

2018 NCSCG
15TH ANNUAL
POST-DDW
SYMPOSIUM

Endoscopy
McKinley
Christian Health Care Services Northern California Society
for Clinical Gastroenterology

Jointly provided by the New Mexico Medical Society (NMMS) through the joint
providership of Rehoboth McKinley Christian Health Care Services (RMCHCS)
and the Northern California Society for Clinical Gastroenterology.

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Bariatrics/Endosurgery

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Disclosures

- Apollo Endosurgery – Consultant, speaker
- Boston Scientific – Consultant, speaker
- Medtronic – Consultant, speaker
- Neptune Medical - Consultant

Objectives

- Review the current status of endoscopic bariatric therapies (EBT)
- Highlight the recent data on EBT and put into context
- Highlight novel therapies

Recent Surgical Volume

| | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|------------------|----------------|----------------|----------------|----------------|----------------|----------------|
| Total | 158,000 | 173,000 | 179,000 | 193,000 | 196,000 | 216,000 |
| BRY | 36.7% | 37.5% | 34.2% | 26.6% | 23.1% | 18.7% |
| Band | 35.4% | 20.2% | 14% | 9.5% | 5.7% | 3.4% |
| Sleeve | 17.8% | 33% | 42.1% | 51.7% | 53.8% | 58.1% |
| BPD/DS | 0.9% | 1% | 1% | 0.4% | 0.6% | 0.6% |
| Revisions | 6% | 6% | 6% | 11.5% | 13.6% | 13.9% |
| Other | 3.2% | 2.3% | 2.7% | 0.1% | 3.2% | 2.6% |
| Balloons | | | | | .03% | 2.7% |
| V-Bloc | | | | | 18 cases | |

> 200,000 Operations per year

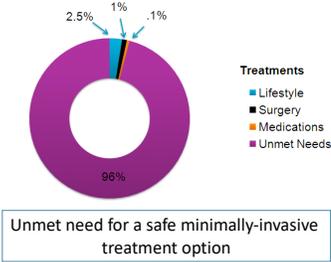
ASMBS.org

Patient Reticence

| Not interested in bariatric surgery (n = 284) | |
|---|------------|
| Fear of other complications from surgery, % | 145 (51.1) |
| Do not need surgery to lose weight, % | 91 (32.0) |
| Fear of dying, % | 70 (24.6) |
| Fear of surgery in general, % | 68 (23.9) |
| Cost, % | 58 (20.4) |
| Pain, % | 39 (13.7) |
| Do not believe it will work, % | 22 (7.7) |
| Fear of judgment, % | 9 (3.2) |
| Religious or cultural reasons, % | 2 (0.7) |

Fung M, et al. Journal of Obesity 2016

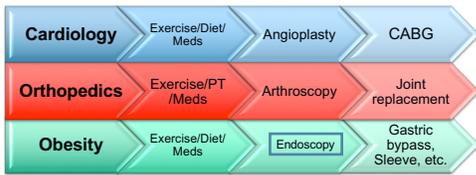
Unmet Need



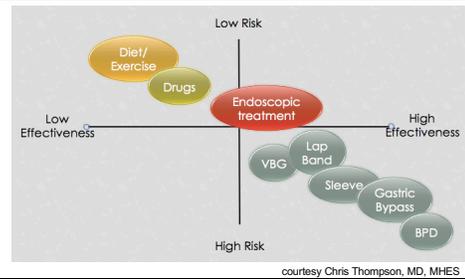
Why the Endoscopic Approach?

- The “99%”
- Vulnerable populations: 33% of US population overweight (BMI 25-29.9)
- Medical approach is ineffective (for now)
- Surgical approach is invasive, expensive, higher complication rate
- Patient demand for minimally invasive approach
 - Cosmesis
 - Reversibility

