Advances in Endoscopy Update

Newer Technologies in Adult GI

NASPGHAN

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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

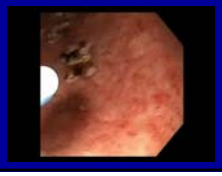
Emphasis on *therapeutic* endoscopy

- 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

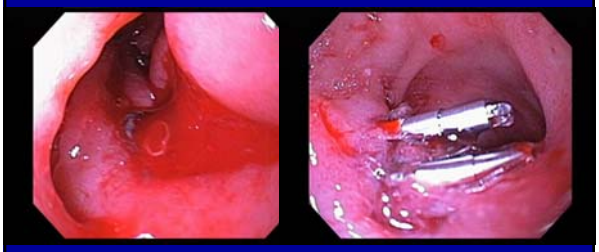
- Thermal devices
  - Coaptive devices: tamponade + coagulation
    - Multipolar electrocoagulation (MPEC) probe or heat probe
    - All forms equivalent; limited data suggest combination with epin more effective than monotherapy
  - APC
    - Non-coaptive therapy for superficial lesions



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

Hemostatic clips



Endoscopic Therapy of UGIB

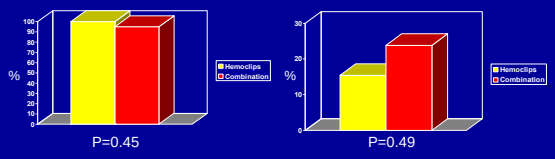
- Therapeutic modalities
  - 2009 meta-analysis of 75 studies show thermal, injectables other than saline/epinephrine, and clips <u>all</u> effective in PUD hemostasis
  - <u>No single modality was superior</u>
  - Epi with second treatment modality more effective than epi alone
  - Epi alone should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

Laine L, McQuaid KR. Clin Gastroenterol Hepatol 2009;7:33-47.

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 | **Rebleeding Rate**



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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

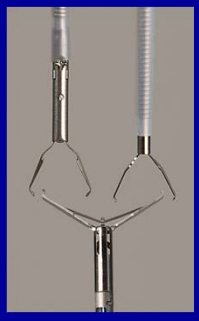
Visible Vessel

Upper GI Vascular Abnormalities

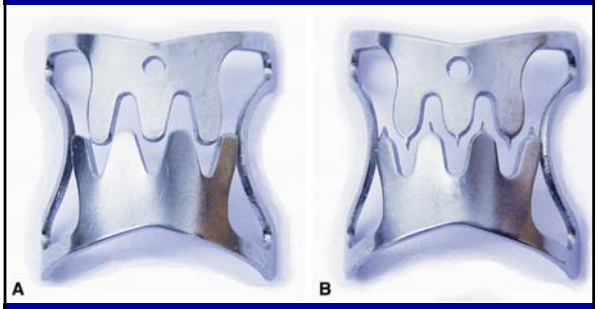
- No prospective trials comparing methods for acute UGIB due to vascular abnormalities
  - Vascular ectasias
  - Dieulafoy lesions
  - GAVE
- Endoscopic marking
  - Consider tattooing difficult-to-locate lesions
  - Place clip whether endotherapy succeeds or fails to facilitate IR / surgical intervention

A Peek at New Technologies in Hemostasis

- New hemostatic clips



Over-the-scope Clip



Kirschniak A. Gastrointest Endosc 2007;66:162

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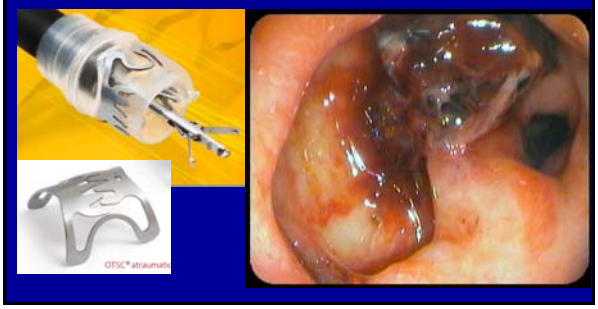

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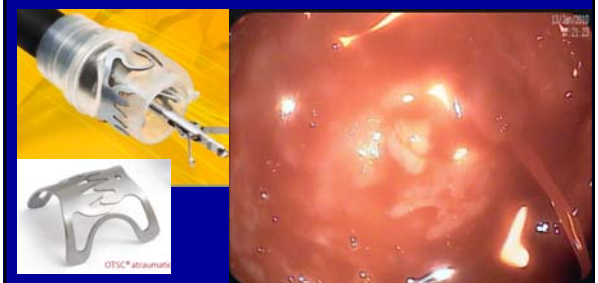

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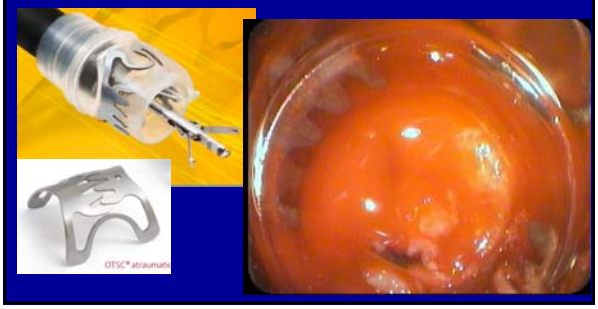

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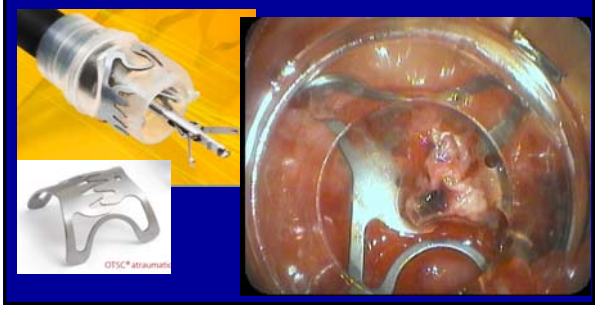

