Advances in Endoscopy Update
Newer Technologies in Adult GI
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Disclosure

In the past 12 months, I have had no relevant financial relationships with the manufacturers of any commercial products and/or providers of commercial services discussed in this CME activity
Presentation foci

Emphasis on *therapeutic endoscopy*
- Upper GI bleeding hemostasis
- Enteroscopy
- Endoluminal stenting and strictureplasty
- Endoscopic therapy of achalasia
- Endoscopic therapy of GERD
- Endoluminal bariatric therapies

GI Bleeding Hemostasis

Endoscopic Hemostatic Modalities

- Thermal devices
  - Coaptive devices: tamponade + coagulation
    - Multipolar electrocoagulation (MPEC) probe or heat probe
    - All forms equivalent; limited data suggest combination with epin more effective than monotherapy
  - APC
    - Non-coaptive therapy for superficial lesions
**Endoscopic Hemostatic Modalities**

- Mechanical therapy
  - Permanent tamponade via mechanical device
    - Clips
    - Bands
  - Tissue, anatomy, operator preference may dictate choice
    - Anatomical location
    - Type of lesion
    - Ease of deployment due to anatomical or technical considerations

**Endoscopic Therapy of UGIB**

- Therapeutic modalities
  - 2009 meta-analysis of 75 studies show thermal, injectables other than saline/epinephrine, and clips all effective in PUD hemostasis
  - No single modality was superior
  - Epi with second treatment modality more effective than epi alone
  - Epi alone should not be used, but should be combined with second modality

Combination Therapy vs. Hemostatic Clips Study

- Prospective randomized controlled trial of acute non-variceal upper GI bleeding
- All pts on high dose proton pump inhibitors

Primary Control vs. Rebleeding Rate

Saltzman JR. Am J Gastroenterol 2005;100:1503

Hemostatic Clips for Upper GI Bleed

- Meta-analysis of 15 RCT’s of 1156 patients
  - 390 clips alone
  - 242 clips and injection
  - 359 injection alone
  - 165 thermocoagulation with or without injection

- Hemoclips superior to injection therapy alone
  - Definitive hemostasis 87% vs. 75%

- Hemoclips comparable to thermal coagulation
  - Definitive hemostasis 82% vs. 81%

Sung JJ. Gut 2007;56:1364

When to Use Hemostatic Clips

- Ideal for hemoclips
  - Lesion pliable
  - Lesion accessible
  - <2 mm vessel
  - <2 cm ulcer defect

- Difficult for hemoclips
  - Indurated or fibrotic base
  - Challenging locations
    - Lesser curve stomach
    - Posterior wall stomach
    - Posterior duodenum
Upper GI Vascular Abnormalities
- No prospective trials comparing methods for acute UGIB due to vascular abnormalities
  - Vascular ectasias
  - Dieulafoy lesions
  - GAVE
- Endoscopic marking
  - Consider tattooing difficult-to-locate lesions
  - Place clip whether endotherapy succeeds or fails to facilitate IR / surgical intervention

A Peek at New Technologies in Hemostasis
- New hemostatic clips

Over-the-scope Clip
Kirschner A. Gastrointest Endosc 2007;66:162
Monopolar Cautery

- **Monopolar device**
  - Designed for endoscopic bleeding
  - Flat jaws for grasping
  - Rotational ability
  - Grounding pad required

- **Optimal settings (stomach)**
  - 50 Watts for 2 or 3 seconds

Role of monopolar cautery in the management of upper GI bleeding needs to be determined

Saltzman JR. Gastrointest Endosc 2010;72(4):796

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A Peek at New Technologies in Hemostasis

- **Doppler probe**

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Doppler Ultrasound

Wong RC. Gastroenterology 2009;137:1897
Doppler Signal Before and After Endoscopic Therapy

Application of Doppler guided hemostasis has the potential to help reduce ulcer rebleeding

Jensen DM. DDW 2010

Hemostatic Nanopowder Spray

Mechanism of action:
- Tamponade (rapid velocity application)
- Dehydration of fluid within blood
- Activation of clotting cascade
- Activation of platelets

Aims: To assess the efficacy and safety of a novel hemostatic nanomaterial in short and long term hemostasis in a survival GI bleeding animal model

Conclusions: Endoscopic application of this nanopowder is safe and highly effective in achieving hemostasis in an anticoagulated severe GI bleeding animal model