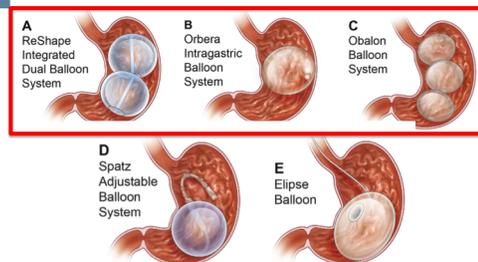
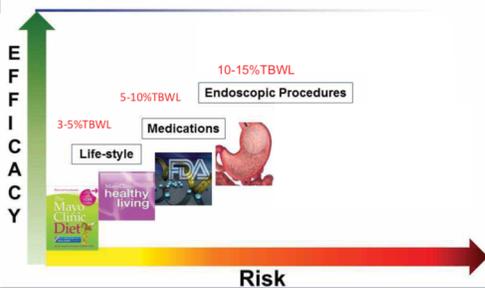
A New Treatment Paradigm



A New Treatment Paradigm



Intragastric Balloons



Intragastric Balloons

UPDATE: Potential Risks with Liquid-filled Intragastric Balloons - Letter to Health Care Providers

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

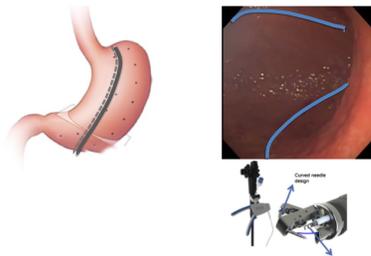
June 4, 2018

- 12 deaths since 2016
- Perforations, MVA, pancreatitis

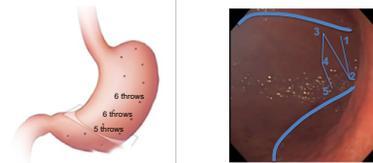
FDA Approves Updated Labeling for Two Obesity Treatments

- The global rate of occurrence was found to be <0.01% for Orbera patients (as of March 31 2018) and 0.06% for ReShape patients (as of April 30 2018)

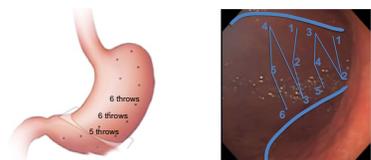
Endoscopic Sleeve Gastroplasty



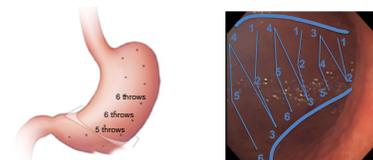
Endoscopic Sleeve Gastroplasty



Endoscopic Sleeve Gastroplasty



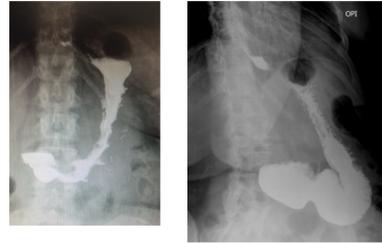
Endoscopic Sleeve Gastroplasty



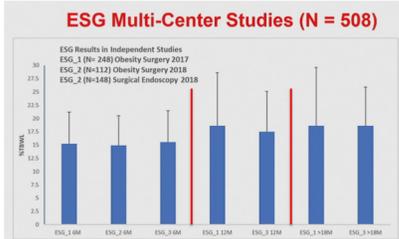
Endoscopic Sleeve Gastroplasty



Endoscopic Sleeve Gastroplasty



Endoscopic Sleeve Gastroplasty



Lopez-Navas G, et al. Obes Surg 2017
 Sartoretto et al. Obes Surg 2018
 Morales et al. Sum Endosc 2018

ESG Improves Metabolic Parameters

- Single center study 91 pts
- Mean preop BMI 40.7 ± 7.0 kg/m²
- %TBWL 20.9% at 24 months
- Statistically significant reductions in:
 - hemoglobin A1c (P =.01),
 - systolic blood pressure (P = .02),
 - waist circumference (P<.001),
 - alanine aminotransferase (P<.001),
 - serum triglycerides (P = .02)



Sharaiha R, et al. Clin Gastro Hep 2017

ESG v LSG v LAGB

- Single center study 278 pts
- ESG, lap sleeve gastrectomy, lap band

| | ESG | LSG | LAGB | p value |
|-----------|-------------|-------------|-------------|----------|
| %TBWL | 17.57% | 29.28% | 13.30% | P <0.001 |
| Morbidity | 2.2%* | 9.17% | 8.96% | P <0.05 |
| LOS | 0.34 ± 0.73 | 3.09 ± 1.47 | 1.66 ± 3.07 | P<0.01 |