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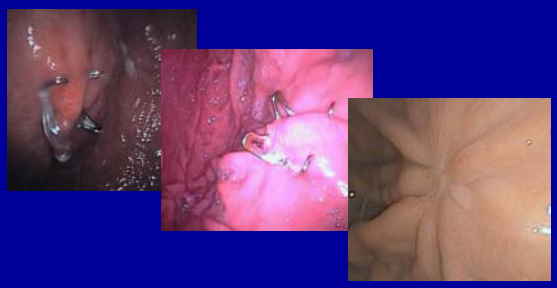


A Peek at New Technologies in Hemostasis

- Monopolar coagulation grasping forcep

Monopolar Cautery

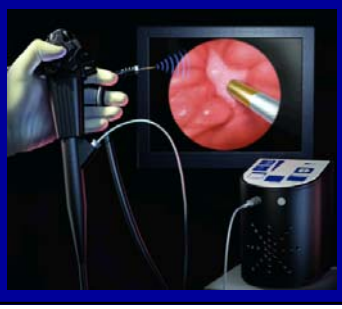
- **Monopolar device**
  - Designed for endoscopic bleeding
  - Flat jaws for grasping
  - Rotational ability
  - Grounding pad required
- **Optimal settings (stomach)**
  - 50 Watts for 2 or 3 seconds

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

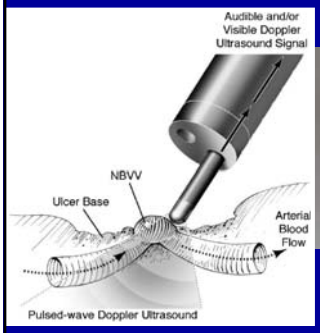
Saltzman JR. Gastrointest Endosc 2010;72(4):796

A Peek at New Technologies in Hemostasis

- **Doppler probe**

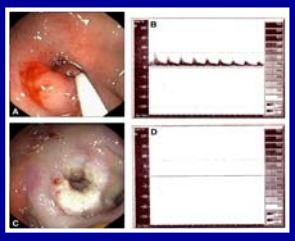


Doppler Ultrasound



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

Cases	Procedure Details/Outcomes			Outcome
Bleeding Indication	*Forrest Score	Ulcer Location	Acute Hemostasis (procedural)	Hemostasis 72 hours post procedure
Melena	1b	Duodenum	Yes	Yes
Melena	1b	Duodenum	Yes	Yes
Hematemesis, Melena	1b	Stomach	Yes	Yes
Melena	1b	Duodenum	Yes	Yes
Melena	1b	Stomach	Yes	Yes
Melena	1b	Stomach	Yes	Yes
Hematemesis, Melena	1a	Stomach	‡No	n/a
Hematemesis, Melena	1b	Duodenum	Yes	†No
Melena	1b	Stomach	Yes	Yes
Melena	1b	Duodenum	Yes	Yes
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Melena	1b	Stomach	Yes	Yes
Melena	1b	Duodenum	Yes	Yes
Melena	1b	Duodenum	Yes	Yes

Human Hemostatic Spray Initial Trial

(Forrest 1b = oozing)

Sung JJY. Endoscopy 2011;43:291

A Peek at New Technologies in Hemostasis

- New hemostatic spray

A Peek at New Technologies in Hemostasis

- New hemostatic spray

Hemospray Considerations

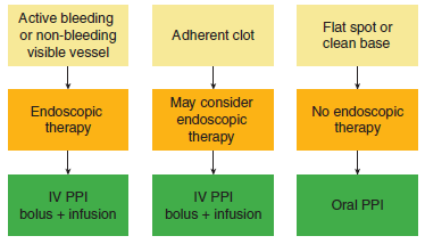
- Effective only in actively oozing or spurting bleeding lesions
- Does not require special expertise
- Can be rapidly used if bleeding occurs after polypectomy or sphincterotomy
- May be effective in difficult locations
- Further clinical studies are needed

Upper GI Bleeding 2012: Summary

- Consult new 2012 ASGE Guidelines at www.asge.org
  - "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

Upper GI Bleeding 2012: Summary

- Consult new 2012 ACG Guidelines at www.gi.org



Laine L, Jensen DM. Management of Patients with Ulcer Bleeding. ACG Practice Guidelines. Am J Gastroenterol 2012;107:345-360.

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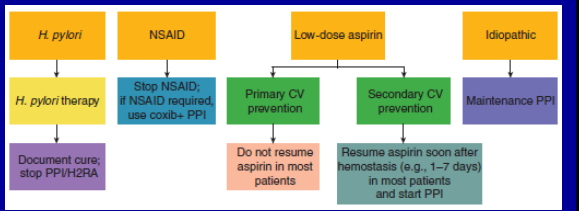

Laine L, Jensen DM. Management of Patients with Ulcer Bleeding. ACG Practice Guidelines. Am J Gastroenterol 2012;107:345-360.

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

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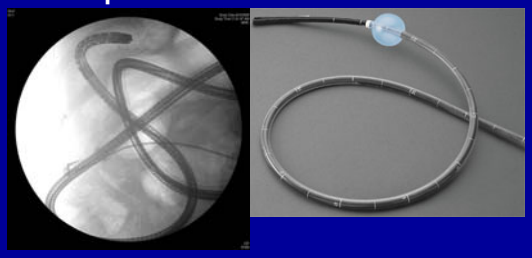
- Deep enteroscopy: diagnostic and therapeutic



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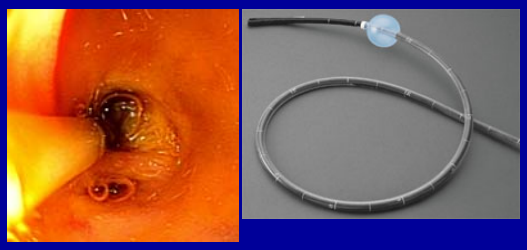
- Deep enteroscopy: diagnostic and therapeutic



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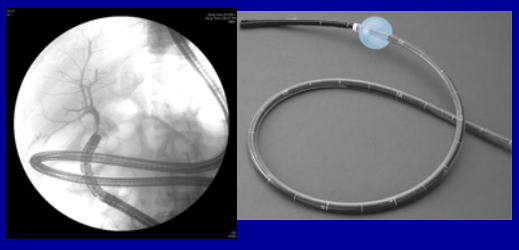