Giday SA. Endoscopy 2011;43:296

<table>
<thead>
<tr>
<th>Location</th>
<th>Procedure Description</th>
<th>Initial Hemostasis</th>
<th>Hemostasis 12 hour post procedure</th>
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<td>Bleeding Source</td>
<td>Bleeding location</td>
<td>Initial Hemostasis</td>
<td>Hemostasis 12 hour post procedure</td>
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<td>Hematemesis, Melena</td>
<td>Stomach</td>
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<td>Yes</td>
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</tbody>
</table>

Human Hemostatic Spray Initial Trial

(Forrest 1b = ooze)

Sung UV. Endoscopy 2011;43:291
New hemostatic spray

A Peek at New Technologies in Hemostasis

Hemospray Considerations

- Effective only in actively oozing or spurting bleeding lesions
- Does not require special expertise
- Can be rapidly used if bleeding occurs after polypectomy or sphincterotomy
- May be effective in difficult locations
- Further clinical studies are needed
Upper GI Bleeding 2012: Summary

- Consult new 2012 ASGE Guidelines at [www.asge.org](http://www.asge.org)
  - “The role of endoscopy in the management of acute non-variceal upper GI bleeding” Gastrointest Endosc 2012;75:1132-1138.
  - Management of PUD with adherent clot is controversial
  - Injection, thermal, and mechanical therapies are all effective
  - Epinephrine alone should not be used in PUD bleeding, but should be combined with 2nd agent

- Consult new 2012 ACG Guidelines at [www.gi.org](http://www.gi.org)
Enteroscopy

Diagnostic and therapeutic options
- Colonoscopy with ileoscopy
- Video Capsule Endoscopy (VCE)
- Push Enteroscopy (with or without overtube)
- Balloon Enteroscopy (peroral or peranal)
- Intraoperative Enteroscopy (laparoscopic or open)
- Rotational Enteroscopy
*UGIS / SBFT (for evaluation of masses, strictures)
- CT enterography / MR enterography
- Contrast angiography
- Tagged-RBC scan
- Meckel’s scan

Background
- Deep enteroscopy: diagnostic and therapeutic
Background

- Deep enteroscopy: diagnostic and therapeutic

Background

- Deep enteroscopy: diagnostic and therapeutic

Background

- Deep enteroscopy: diagnostic and therapeutic

Background

- Deep enteroscopy: diagnostic and therapeutic
Background

Deep enteroscopy: diagnostic and therapeutic
  * Rotational enteroscopy

Performance characteristics

- Deeper insertion = superior visualization compared to push enteroscopy
- Total small intestinal examination in 12-25%; diagnostic yield 40%
- Clinical yield for VCE and DBE equivalent: 60%

Balloon enteroscopy caveats

- It takes a long time...
  - 120-200 minutes peroral or retrograde
- Effortful
  - May require anesthesia (logistical issues, risk, cost)
  - Skill acquisition
- Requisite expertise
  - Diagnostic
  - Therapeutic

Balloon enteroscopy caveats

- Surgical anatomical caveats: fixed bowel
  - Peritoneal adhesions
  - Anatomotic strictures
  - Esophageal strictures

Balloon enteroscopy caveats

- Surgical anatomical caveats: fixed bowel
  - Roux-en-Y anatomy
    - Anastomoses
      - Ectatic anastomoses
        - Hairpin turns
        - Fixed
        - Scope radius
        - Scope stiffness
    - Peritoneal windows
    - Gastric looping
      - Hiatal hernia
Balloon enteroscopy caveats

- Surgical anatomical caveats: fixed bowel
  - Roux-en-Y anatomy
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      - Ectatic anastomoses
      - Hairpin turns
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        - Scope radius
        - Scope stiffness
    - Peritoneal windows
    - Gastric looping
      - Hiatal hernia

Choosing Your Equipment
What Gets Me Farther?

- In randomized trials, double balloon and single balloon enteroscopy achieved comparable antegrade insertion distances\(^1,2\)
  - In a single study, insertion depth with DBE was ~50 cm greater than SBE but this did not hold significance after comparisons
- In a study comparing total enteroscopy (both antegrade and retrograde in same patients), total enteroscopy rate for SBE was 0% and 57.1% in DBE groups\(^3\)

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Enteroscopy for Small Bowel Bleeding
Effective?