*migraine HA, leak d/t dietary noncompliance

Sharaiha R, et al. J Gastro Surg 2018

COST-EFFECTIVENESS ANALYSIS OF TWO ENDOSCOPIC BARIATRIC AND METABOLIC THERAPEUTIC APPROACHES: INTRAGASTRIC BALLOONS VS. ENDOSCOPIC SLEEVE GASTROPLASTY

- Monte Carlo simulation of intragastric balloon vs ESG from healthcare system perspective
- 100,000 pts age 35, BMI 32.5 kg/m² without obesity-related comorbidities followed for their lifetime
- If patients remained obese after EBT, may undergo surgery
- Willingness-to-pay (WTP) threshold was defined at \$150,000 per QALY gained

Bazerbachi F, et al. DDW 2018

COST-EFFECTIVENESS ANALYSIS OF TWO ENDOSCOPIC BARIATRIC AND METABOLIC THERAPEUTIC APPROACHES: INTRAGASTRIC BALLOONS VS. ENDOSCOPIC SLEEVE GASTROPLASTY

- At 120 years:
 - Cumulative costs per person, QALYs:
 - IGB: \$17,227, 31.82
 - ESG \$20,227, 31.84
 - ESG > IGB at ICER \$131,671 per QALY gained
 - ESG remained superior up to \$15,050

Bazerbachi F, et al. DDW 2018

BARIATRIC ENDOSCOPY EFFECTIVENESS IN HEALTH RELATED QUALITY OF LIFE

- 107 pts treated with IGB (n=79) and ESG (n=28)
- Health Related Quality of Life (HRQL) measured with the 8 scales of the questionnaire SF-36 at baseline and at follow up (8-12 months)

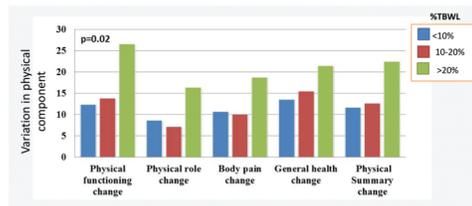
Lopez-Navas G, et al. DDW 2018

| VARIABLE | SPANISH AVERAGE HRQL | PATIENTS BASE LINE HRQL | POST PROCEDURE HRQL | HRQL IMPROVEMENT | |
|----------|----------------------------|-------------------------|---------------------|------------------|--------|
| PHYSICAL | Physical Function | 84,7 | 73,5 | 90,5** | 23,13% |
| | Physical Rol | 83,2 | 77,8 | 88,7* | 14,01% |
| | Body Pain | 79,0 | 69,7 | 82,9** | 18,94% |
| | General Health | 58,3 | 57,0 | 74,3** | 30,35% |
| | Vitality | 66,9 | 48,9 | 66,5** | 35,99% |
| MENTAL | Social Function | 90,1 | 74,5 | 88,0** | 18,12% |
| | Emotional Role | 86,6 | 73,2 | 85,3** | 16,53% |
| | Mental Health | 73,3 | 63,3 | 61,5 | -2,84% |
| | Change in health over time | --- | 40,1 | 80,3** | |