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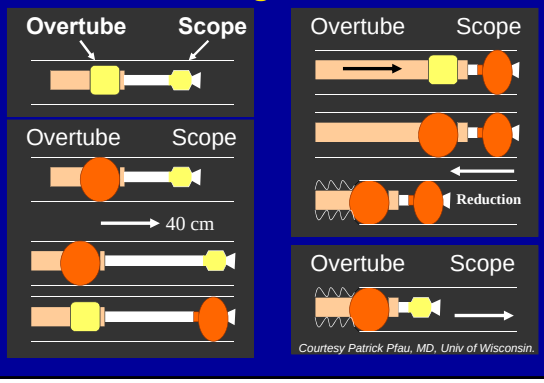


Courtesy Patrick Pfau, MD, Univ of Wisconsin.

Background

- Deep enteroscopy: diagnostic and therapeutic
  - Rotational enteroscopy

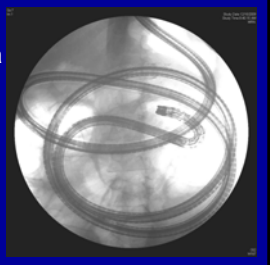
Performance characteristics

- 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%

Kawamura T. GIE 2008. Pasha S. Clin Gastro Hep 2008.

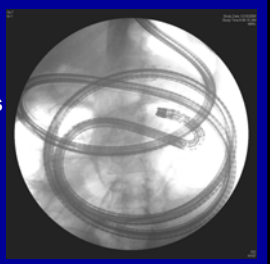
Balloon enteroscopy caveats

- 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



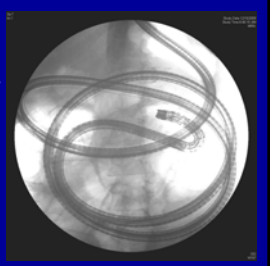
Balloon enteroscopy caveats

- 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



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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]

[1]*Efthymiou M et al, GIE, 2012,* [2] *Domagk D et al, Endoscopy, 2011,* [3] *Takano N et al, GIE, 2011*

Enteroscopy for Small Bowel Bleeding
Effective?

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

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

Mensink P. Endoscopy 2007.
Kamal A. GIE 2008.

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 TI
    - 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

Biliary Endoscopy

CCD-video choledochoscopy

CCD-video choledochoscopy with NBI

Image courtesy Professor Takao Itoi, MD, Tokyo Medical University

CCD-video choledochoscopy

CCD-video choledochoscopy with NBI

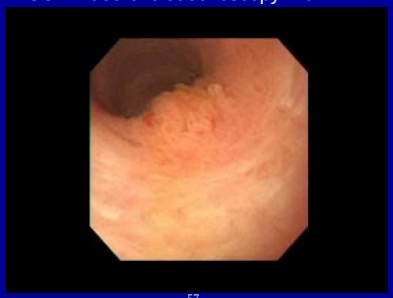
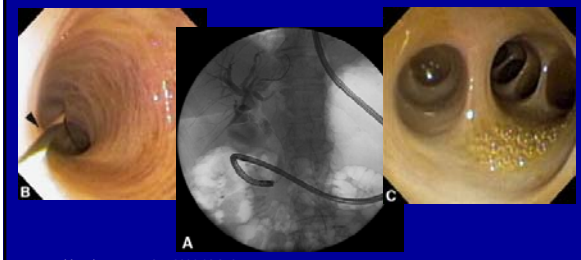


Image courtesy Professor Takao Itoi, MD, Tokyo Medical University

Per-oral choledochoscopy (POCS)

Direct-video choledochoscopy



Larghi and Waxman, GIE 2006;63:853.

58

Per-oral choledochoscopy (POCS)

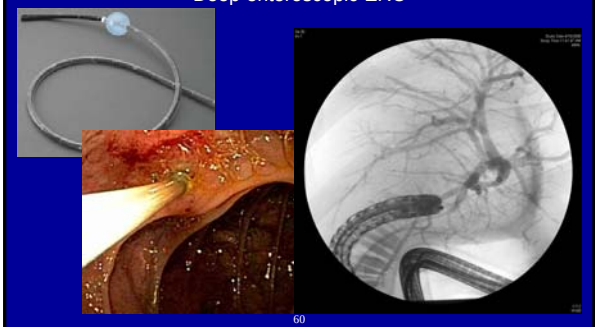
CCD-video choledochoscopy with NBI

59

Image courtesy Irving Waxman, MD, University of Chicago

Altered-anatomy ERCP

Deep-enteroscopic ERC



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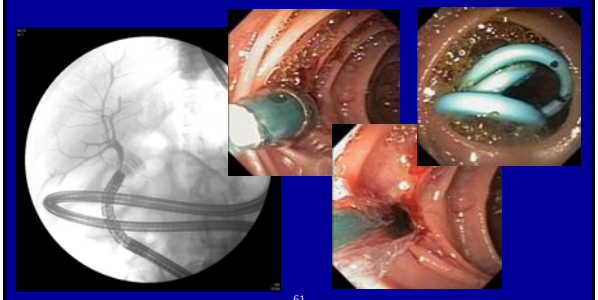
Altered-anatomy ERCP

Deep-enteroscopic ERC



61

Luminal Stenting

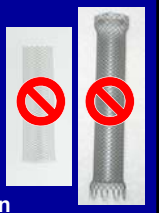
Benign esophageal stricture management

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

Treatments: Stents

Treatments: Stents

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



Treatments: Stents

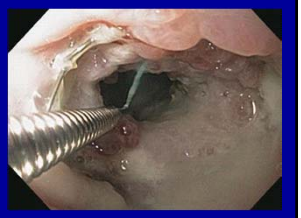
- Stent therapy: concept in benign esophageal strictures
  - *Temporary*, long-term/continuous/gradual dilator
  - Stricture remodeling
  - Initial enthusiasm was tempered by
    - Migration
    - Chest pain
    - Not durable
    - AE fistulas (Rogart, et al., Endoscopy 2007)
- Biodegradable stents
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

Treatments: Stents

deWijkerslooth LRH, et al., *Am J Gastroenterol* 2011;*106*:2080.