<table>
<thead>
<tr>
<th>Study</th>
<th>Follow-up Duration</th>
<th>Findings</th>
<th>Rebleeding rate (%)</th>
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</thead>
<tbody>
<tr>
<td><strong>Double Balloon Enteroscopy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gerson (2009)</td>
<td>30 months</td>
<td>Vascular lesions</td>
<td>45</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Normal DBE</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overall</td>
<td>42</td>
</tr>
<tr>
<td>Shinozaki (2010)</td>
<td>29.7 months</td>
<td>Vascular lesions</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Normal DBE</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overall</td>
<td>39</td>
</tr>
<tr>
<td>May (2011)</td>
<td>55 months</td>
<td>Vascular lesions</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Normal DBE</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overall</td>
<td>N/A</td>
</tr>
<tr>
<td>Samaha (2012)</td>
<td>22.6 months</td>
<td>Vascular lesions</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Normal DBE</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overall</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Single Balloon Enteroscopy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kushnir (2013)</td>
<td>23.9 months</td>
<td>Vascular lesions</td>
<td>48</td>
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<tr>
<td></td>
<td></td>
<td>Normal SBE</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overall</td>
<td>46</td>
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</tbody>
</table>


Kushnir VM, Dig Dis Sci, 2013
Deep enteroscopy complications

- Balloon enteroscopy
  - Post-procedure distention/pain common (> 20%)
  - Major complication rate 0.8 – 5%
    - Perforation 1-3%
    - Higher when intervention added
    - Rare pancreatitis


Deep enteroscopy: indications

- Suspected Small Bowel Bleeding
  - Obscure Occult
  - Obscure Overt
  - Detection or Resection of small bowel polyps/tumors
  - Suspected inflammatory bowel disease/enteropathy
  - Therapy of small bowel stricture
  - Altered anatomy ERCP

Clinical application

- Capsule enteroscopy and balloon / rotational enteroscopy are complimentary
- Per Dr. Rosh’s lecture
  - Consider capsule first given non-invasive, with lower complication risk and no sedation requirement
  - Consider going straight to rotational or balloon enteroscopy if suspicion for treatable lesion is high
Clinical application

- Capsule enteroscopy and balloon / rotational enteroscopy are complimentary (continued)
  - Positive capsule findings
    - Tissue acquisition
    - Treatment
  - Negative capsule findings
    - …with persistent strong clinical suspicion for intestinal pathology

Clinical application

- Choice of deep enteroscopy platform is largely institution-dependent, and institutionally-driven
  - Endoscope manufacturer holding contract for unit
  - Availability of local operator experience and expertise
  - Applies to capsule as well as balloon / rotational enteroscopy

Clinical application

- On the other hand...
  - Choose capsule if
    - Purely diagnostic
    - Stricture unlikely or excluded
    - Radiologic studies are negative
  - Choose push enteroscopy with colonoscope if likely to be near ligament of Treitz or T1
    - Easier, faster
    - Larger channel for aspiration, accessories
    - Dial-in stiffening feature, flushing pump capability
  - Consider quick repeat EGD first in appropriate cases, particularly if you didn’t perform the index EGD
Per-oral cholecystoscopy (POCS)

Direct-video cholecystoscopy

Per-oral cholecystoscopy (POCS)

CCD-video cholecystoscopy with NBI

Image courtesy Irving Waxman, MD, University of Chicago

Altered-anatomy ERCP

Deep-enteroscopic ERCP
Deep-enteroscopic ERC

Altered-anatomy ERCP

Luminal Stenting

Benign esophageal stricture management

- Dilation
  - Passage
  - Balloon
- Intraluminal corticosteroid injection
- Strictureplasty
  - Needle-knife
  - Endoscopic scissors
  - Argon Plasma Coagulation (APC)
- Stent therapy: long-term/continuous/gradual dilator
  - Migration
  - Chest pain
  - Not durable
Treatments: Stents

- Increasing literature in benign disease, but all small series
- \(^*\)For SEMS (all): use in benign disease is \textit{off-label}
- No role for uncovered or partially-covered SEMS
- Only fully-covered stents in benign indications
  - FC-SEPS: FDA approved indication
  - \(^*\)FC-SEMS: \textit{off-label use}

Treatments: Stents

- Stent therapy: concept in benign esophageal strictures
  - Temporary, long-term/continuous/gradual dilator
  - Stricture remodeling
  - Initial enthusiasm was tempered by
    - Migration
    - Chest pain
    - Not durable
    - AE fistulas (Rogart, et al., Endoscopy 2007)
- Biodegradable stents
  - Tissue ingrowth
  - Potential for serial stenting without removal
- \textit{Caveat: radiation and chemotx increase stent complications}
Treatments: Stents

- PC-SEMS: partially-covered metallic
- FC-SEMS: fully-covered metallic
- SEPS: fully-covered plastic