Note: *p<0.05) **p<0.01

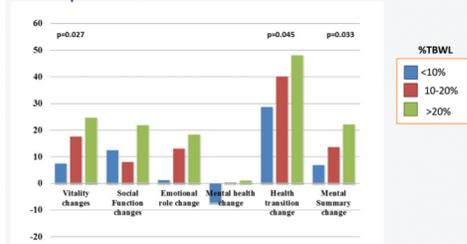
Lopez-Navas G, et al. DDW 2018

BARIATRIC ENDOSCOPY EFFECTIVENESS IN HEALTH RELATED QUALITY OF LIFE



Lopez-Navas G, et al. DDW 2018

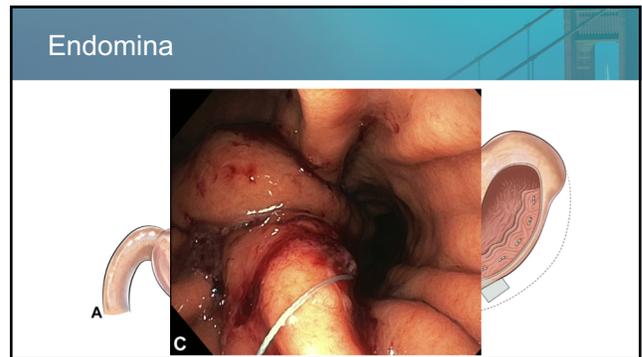
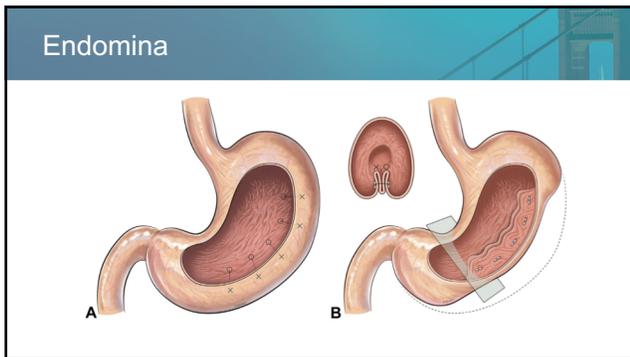
BARIATRIC ENDOSCOPY EFFECTIVENESS IN HEALTH RELATED QUALITY OF LIFE



Lopez-Navas G, et al. DDW 2018

Endomina



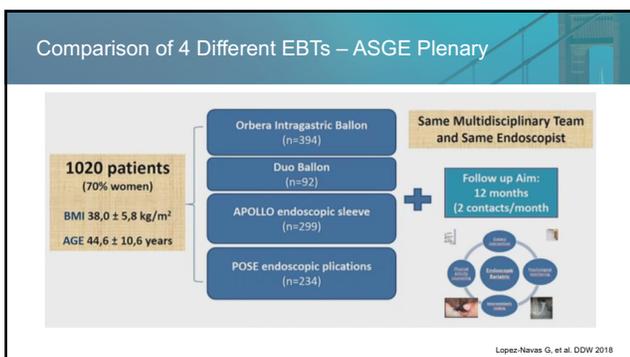


Endomina

| Parameter | Baseline | 1 m | 3 mo | 6 mo | 9 mo | 12 mo |
|--------------------------|----------|------|------|------|------|-------|
| n | 51 | 50 | 49 | 49 | 48 | 45 |
| BMI (kg/m ²) | 35.1 | 33.2 | 32.5 | 32.2 | 32.3 | 32.6 |
| Weight loss (kg) | - | 5.3 | 7.4 | 8.1 | 8.2 | 7.1 |
| %EWL | - | 20 | 28 | 31 | 33 | 29 |
| %TBWL | - | 5 | 8 | 8 | 8 | 7 |

Huberty V, et al Endoscopy 2018

- ### Comparison of 4 Different EBTs – ASGE Plenary
- Single Center (Madrid), 4 EBTs:
 - Orbera – 394 pts
 - ReShape Duo – 92 pts
 - ESG – 299 pts
 - POSE – 234 pts
 - 400 (40.1%) pts completed 1 year f/u
- Lopez-Navas G, et al. DDW 2018



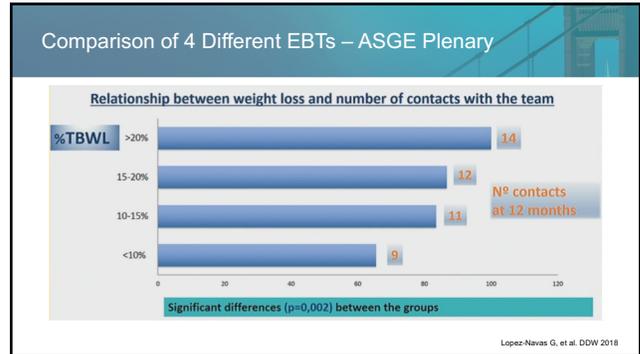
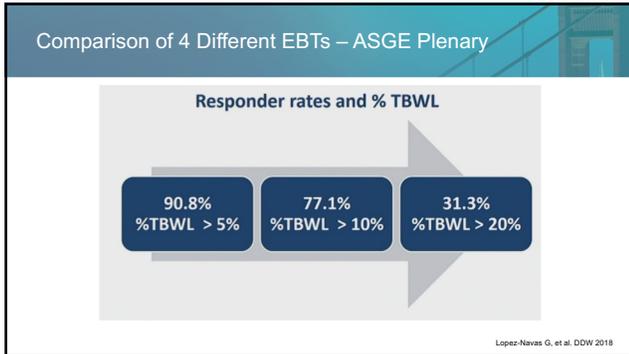
Comparison of 4 Different EBTs – ASGE Plenary