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

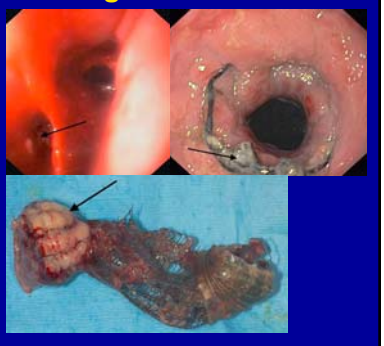
Why we don't use partially covered SEMS in benign disease



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

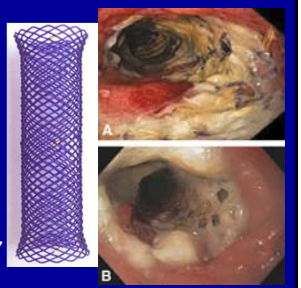
Study	n	Stricture type	Stent type	Duration stenting	Outcome	Migrations Complic's
Repici 2004 GIE	15	Mixed	Polyflex SEPS	6 wks	80% dys-free at mean 22 mos	Migr 7% Complic 0
Evrard 2004 GIE	21	Mixed	Polyflex SEPS	2d-56 wks	80% dys-free at median f/u 21 mos	Migr 52% Airway compr 5%
Dua 2008 AJG (prosp)	40	Mixed; most anast /corrosive/ XRT	Polyflex SEPS	4 wks	40% dys-free at median 53 wk follow up	Migr 22% Death 1 bld Fistula 1 Perf 2
Oh 2010 DDS	13	Anast 11/13	Polyflex SEPS	6 wks	23% dysph-free @ μ 37 d, r 6-120 d	Migr 30% No major complic's
Repici 2010 APT	130 Sys Rvw	Mixed	Polyflex SEPS	?; med f/u 13 mo	52% symp free at med 13 mo f/u	Migr 24% Maj comp 9%, dth 1%

Treatments: FC-SEMS stents

Study	n	Stricture type	Stent type	Duration Stent/post	Outcome	Migrations + Complications
Kim 2009 Eur Radiol	55 PR	Corrosive 80%; else mixed	Tae-woong Niti-S	1 wk-6 mo/ μ 38 mos	38% patency at 6 mos; 33% at 1 yr	Migr 25% Ovrgrth 31%
Senousy 2010 DDS	7 RT	Mixed anast/pep/ XRT/PDT	Alimaxx	4-84 d, μ 37 d/ μ 172 d	"Clin impvmt dysphagia" 100%	Migr 39% Minor complic only
Eloubeidi 2011 GIE	19 PR	Mixed	Alimaxx	6-300 d, 64±74d/ 24-360 d total f/u	30d median symptom - free post stent plcmt	Migr 37% No major compl
Hirdes 2012 GIE	15	Mixed	Wallflex	Med 109 d or to migr/ obstr/pain	100% dysph recur med15 d post-remvl	Migr 33% Asp pneum 7% Ovgrth 50%

New technology: biodegradable stent

- **Biodegradable esophageal stent: Ella-CS**
  - **Uncovered stent**
  - **25mm dia, 60-135mm length**
  - **Polydioxanone**
  - **Similar to polyester**
  - **Degrades by hydrolysis**
  - **Hydrolysis accelerated by low pH**
  - **Not removable**
  - **Radial force begins to deteriorate ~ 5 wks at pH 7 and 37°C in vitro**
    - **2/3 at 7 wks**
    - **50% at 9 wks**



Repici, et al., GIE 2010;72:927

Treatments: biodegradable stents

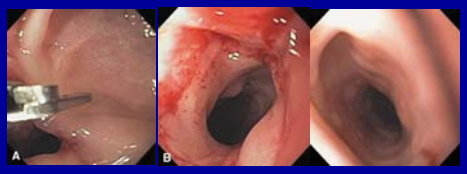
Study	n	Stric type	Stent type	Duration	Outcome	P	Migrations + Complic's
Repici 2010 GIE	21	Mixed Peptic/ caustic /anast	Ella-BD	53 wks median follow up	45% dys-free @ 53 wks f/u; med Δ dys score 3 to 1	<0.01	Migr 10% Bleeding 1/21
Van Boeckel 2011 CGH	18	Mixed	Ella-BD	166 days median follow up	33% dys-free @ 166 d f/u; med Δ dys score 3 to 0	<0.0001	Migr 22% Bleeding 1/18 Obstr 2/18 Ovrgrth 2/18
Canena 2012 BMC Gastro	10	Mixed Peptic/ anast/ XRT	Ella-BD	18.5 mo median follow up	30% dys-free @ median f/u 18.5 mo (r 11-21 mo)		Migr 20%

Treatments: incisional therapy

Incisional therapy

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

Hordijk GIE 2009



Beilstein GIE 2005

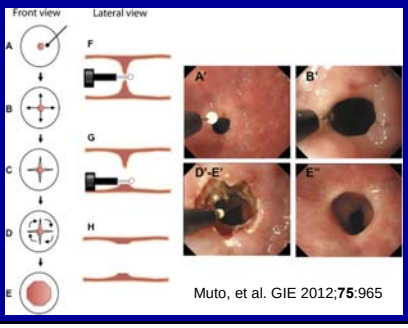
Treatments: incisional therapy

Needle-knife incisional strictureplasty

- Hordijk, et al. GIE 2009;70:849.
- 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



Muto, et al. GIE 2012;**75**:965

Treatments: incisional therapy

- Endoscopic radial incision and cutting
  - Muto, et al. GIE 2012;75:965.
  - 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