Why we don’t use partially covered SEMS in benign disease

Hirdes, et al., Endoscopy 2011;43:156
- 4 patients
- PC-SEMS for benign perforation or leak
- Median dwell time 29 days
- Endoscopic removal led to perforation in 4/4
### Treatments: SEPS stents

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Stricture type</th>
<th>Stent type</th>
<th>Duration stenting</th>
<th>Outcome</th>
<th>Migrations + Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repici 2004 GIE</td>
<td>15</td>
<td>Mixed</td>
<td>Polyflex SEPS</td>
<td>6 wks</td>
<td>80% dys-free at mean 22 mos</td>
<td>Migr 7% Complic 0</td>
</tr>
<tr>
<td>Evrard 2004 GIE</td>
<td>21</td>
<td>Mixed</td>
<td>Polyflex SEPS</td>
<td>26-56 wks</td>
<td>80% dys-free at median f/u 21 mos</td>
<td>Migr 52% Airway compr 5%</td>
</tr>
<tr>
<td>Dua 2006 AJG (prosp)</td>
<td>40</td>
<td>Mixed; most anast/corrosive/XRT</td>
<td>Polyflex SEPS</td>
<td>4 wks</td>
<td>40% dys-free at median 53 wk follow up</td>
<td>Migr 22% Death 1 fistula 1 Perf 2</td>
</tr>
<tr>
<td>Ch 2010 DDS</td>
<td>13</td>
<td>Anast 11/13</td>
<td>Polyflex SEPS</td>
<td>6 wks</td>
<td>23% dysph-free @ μ 37 d, r 6-120 d</td>
<td>Migr 30% No major complic's</td>
</tr>
<tr>
<td>Rezai 2010 APT</td>
<td>130</td>
<td>Mixed</td>
<td>Polyflex SEPS</td>
<td>≥ med f/u 13 mo</td>
<td>52% symp free at med 13 mo f/u</td>
<td>Migr 24% Maj comp 9%, dth 1%</td>
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</tbody>
</table>

### Treatments: FC-SEMS stents

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Stricture type</th>
<th>Stent type</th>
<th>Duration stent/post</th>
<th>Outcome</th>
<th>Migrations + Complications</th>
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</thead>
<tbody>
<tr>
<td>Kim 2009 Eur Radial</td>
<td>55</td>
<td>PR</td>
<td>Tae-won</td>
<td>1 wk-6 mos μ 38 mos</td>
<td>38% patency at 6 mos; 33% at 1 yr</td>
<td>Migr 25% Ovgrth 31%</td>
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<td>Senousy 2010 DDS</td>
<td>7</td>
<td>RT</td>
<td>Mixed anast/corrosive/XRT/PCT</td>
<td>Alimaxx</td>
<td>4.84 d, μ 37 d/μ 172 d</td>
<td>Clin impvmt dysphagia 100%</td>
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<td>Eloubeidi 2011 GIE</td>
<td>19</td>
<td>PR</td>
<td>Mixed</td>
<td>Alimaxx</td>
<td>6-30 d, 64±74d/24-360 d total f/u</td>
<td>Clin impvmt dysphagia 100%</td>
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<td>Hirdes 2012 GIE</td>
<td>15</td>
<td>Mixed</td>
<td>Wallflex</td>
<td>Med 159 d or to migr/obstr/pain</td>
<td>100% dysph recur: med 60 d post-removal</td>
<td>Migr 33% Asp pneum 7% Ovgrth 50%</td>
</tr>
</tbody>
</table>

### New technology: biodegradable stent

- Biodegradable esophageal stent: Ella-CS
  - Uncovered stent
  - 25mm dia, 60-135mm length
  - Polydioxanone
  - Similar to polyester
  - Degradation by hydrolysis
  - Hydrolysis accelerated by low pH
  - Not removable
  - Radial force begins to deteriorate ~ 5 wks at pH 1 and 37°C in vitro
  - 2/3 at 7 wks
  - 50% at 3 wks