Initial characteristics and weight changes after bariatric endoscopy procedures

| | Orbera IGB | Duo IGB | APOLLO | POSE | p |
|----------------------------------|------------|---------|--------|--------|------|
| Initial BMI (kg/m ²) | 37,49 | 38,46 | 38,17 | 37,63 | n.s. |
| Final BMI (kg/m ²) | 32,28 | 32,43 | 31,84 | 32,39 | n.s. |
| TBWL | 17,87 | 16,35 | 19,53 | 16,76 | n.s. |
| % TBWL | 16,13% | 15,39% | 17,51% | 15,38% | n.s. |
| >10% TBWL | 74,4% | 75,4% | 81,1% | 72,3% | n.s. |
| >20% TBWL | 34,4% | 24,5% | 36,1% | 26,6% | n.s. |

12 months later

Lopez-Navas G, et al. DDW 2018

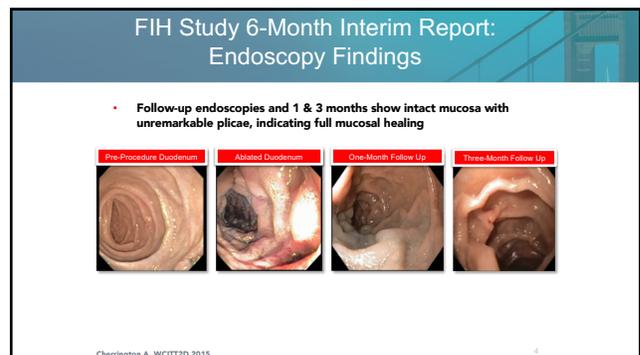
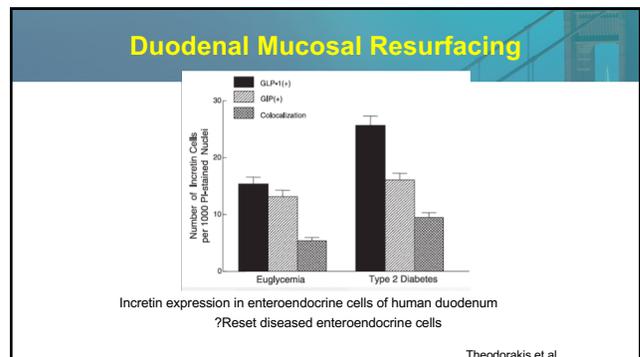


Small Bowel Therapies

- Bypass of the upper GI tract exerts potent corrective effects on metabolism through insulin sensitizing pathways
- Nutrient re-exposure to the 'Roux' elicits return to hyperglycemia
- Abnormal hypertrophy and hyperplasia of mucosa in upper GI tract of diabetic patients
- Abnormal entero-endocrine cellular sub-population in upper GI mucosa of diabetic patients

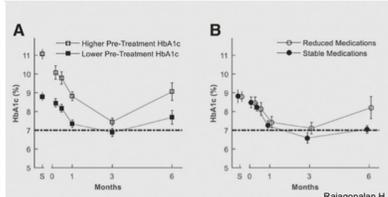
After Surgery: Stomach (bypassed), Pouch, Jejunum, Duodenum (bypassed)

Porter et al. Ann Surg. 2012; 255(5): 859-865; Wabnitz et al. BMC 2009, 2013; Dumas et al. Diabetes Care. 2012;35(2):216-22; Vanden et al. JGIM. 2012; 27(9):1033-1037; Theodorakis et al. AJP. 2003;157(5):854-858; Conzel et al. Diabetologia. 2011; 54(10):2233-40, 2010.