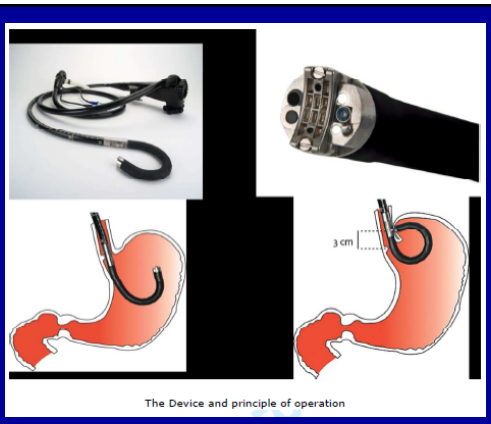
- More "beg-borrow-steal"
- Better, more durable biodegradable stents
  - Cardiac armamentaria
- Stable, non-migrating, easily removable FC-SEMS designs
- New knives
  - ESD armamentaria
- New scissors
  - NOTES armamentaria: monopolar
  - Made for tissue, not sutures
- Better self-dilation methods
-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

Endoluminal Achalasia Therapy

Pasricha P, Hawari R, Ahmed I , Chen J, Cotton P, Hawes R, Kalloo A, Kantsevoy S, Gostout CJ. Endoscopic Submucosal Esophageal Myotomy. Endoscopy 2007;39:761-764, and DDW 2007, Washington, DC

Northwestern Interdisciplinary NOTES group

Endoluminal GERD Therapy



The Device and principle of operation

Roy-Shapira A. Endoscopy 2013 in press.

Roy-Shapira A. Endoscopy 2013 in press.

Daniloglu A, et al. Digestive Endoscopy 2013.

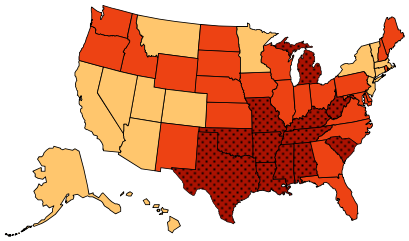
Daniloglu A, et al. Digestive Endoscopy 2013.

Bariatric Endoscopy

The problem

Obesity Trends* Among U.S. Adults: BFRSS, 2010

(*BMI ≥30, or ~ 30 lbs. overweight for 5' 4" person)



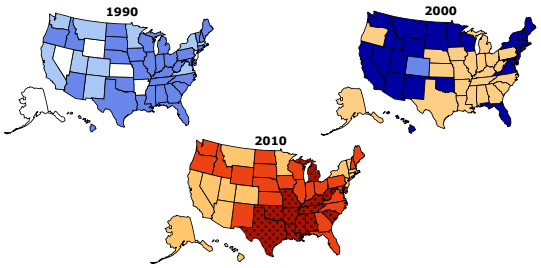
No Data | <10% | 10%–14% | 15%–19% | 20%–24% | 25%–29% | ≥30%

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)



No Data | <10% | 10%–14% | 15%–19% | 20%–24% | 25%–29% | ≥30%

Source: Behavioral Risk Factor Surveillance System, CDC.

The problem

- Obesity is now more prevalent world-wide 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.

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

World Health Organization, Obesity: preventing and managing the global epidemic: Report of a WHO consultation, *WHO Technical Report Series 894*, World Health Organization, Geneva, Switzerland (2000).

The solution

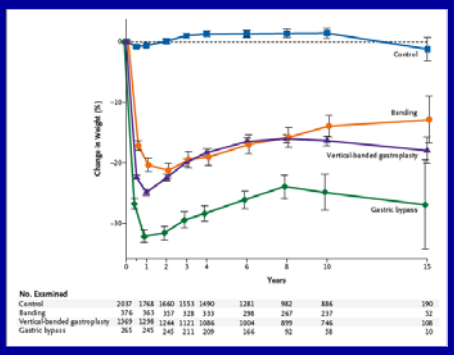
- Lifestyle modification
  - Diet
  - Exercise
- Medication
- Surgery ⬅
- Minimally invasive options

Why surgery?

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

Mediano MF, et al. A randomized clinical trial of home-based exercise combined with a slight caloric restriction on obesity prevention among women. Prev Med. 2010 Sep-Oct;51(3-4):247-52.



Sjostrom, et al. N Engl J Med 2007;357:741. Effects of Bariatric Surgery on Mortality in Swedish Obese Subjects.

Understanding bariatric surgical anatomy

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

Restrictive Procedures

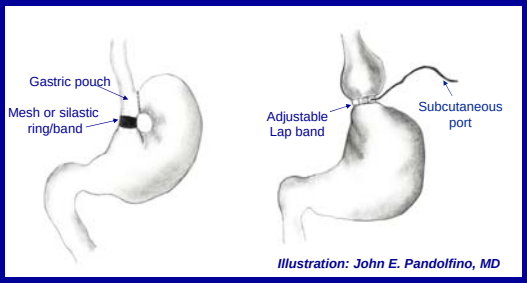
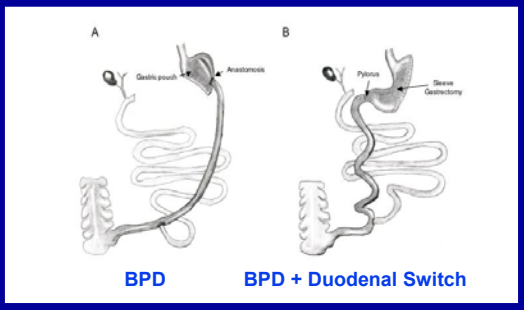


Illustration: John E. Pandolfino, MD

VBG Lap Band

Malabsorptive Procedures



BPD BPD + Duodenal Switch

Illustrations: John E. Pandolfino, MD

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

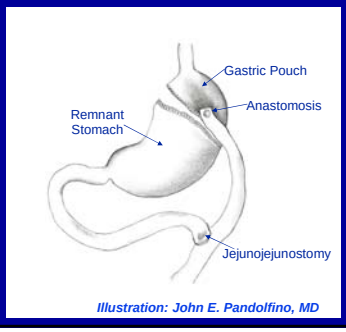
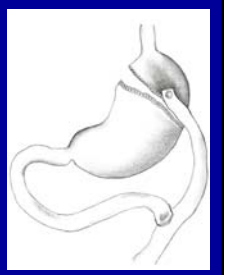


Illustration: John E. Pandolfino, MD

Upsides of bariatric surgery

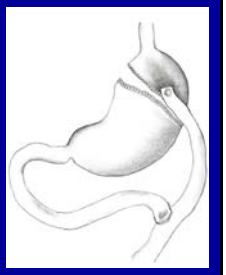
- Safe and effective
  - Rapid weight loss
  - Improved comorbidities
  - Durable results



Illustrations: John Pandolfino, MD

Upsides of bariatric surgery

- The only durably effective therapy for severe obesity is currently surgery
- Significantly reduces the risk of *mortality* associated with obesity



Illustrations:
John Pandolfino, MD

M. Magnusson, et al. Five-year results of laparoscopic vertical banded gastroplasty in the treatment of massive obesity, *Obes Surg* 12 (2002), pp. 826–830.