*Repici, et al., GIE 2010;72:927*
Treatments: biodegradable stents

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<th>Study</th>
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<th>Stent type</th>
<th>Duration</th>
<th>Outcome</th>
<th>P</th>
<th>Migrations + Complic's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repici 2010 GIE</td>
<td>21</td>
<td>Mixed Peptic/caustic/anast</td>
<td>Ella-BD</td>
<td>53 wks median follow up</td>
<td>45% dys-free @ 53 wks fu; med dys score 3 to 1</td>
<td>&lt;0.01</td>
<td>Mgr 10% Bleeding 1/21</td>
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<td>Van Boeckel 2011 CGH</td>
<td>18</td>
<td>Mixed</td>
<td>Ella-BD</td>
<td>166 days median follow up</td>
<td>33% dys-free @ 166 d fu; med dys score 3 to 0</td>
<td>&lt;0.0001</td>
<td>Mgr 22% Bleeding 1/18 Obstr 2/18 Ovrgrth 2/18</td>
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<td>Canena 2012 BMC Gastro</td>
<td>10</td>
<td>Mixed Peptic/anast/XRT</td>
<td>Ella-BD</td>
<td>18.5 mo median follow up</td>
<td>30% dys-free @ median fu 18.5 mo (11-21 mo)</td>
<td></td>
<td>Mgr 20%</td>
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Treatments: incisional therapy

Incisional therapy
- For anastomotic strictures
- Needle-knife incision
- Radial incision & cutting
- Scissor incision

Needle-knife incisional strictureplasty
- 62 pts previously untreated anastomotic strictures
- Randomized, controlled, prospective: 31:31 Savary:IS
- Not blinded
- Outcomes examined at 1, 3, 6 mos
  - Mean dilations: 2.9 vs 3.3; P = 0.46
  - Success rate (% pts with ≤5 dilations / 6 mos): 80.6% vs 67.7%; P = 0.26
Treatments: incisional therapy
Endoscopic radial incision and cutting


- Non-randomized, retrospective
- 54 pts with refractory anastomotic strictures
- Procedure time mean 14 min (r 5-40)

Outcome
- DS 0-1
  - 6 mos: 63%
  - 12 mos: 62%
- Complications
  - Perforation 3.5%

The future
- More “beg-borrow-steal”
- Better, more durable biodegradable stents
  - Cardiac armamentaria
- Stable, non-migrating, easily removable FC-SEMS designs
- New knives
- ESD armamentaria
- New scissors
- NOTES armamentaria: monopolar
  - Made for tissue, not sutures
- Better self-dilation methods
- Oral fluticasone ± other therapies
- ESD armamentaria
- Medication-eluting stents
  - Cardiology/oncology armamentaria
Endoluminal Achalasia Therapy


Northwestern Interdisciplinary NOTES group
Endoluminal GERD Therapy

The Device and Principle of Operation

Roy-Shapira A. Endoscopy 2013 in press.
The problem

Obesity Trends® Among U.S. Adults: BRFSS, 2010
(*BMI ≥ 30, or ~ 30 lbs. overweight for 5’4” person)

Source: Behavioral Risk Factor Surveillance System, CDC.

Obesity Trends® Among U.S. Adults
BRFSS, 1990, 2000, 2010
(*BMI ≥ 30, or about 30 lbs. overweight for 5’4” person)

Source: Behavioral Risk Factor Surveillance System, CDC.

The problem

- Obesity is now more prevalent worldwide than malnutrition from hunger
- 1.6 billion adults are overweight
  - ≥ 400 million adults are obese
- By 2015, 2.3 billion adults will be overweight
  - > 700 million adults will be obese.

Source: http://www.cdc.gov/obesity/data/trends.html

The solution

- Lifestyle modification
  - Diet
  - Exercise
- Medication
- Surgery
- Minimally invasive options

Why surgery?

- 203 women
  - randomized to control group vs home exercise
- Results
  - Some weight reduction in first 6 months, but no difference noted at 1 year

Why surgery?

- 203 women
  - randomized to control group vs home exercise
- Results
  - Some weight reduction in first 6 months, but no difference noted at 1 year
Understanding bariatric surgical anatomy

- Restrictive procedures
- Malabsorptive procedures
- Combination restrictive and malabsorptive procedures

Restrictive Procedures

- Gastric pouch
- Mesh or silastic ring/band
- Adjustable Lap band
- Subcutaneous port

Illustration: John E. Pandolfino, MD
### Malabsorptive Procedures

- **BPD BPD + Duodenal Switch**

Illustrations: John E. Pandolfino, MD

### Roux-en-Y Gastric Bypass: restrictive and malabsorptive

- **Gastric Pouch**
- **Remnant Stomach**
- **Jejunojunostomy**

Illustration: John E. Pandolfino, MD

### Upsides of bariatric surgery

- **Safe and effective**
  - Rapid weight loss
  - Improved comorbidities
  - Durable results

Illustrations: John E. Pandolfino, MD
The only durably effective therapy for severe obesity is currently surgery. Significantly reduces the risk of mortality associated with obesity.

Illustrations: John Pandolfino, MD

If surgery is so effective, why deliver bariatric interventions endoluminally?