Duodenal Mucosal Resurfacing

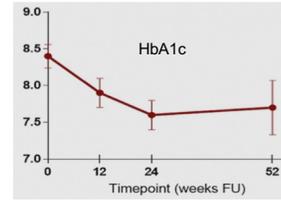
- Metabolic improvements in diabetic patients with DMR (n=28)



Rajagopalan H, et al. Diabetes Care 2016

Duodenal Mucosal Resurfacing

- Durable effects to 12 months



Rajagopalan H, et al. Diabetes Care 2016

Overview of Change in Metabolic Parameters: LS Cohort

| | Screening | 1 Month | 3 Month | 6 Month | Normal* |
|-------------|-----------|---------|---------|---------|---------|
| HbA1c - % | 9.6±1.4 | 7.9±1.1 | 7.1±0.9 | 8.2±1.6 | 4.0-6.0 |
| Weight - kg | 86±11 | 82±11 | 83±12 | 85±11 | -- |
| ALT - IU/L | 40±23 | 32±17 | 27±14 | 27±12 | ≤ 38 |
| AST - IU/L | 32±17 | 27±11 | 23±8 | 22±6 | ≤ 40 |

*Normal range based on ranges reported by lab that processed the samples. All numbers reported as mean ± SD.

Rajagopalan H, et al. Diabetes Care 2016

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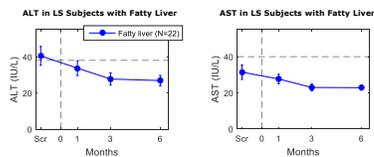
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Rajagopalan H, et al. Diabetes Care 2016

DMR Reduced ALT & AST in Patients with Radiological Evidence of NAFLD

- Patients with incidental finding of fatty liver identified on ultrasound

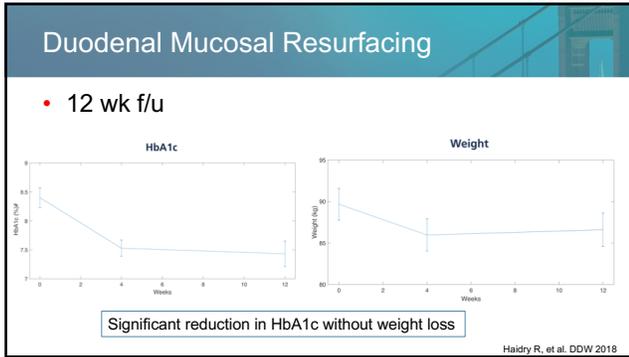


Rajagopalan H, et al. Diabetes Care 2016

Duodenal Mucosal Resurfacing

- Revita 2 Multicenter RCT
- 24 pts, mean age 58, DM2 x 8 yrs
- Open-label training phase
- Medications held stable ≥ 6 months

Haidry R, et al. DDW 2018



| Indices | Baseline | 12 weeks | P value |
|---------------------|-----------|-----------|---------|
| HbA1C (%) | 8.4±0.17 | 7.4±0.22 | <0.001 |
| FPG (mg/dl) | 186±8 | 160±10 | <0.002 |
| F-TGs (mg/dl) | 209±32 | 150±20 | =0.008 |
| F-HDL (mg/dl) | 45.7±2.8 | 49.2±3.2 | =0.02 |
| FPI* (µU/ml) | 13.6±1.8 | 9.8±1.1 | =0.03 |
| F-C-peptide (ng/ml) | 3.22±0.29 | 2.63±0.17 | =0.01 |
| ALT (U/L) | 35.8±4.1 | 26.8±2.4 | <0.001 |
| Ferritin** (ng/ml) | 98.1±20.9 | 72.0±18.7 | <0.001 |
| Body weight (kg) | 89.7±1.9 | 86.6±2.0 | <0.001 |