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

Postoperative Complications

Perioperative mortality of bariatric surgery is less than 1% but morbidity can be substantial:

Early (within 30 days)

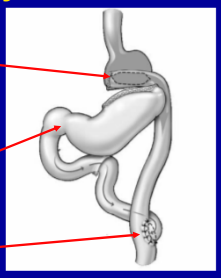
- Mortality 1%
- Anastomotic Leak 1.5%
- Pulmonary Embolism 2%
- Acute Gastric Distention rare
- Pneumonia 1.9%
- Wound Infection 6%

Late

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

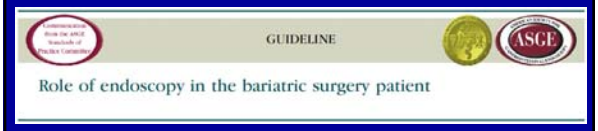
Anastomotic Complications: where do they occur?

- 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



Anderson, MA, et al. Gastrointest Endosc 2008;68:1.

Access at: www.asge.org

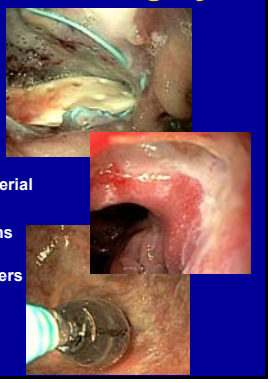
AGA Guidelines & Technical Review

Coming soon:

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

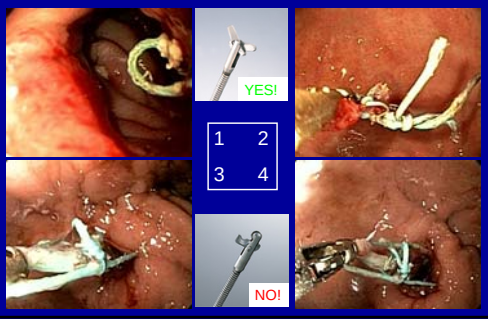
Downsides of bariatric surgery

- 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



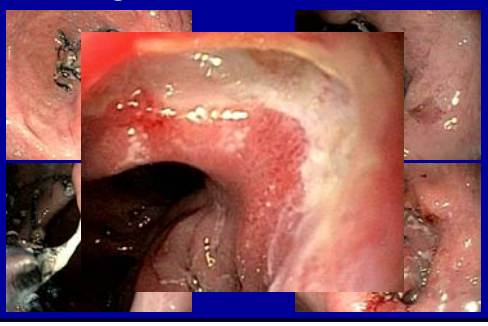
Removing Foreign Material

Removing retained sutures: more than meets the eye



Removing Foreign Material

Removing retained sutures: what to do



Downsides of bariatric surgery

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

Downsides of bariatric surgery

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

Laparoscopic Adjustable Gastric Band

Gastric Banding Complications

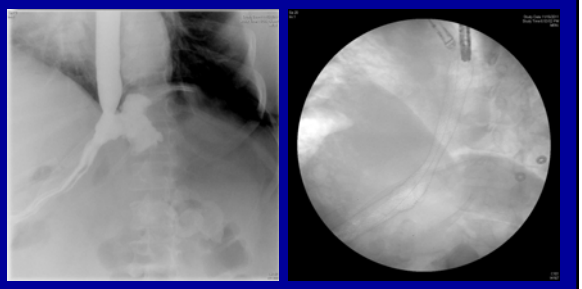
- Food impaction / pouch outlet obstruction
- Band displacement / slippage
- Band erosion
- Gastric pouch dilatation
- Esophageal dilatation

Gastric Banding Complications

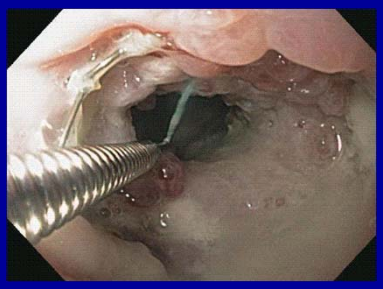
- Band erosion (partially migrated)

Video courtesy Prof. Raul Monserrat, Caracas, Venezuela

Sleeve Gastrectomy Complications

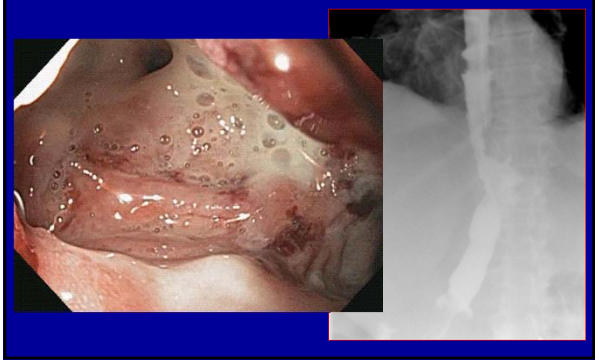


Sleeve Gastrectomy Complications



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

TABLE 1. Potential endoscopic obesity procedure categories

Procedure category	Procedure aim
Early intervention	Providing weight loss or stabilization in early stage obese patients who do not yet qualify for traditional surgery
Bridge to surgery	Reducing the obesity-related operative risk for various bariatric and nonbariatric surgeries
Metabolic	Primarily addressing comorbid illness (eg, diabetes)
Primary	Endoscopic option for the traditional surgical population, with outcomes and risk profiles similar to those of current surgeries
Revision	Repairing failed bariatric surgical procedures

Thompson CC. Endoscopic Therapy of Obesity: a new paradigm in bariatric care. *Gastrointestinal Endoscopy* 2010;72:505-507.

