Consultant); GI Dynamics (Grant/Research Support)

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No conflicts of interest.

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ACG Women in GI Circle
ACG GI Circle

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