Postoperative Complications

**Early (within 30 days)**
- Mortality 1%
- Anastomotic Leak 1.5%
- Pulmonary Embolism 2%
- Acute Gastric Distention rare
- Pneumonia 1.9%
- Wound Infection 6%

**Late**
- Stomal Stricture 3 – 20 %
- Stomal Ulceration 3 – 25 %
- Marginal ulcer (J)
- Stomal ulcer (GP)
- Staple line disruption 1%
- Internal Hernia rare
- Incisional Hernia 15%
- Fistula rare

Perioperative mortality of bariatric surgery is less than 1% but morbidity can be substantial.
Anastomotic Complications: where do they occur?

- Pouch
  - Stomal ulcer
- Anastomosis
  - Marginal ulcer
  - Anastomotic stricture
- Remnant stomach
  - PUD
- Duodenum
  - PUD
- Roux Anastomosis
  - Bleeding
  - Stricture
  - Ulceration

Illustrator: John E. Pandolfino, MD

ASGE Clinical Practice Guideline

Role of endoscopy in the bariatric surgery patient


Access at: www.asge.org

AGA Guidelines & Technical Review

Coming soon:

AGA Management of Post-bariatric Surgery Complications Guidelines and Technical Review
Downsides of bariatric surgery

- Complications
  - Surgical / technical
    - Anastomotic
      - Ulcers
      - Strictures
      - Bleeding
      - Retained foreign material
    - Non-anastomotic
      - Staple-line disruptions
      -Leaks and fistulas
      - Non-anastomotic ulcers
    - Parietal
      - Wound infections
      - Hernias

Removing Foreign Material

Removing retained sutures: more than meets the eye
Downsides of bariatric surgery

- Complications
  - Functional
    - Motility abnormalities
    - Dumping
    - SIBO
  - Nutritional
    - Vitamins
    - Minerals
    - Trace elements
    - Secondary hyperparathyroidism: bone disease
  - Loss of endoscopic access to biliary tree in high-risk population

Laparoscopic Adjustable Gastric Band
Gastric Banding Complications

- Food impaction / pouch outlet obstruction
- Band displacement / slippage
- Band erosion
- Gastric pouch dilatation
- Esophageal dilatation

Gastric Banding Complications

- Band erosion (partially migrated)

Sleeve Gastrectomy Complications
Sleeve Gastrectomy Complications

Sleeve Gastrectomy Complications

Sleeve Gastrectomy Complications
Downsides of bariatric surgery

- Cost
- Limited access
- Irreversibility

Potential advantages of endoluminal bariatrics

- No anastomosis
- Non-resective
- Some completely reversible
- Potentially less expensive
  - No OR time
  - Recover in endoscopy unit
  - Outpatient basis
- Less invasive third option between medication / lifestyle and surgery

Potential advantages of endoluminal bariatrics

The role of the gastroenterologist

- Now: managing complications
  - Robust impact for endoscopy
  - Increasing need
  - Role in bariatric surgery revision under active study
- The future: endoluminal bariatric interventions?
  - No FDA-approved, presently marketed, dedicated devices in US
  - Restrictive, space-occupying, diversion devices in various stages of development

Endoluminal bariatrics: today’s paradigms

- Restrictive
- Malabsorptive
- Diverting

Endoluminal bariatrics: today’s paradigms

- Restrictive
  - Volume-occupying devices
    - Intragastric balloons
  - Restrictive procedures
    - Transoral gastroplasty
    - Endoluminal vertical gastroplasty
    - TERIS
- Malabsorptive
  - Duodeno-jejunal sleeve
  - Gastro-duodeno-jejunal sleeve (requires laparoscopic assistance)
- Diverting
  - Aspiration system
Intragastric balloons

- Presently available balloons (not in US)
  - BioEnterics Intragastric Balloon (BIB) (Inamed-US)
  - Heliosphere BAG (Helioscopic-France)
  - Endogast (Combined endoscopic-surgical insertion; Districlass-France)

BIB Complications

- Meta-analysis: 20 studies; 4240 pts
  - Mortality 0.07%: 3 patients
    - 2 gastric perforation in post-Nissen patients
    - 1 aspiration during BIB insertion
  - Gastric perforation 0.21%: 9 patients
    - 5 / 9 had prior gastric surgery
  - Bowel obstruction requiring endoscopy, surgery, or both for removal 0.17%: 7 pts
  - Gastroduodenal ulcers 0.4%
  - Esophagitis 18.2%