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

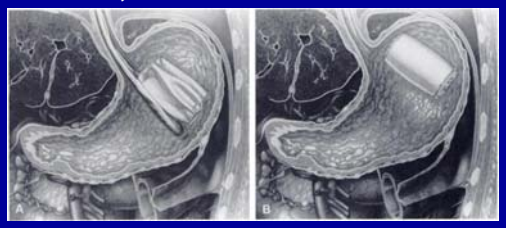
Full disclosure: ENDOLUMINAL BARIATRIC THERAPIES

STOP

NONE OF THE DEVICES BEING DISCUSSED TODAY ARE APPROVED BY THE US FDA FOR THE ENDOLUMINAL TREATMENT OF OBESITY IN THE UNITED STATES

Intragastric balloons

- Historical precedent: Garren-Edwards Gastric Bubble (GEGB), b. 1985; d. 1988



From Velchik, et al. J. Nucl Med 1989;30:692.

Intragastric balloons

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

Images: Kahtani K, 2008; Trande P, 2008.

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%

Dumonceau. Obes Surg 2008;18:1611.

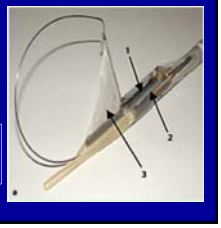
Intragastric balloon: synopsis

- 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

Dumonceau. Obes Surg 2008;18:1611.

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



Moreno, et al., Endoscopy 2008;40:406.

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

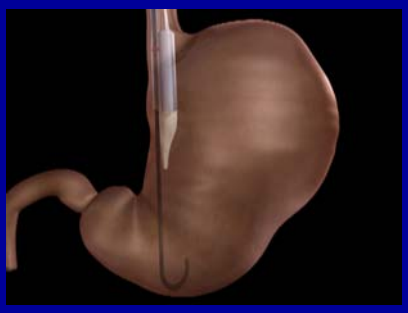
Transoral gastroplasty (TOGa)

- Endoluminal gastric stapling
  - Two components
    - TOGa sleeve stapler

Transoral gastroplasty (TOGa)

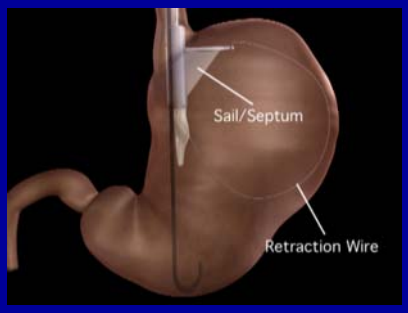
- Endoluminal gastric stapling
  - Two components
    - TOGa sleeve stapler
    - TOGa restrictor
      - 45 Fr
      - Delivered alongside scope
      - Staples "pleats" at distal end of sleeve to restrict outflow

Transoral gastroplasty (TOGa)



Sleeve stapler inserted, positioned along lesser curvature.

Transoral gastroplasty (TOGa)



Sail, wire deployed to spread tissue and keep separated.

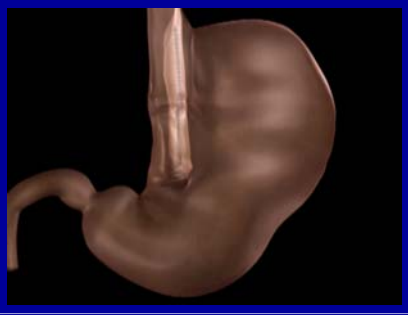
Transoral gastroplasty (TOGa)

Vacuum applied to collect anterior and posterior wall tissue.

Transoral gastroplasty (TOGa)

Stapler jaws closed and fired.

Transoral gastroplasty (TOGa)

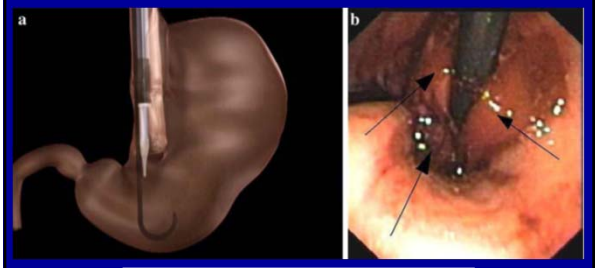


Stapled sleeve: repeat to lengthen (2 segments shown)

Transoral gastroplasty (TOGa)

Restrictor inserted into sleeve; scope alongside.

Transoral gastroplasty (TOGa)



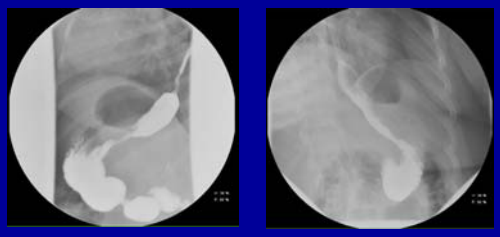
Restrictions in place, retroflexion view.

Deviere, et al. Surg Endosc 2008;22:589.

