Disclosure Statement

Covidien: Consultant, Grants
Non-Invasive Bariatric Procedures

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Outline for Non-Invasive Bariatrics Procedures

- Rationale
- Indications
- Techniques
- Outcomes
ASMBS Guidelines For Endoluminal Procedures

Theoretical goals include decreasing the invasiveness, risk, and barriers to acceptance.

Outcomes cannot be assumed and must be proven.

Limit to clinical trials.

Part of comprehensive treatment program.
Transoral Gastroplasty (TOGA)
Transoral Gastroplasty (TOGA)

Figure 3. A, The TOGA device. A “sail septum” is used to keep the stomach in the desired position for the procedure. B, Gastric mucosa being suctioned into the TOGA device to create restrictive pouch. C, restrictive pouch.
Transoral Gastroplasty (TOGA)

Does similar anatomy to VBG destines TOGA to same outcomes?
Transoral Gastroplasty (TOGA)

Safety, feasibility and weight loss of transoral-gastroplasty: First human multicenter study

21 patients were enrolled
Mean age 43 (22-57) years
Mean BMI 43 (35-53) kg/m
Device introduction was completed safely in all patients
Vomiting, pain, nausea, and transient dysphagia

Devière et al  Surg Endosc. 2008
Transoral Gastroplasty (TOGA) cont’d

At 6 months, all patients had full or partial staple lines

Patients lost an average
  17.6 pounds at 1 month,
  24.5 pounds at three months
  26.5 pounds at 6 months

EWL: 16%, 22%, and 24%, respectively]

Devière et al  Surg Endosc. 2008
Transoral gastroplasty for morbid obesity: a multicenter trial with a 1-year outcome.

- 67 patients
- Mean age 41 years
- Mean BMI 41.5 kg/m²
- TOGA using 2 stapling devices
- 53 pts available at the 12-month follow-up
- 21% lost to follow-up
- %BMI loss was 44

Devière J et al. Gastrointest Endosc. 2011
Transoral Gastroplasty (TOGA)

Transoral gastric volume reduction as intervention for weight management: 12-month follow-up of

18 patients
mean age 40 years
Mean BMI was and 38 kg/m
Average plications was 6
Mean procedure time was 2.1 hours

Brethauer et al. SOARD 2012
Transoral Gastroplasty (TOGA)

**Transoral gastric volume reduction as intervention for weight management: 12-month follow-up of**

- Mean weight: \(-11.0 \pm 10.0\) kg
- Mean BMI: \(-4.0 \pm 3.5\) kg/m
- Mean waist circ: \(-12.6 \pm 9.5\) cm
- Mean EWL: \(27.7\% \pm 21.9\%\)

Endoscopy showed partial or complete release of plications in 13 patients

Brethauer et al SOARD 2012
Transoral Gastroplasty (TOGA)

Can not log on www.satietyinc.com
Company on sale on Feb 2011
Had raised 30 millions
470 patients treated
Trans-oral Endoscopic Restrictive Implant System (TERIS)
Trans-oral Endoscopic Restrictive Implant System (TERIS)

Short-term safety and efficacy of the Transoral Endoscopic Restrictive Implant System for the treatment of obesity

13 patients
BMI 35-50
1 patient gastric perforation
2 patients, pneumoperitoneum
median EWL: 28%.
Median BMI decreased from 42 to 38 kg/m²

de Jong et al Gastrointest Endosc. 2010
Vagal Pathways in GI Tract

Berthoud et al. Reg Peptides 2008

Brain
(Homeostatic Regulator)

Cortex

Hypothalamus

Medulla

Insulin
Amylin
Glucagon
PP

Hormones & Fuels

Adipose Tissue
Adiponectin
Leptin
TNFa, IL-1

β-cell

Incretins

Muscle
IL-6, ?

Liver

Brain

Start / Stop Eating

Autonomic & Endocrine Outflow

Food

Taste

Ghrelin

GHS-R

Distension

Leptin

ObRb

CCK1R

CCK

Fat

Protein

Glucose

Glucagon

GLP1R

GLP-1

PYY3-36

Y2R

5HT3R

5HT

Portal Vein
Hormones & Fuels

Berthoud et al. Reg Peptides 2008
Neuromodulation and Vagal Blockade
Metabolic and Bariatric Surgery

EMPOWER study: randomized, prospective, double-blind, multicenter trial of vagal blockade to induce weight loss in morbid obesity

Conducted in USA and Australia.
294 pts implanted with the vagal blocking system
- treated: n = 192
- control: n = 102
BMI: 41 ± 1 kg/m²
Age: 46 ± 1 years

EMPOWER study: randomized, prospective, double-blind, multicenter trial of vagal blockade to induce weight loss in morbid obesity

Device-related complications: 3%

EWL
Treatment: 17±2 %
Control : 16±2%

Weight loss was related linearly to hours of device use

Vagatomy and RYGB in Rats

Shin et al Ann Surgery 2012
Duodeno-Jejunal Sleeve

Endoscopic Gastrointestinal Sleeves
- Inserted endoscopically
- Food is segregated from the digestive juices
- Mal-absorption or Mal-digestion
Duodeno-Jejunal Sleeve

[Diagram showing the anatomy of the digestive system with labels for duodenal jejunal bypass sleeve and biliary and pancreatic secretions]
Duodeno-Jejunal Sleeve

First Human Experience by Tarnoff

12 patients enrolled
10 complete insertion
EWL at 12 weeks is 23%
Normal FBG in 4 diabetics

Tarnoff et al SOARD, 2008
Improvement of Metabolic Parameters

Longer duration 6 months
Weight loss: 12% of baseline
70% of diabetic dropped HBA1C <7

de Moura et al; Obes Surg. 2011
Duodeno-Jejunal Sleeve

Open-label, sham-controlled trial of an endoscopic duodenojejunal bypass liner

13 patients with liner vs 24 sham control
12 weeks duration
EWL 12% vs 3%
Weight -8 vs -2 kg
8 liners explanted because of device complications

Gersin et al; Gastro Endo 2010 2011
Duodeno-Jejunal Sleeve

Multicenter, randomized study of the EndoBarrier Gastrointestinal Liner for pre-surgical weight loss

26 device implanted
4 device could not be implanted
BMI: 48.9 vs 47.4 kg/m
3-month EWL: 19.0% vs 6.9% for control
T2DM improved in 7/8 patients during the study

Schouten et al Ann Surg. 2010
Intra-Gastric Balloons
BioEnterics Intragastric Balloon (BIB): a short-term, double-blind, randomised, controlled, crossover study

32 patients

Age 36 yr

BMI 44

At 3 months BMI dropped to 38

Intra-Gastric Balloons

Evidence-based review of the Bioenterics intragastric balloon for weight loss

12 retrospective studies; 4,877 patients

Weight loss: 17.8 kg (range, 4.9-28.5)

BMI change: 4.0-9.0 kg/m

BIB removal in 2.5% of patients

Dumonceau et al, Obes Surg. 2008
Non-Invasive Bariatric Procedures

- Desired vs current state
- Bridge to definitive treatment
- Comprehensive treatment
- Triumph of technology over reason
- Surgeons lead the way