Intragastric balloon: synopsis

- Effective in promoting short-term weight loss in ~2/3 patients: mean weight loss 17.8 kg
- Safe if contraindications observed
- Significant improvement in comorbidities in the short-term
- No data regarding durable weight loss ≥ 2 yrs after BIB removal, or predictive factors for long-term success
- May have role in pts with BMI 30.0-39.9 kg/m² who have failed other weight loss approaches
- May have role in superobese patients in preparation for and facilitating bariatric surgery


Transoral gastroplasty (TOGa)

- Endoluminal gastric stapling
  - Transoral Gastroplasty (TOGa, Satiety, Inc., Palo Alto, CA, USA)
  - Vertical line of titanium staples from His parallel to lesser curve
  - Direct visualization
  - Tubularization of proximal stomach
  - Adjustable and revisable
  - Outpatient procedure

Transoral gastroplasty (TOGa)

- Endoluminal gastric stapling
  - Two components
    - TOGa sleeve stapler
      - 54 Fr, 8.6 mm scope through dedicated channel
      - Anterior and posterior walls into 2 vacuum pods
      - Stapler closed and fired
      - 3 rows of 11 Ti transmural staples
      - 1 cm prox to Z-line extending 4.5 cm distally, parallel to lesser curvature; can be extended

- TOGa restrictor
  - 45 Fr
  - Delivered alongside scope
  - Staples “pleats” at distal end of sleeve to restrict outflow
Transoral gastroplasty (TOGa)

Sleeve stapler inserted, positioned along lesser curvature.

Transoral gastroplasty (TOGa)

Sail, wire deployed to spread tissue and keep separated.

Transoral gastroplasty (TOGa)

Vacuum applied to collect anterior and posterior wall tissue.
Stapler jaws closed and fired.

Stapled sleeve: repeat to lengthen (2 segments shown)

Restrictor inserted into sleeve; scope alongside.
Restrictions in place, retroflexion view.


TOGa in action: Sreeni Jonnalagadda, MD, Christopher Eagon, MD, Washington University in St. Louis.

1 day post-TOGa
Transoral gastroplasty (TOGa)

- Pilot study (Deviere 2008, Moreno 2008)
  - Initial 21 patients treated with original version of device
  - Original protocol followed patients 6 mos
  - Extended protocol now reporting 12 month data (n=20)
  - Phase II now n=141

Intact sleeve, 3 months
**Transoral gastroplasty (TOGa)**

- Pilot study (Deviere 2008, Moreno 2008)
  - 21 patients treated Feb-May 2006
  - Procedure time 2 hr 11 min
  - Anesthesia time 3 hr 8 min
- Technical results
  - 18 full double sleeves
  - 1 single sleeve
  - 2 partial second sleeves
  - Staple line gaps (mean 2.4 cm) in 13/21 pts at 6 mos

**Transoral gastroplasty (TOGa)**

![Graph showing % excess weight loss and % excess BMI loss over time](image)

**Transoral gastroplasty (TOGa)**

![Graph showing BMI decrease over time](image)

BMI decrease at 3, 6, 12 mos; p<0.0001 at 6 mos
Transoral gastroplasty (TOGa)

12 mo follow up data phases I and II: Moreno, et al

Transoral gastroplasty (TOGa)

Follow-up Point

%EWL - Belgian Patients

24 mo follow up data; n=38 at study inception

Transoral gastroplasty (TOGa)

- Current US, IDE-approved, multi-center study for FDA approval
  - Randomized, blinded, sham-controlled
  - N=303 (273 US, 30 international)
  - 9 US centers, 1 in Belgium
  - 2:1 randomization (TOGa:sham)
  - 1-year blinded period, crossover is allowed thereafter
  - Primary endpoint: difference in %EWL between arms
  - Other endpoints: comorbidity improvement, BMI change, QOL scores
Duodenojejunal bypass sleeve (DJBS)

Nitinol anchor with barbs and retrieval drawstring attached to impermeable fluoropolymer liner 2 feet long

Duodenojejunal bypass sleeve (DJBS)

- First human study
  - n=12, prospective, open-label, single-center
  - Endoscopic / fluoroscopic deployment under GA
  - Diet: liquid > puree > solid over 4 weeks
  - Device removed after 12 weeks
  - 71 adverse events: mainly abdo pain/N/V, but 1 oropharyngeal and 1 esoph tear