Transoral gastroplasty (TOGa)

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

Transoral gastroplasty (TOGa)



1 day post-TOGa

Transoral gastroplasty (TOGa)


Intact sleeve, 3 months

Transoral gastroplasty (TOGa)


Intact sleeve, 3 months

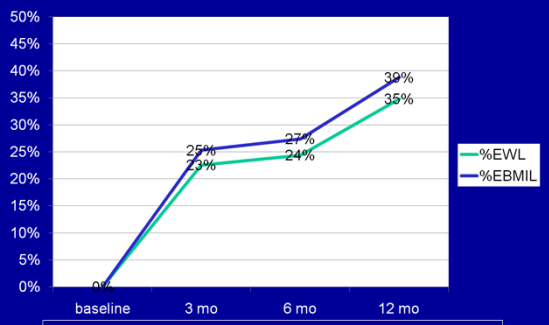
Transoral gastroplasty (TOGa)

- **Pilot study (Deviere 2008, Moreno 2008)**
  - **Initial 21 patients treated with original version of device**
  - **6 month results published Deviere, et al, Surg Endosc 2008;22:589**
  - **Original protocol followed patients 6 mos**
  - **Extended protocol now reporting 12 month data (n=20)**
  - **Phase II now n=141**

Transoral gastroplasty (TOGa)

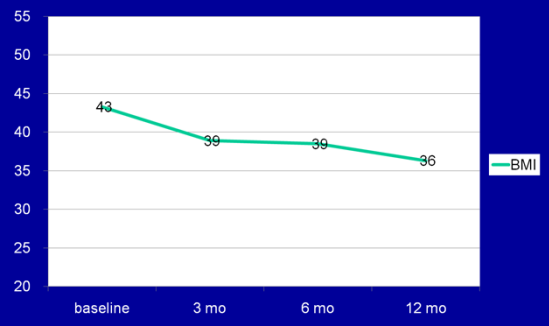
- Pilot study (Deviere 2008, Moreno 2008)
  - 21 patients treated Feb-May 2006
  - Procedure time 2 hr 11 min
  - Anesthesia time 3 hr 8 min
  - Technical results
    - 18 full double sleeves
    - 1 single sleeve
    - 2 partial second sleeves
    - Staple line gaps (mean 2.4 cm) in 13 / 21 pts at 6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

Transoral gastroplasty (TOGa)



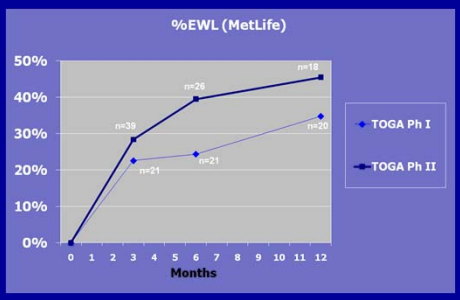
% excess weight loss and % excess BMI loss

Transoral gastroplasty (TOGa)



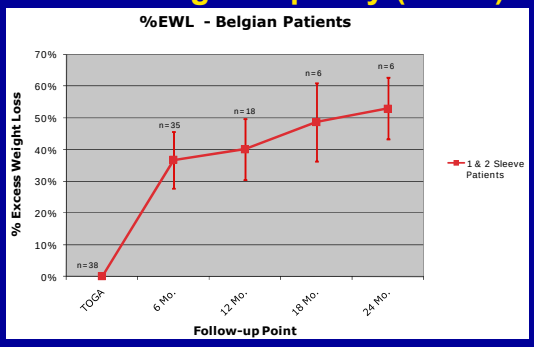
BMI decrease at 3, 6, 12 mos; p<0.0001 at 6 mos

Transoral gastroplasty (TOGa)



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

Transoral gastroplasty (TOGa)



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**

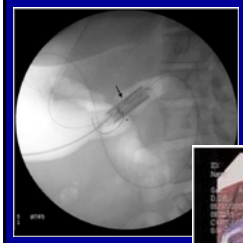
Duodenojejunal bypass sleeve (DJBS)

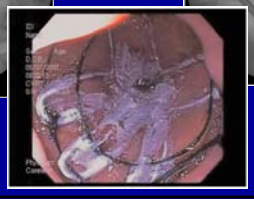
Nitinol anchor with barbs and retrieval drawstring attached to impermeable fluoropolymer liner 2 feet long

Duodenojejunal bypass sleeve (DJBS)

Gersin, et al., Surg Innovation 2007;14:275.

Duodenojejunal bypass sleeve (DJBS)





Gersin, et al., Surg Innovation 2007;14:275.

Duodenojejunal bypass sleeve (DJBS)

- First human study
  - Rodriguez-Gunert, Surg Obes Rel Dis 2008;4:55.
  - 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

Duodenojejunal bypass sleeve (DJBS)

- First human study
  - 2 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/m^2 → 38.7 kg/m^2
  - Mean BMI decrease 3.8 kg/m^2
  - 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

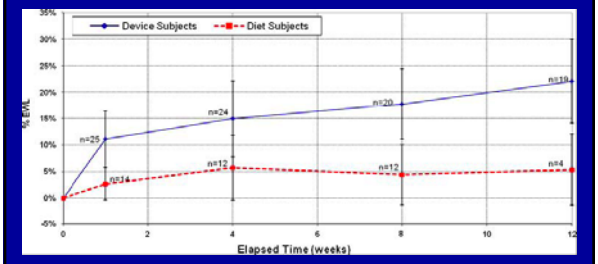
Duodenojejunal bypass sleeve (DJBS)

- First randomized, controlled study
  - Tarnoff, et al. Surg Endosc 2009; 23:650.
  - 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)

Subject	Baseline HbA1c (%)	Week 12 HbA1c (%)	Medication status	%EWL (%)
101 (diet)	12.6	7.8	Discontinued at week 1	+0.8
122 (device)	5.5	5.8 (week 8)	Discontinued at week 1	31.6
202 (device)	7.8	7.1	Decreased at week 9	20.3
219 (device)	6.6	6.0	Decreased at week 8	22.9

Type 2 DM outcomes

Gastroduodenojejunal bypass sleeve (ValenTx)

Combined 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

Transoral Endoscopic Restrictive Implant System (TERIS)

De Jong, et al, DDW 2010

Transoral Endoscopic Restrictive Implant System (TERIS)

De Jong, et al, DDW 2010

Transoral Endoscopic Restrictive Implant System (TERIS)

De Jong, et al, DDW 2010

Transoral Endoscopic Restrictive Implant System (TERIS)

- De Jong 2010: TERIS pilot study
  - 13 patients, median BMI 42.1 kg/m^2
  - 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, CO_2 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/m^2 (30-47)
  - Authors conclusions
    - Weight loss was excellent
    - Results comparable to LAGB
  - De Jong, et al. *Gastrointestinal Endoscopy* 2010;72:497-504.

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

AspireAssist Aspiration Therapy System

AspireAssist Aspiration Therapy System

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

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