- First explanted day 9 due to abdominal pain
  - Mean EWL 23.6% (12.5-41.5)
  - Mean total weight loss 10.2 kg (6.1-16.6)
  - Average BMI 43 kg/m² → 38.7 kg/m²
  - Mean BMI decrease 3.8 kg/m²
  - All patients reported greater satiety, decreased food intake
  - 3/4 pts with type 2 DM resolved, 2/4 pts with HTN improved, 2/3 pts with hyperlipidemia improved

- First randomized, controlled study
  - Open-label, randomized, controlled trial
  - DJBS vs low-calorie diet
  - 12 wks, 25 study pts / 14 controls
  - Mean BMI 42 study group / 40 in controls
  - 4 had type 2 DM
  - Primary endpoint: difference in % EWL
  - Secondary endpoints
    - Reduction HbA1C of 0.5% or off DM medication
    - Percentage with > 10% EWL
**Duodenojejunal bypass sleeve (DJBS)**

- First randomized, controlled study
  - 80% maintained DJBS for 12 weeks without adverse events
  - UGI bleeding in 3 patients: mean 13.8 days, no transfusions
  - Anchor migration: 1 patient
  - Sleeve obstruction: 1 patient
  - Mean excess weight loss at 12 weeks
    - 22% device patients
    - 5% control group
    - \( p = 0.02 \)

---

**Duodenojejunal bypass sleeve (DJBS)**

\[ p = 0.02 \]

---

**Duodenojejunal bypass sleeve (DJBS)**

<table>
<thead>
<tr>
<th>Subject</th>
<th>Baseline HbA1c (%)</th>
<th>Week 12 HbA1c (%)</th>
<th>Medication status</th>
<th>%EWL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>101 (diet)</td>
<td>7.6</td>
<td>6.1</td>
<td>Discontinued at week 1</td>
<td>+0.8</td>
</tr>
<tr>
<td>122 (device)</td>
<td>8.5</td>
<td>7.8 (week 8)</td>
<td>Discontinued at week 1</td>
<td>-1.6</td>
</tr>
<tr>
<td>202 (diet)</td>
<td>8.0</td>
<td>7.1</td>
<td>Discontinued at week 9</td>
<td>20.3</td>
</tr>
<tr>
<td>219 (device)</td>
<td>7.6</td>
<td>6.0</td>
<td>Discontinued at week 8</td>
<td>22.9</td>
</tr>
</tbody>
</table>

Type 2 DM outcomes
**Gastroduodenjejunal bypass sleeve (ValenTx)**

**Combining endoluminal-laparoscopic**

**Transoral Endoscopic Restrictive Implant System (TERIS)**

- DDW 2010 AGA Research Forum
  - De Jong, Mathus-Vliegen, Verlaan, Eshuis, Veldhuyzen, Fockens, Amsterdam
  - Overtube placed
  - 5 transmural plications stapled near EGJ
  - 5 silicone anchors placed through plications
  - Restrictive silicone device with 10 mm orifice attached to anchors

**De Jong, et al, DDW 2010**
De Jong 2010: TERIS pilot study
- 13 patients, median BMI 42.1 kg/m²
- Median procedure time 142 min (93-184)
- Pneumoperitoneum in 2 (1 deflated percutaneously, other self-resolved)
- Gastric perforation pt #7 (to surgery)
- Stapling device subsequently redesigned, CO₂ insufflation used → no complications since
- Followed for 6 months
Transoral Endoscopic Restrictive Implant System (TERIS)

- De Jong 2010: TERIS
  - No side-effects at 6 months
  - Median EWL 37.6% (9-56) at 6 months
  - Median BMI decreased from 42.1 to 35.8 kg/m² (30-47)
- Authors conclusions
  - Weight loss was excellent
  - Results comparable to LAGB

AspireAssist Aspiration Therapy System

- Currently in clinical trials
  - Endoscopically placed implant very similar to PEG tube
  - Aspiration takes place 20 min after meal
    - Patient connects tube to companion valve device which allows passive drainage of gastric contents with water lavage
    - 1/3 – 1/2 of stomach contents removed
Endoscopic technologies are delivering more and more formerly surgical therapies endoluminally.

Traditional endoscopic therapies and algorithms are being refined actively.

Results from longer-term, large, randomized, prospective, studies are needed and eagerly anticipated.

Regulatory approval, comparative cost, and reimbursement remain major hurdles in delivery of these therapies.

**Conclusion**

- Endoscopic technologies are delivering more and more formerly surgical therapies endoluminally.
- Traditional endoscopic therapies and algorithms are being refined actively.
- Results from longer-term, large, randomized, prospective, studies are needed and eagerly anticipated.
- Regulatory approval, comparative cost, and reimbursement remain major hurdles in delivery of these therapies.