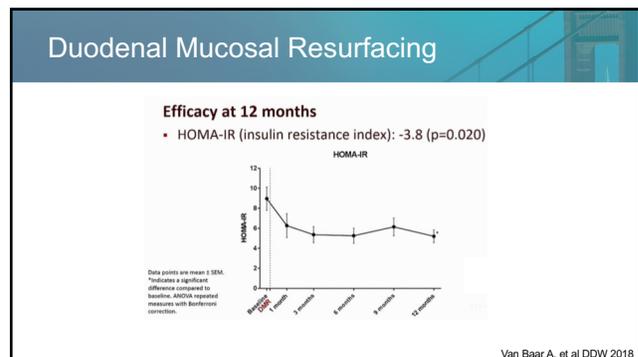
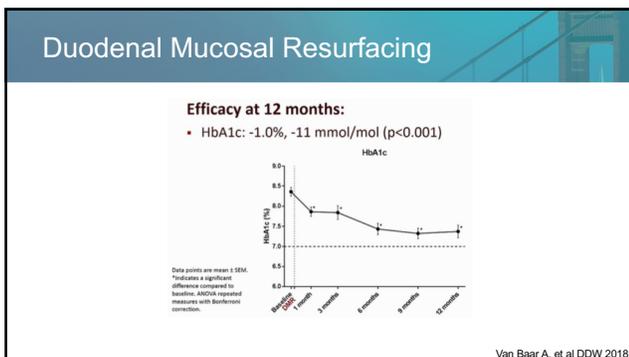
Values are all mean (±SEM); n = 24 except where indicated; * n=22; ** n=18; HbA1c: Glycated Hemoglobin A1c; FPG: Fasting Plasma Glucose; FPI: Fasting Plasma Insulin; HOMA-IR: F-TGs: Fasting Triglycerides; F-HDL: Fasting HDL; ALT: Alanine Aminotransferase
Haidry R, et al. DDW 2018

Duodenal Mucosal Resurfacing

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| FPG (mg/dl) | 186±8 | 160±10 | <0.002 |
| F-TGs (mg/dl) | 209±32 | 150±20 | =0.008 |
| No Significant Adverse Events | | | |
| F-C-peptide (ng/ml) | 3.22±0.29 | 2.63±0.17 | =0.01 |
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Haidry R, et al. DDW 2018

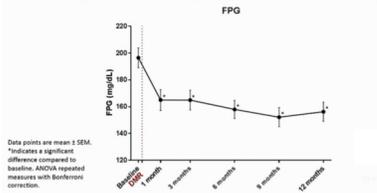
- ### Duodenal Mucosal Resurfacing
- Revita-1 study – multicenter, safety, efficacy, dosimetry
 - Complete DMR in 37/47 (79%) defined as 9-10 cm in length
 - 1 significant AE: Fever to 38, elevated CRP, discharged next day
- Van Baar A, et al DDW 2018



Duodenal Mucosal Resurfacing

Efficacy at 12 months

- Fasting glucose: -40 mg/dL, -2.2 mmol/L (p<0.001)

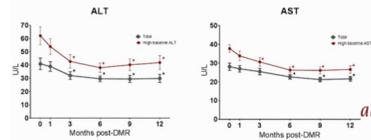


Van Baar A, et al DDW 2018

Duodenal Mucosal Resurfacing

Efficacy at 12 months

- Decreased transaminase levels
- More pronounced in high baseline tertiles



Van Baar A, et al DDW 2018

Duodenal Mucosal Resurfacing

- Metabolic improvements sustained to 12 months
- Possibly improvements in fatty liver disease
- Well-tolerated, no implant, no patient participation (+/-)

Van Baar A, et al DDW 2018

Treatment of Weight Regain After Gastric Bypass Surgery

Transoral Outlet Reduction (TORe)

- Endoscopic Suturing



Van Baar A, et al DDW 2018

Argon Plasma Coagulation

- Application to circumference of GJA results in cicatrization
- Widely available, standard skillset, time
- Repeated until desired GJA diameter
- Contact or non-contact methods
- Various settings:
 - 45-90 Watts
 - 0.8 – 2 L/min



APC or Suturing?

- Single center retrospective study
- Weight regain + GJA 10 – 30 mm
- APC: Contact 0.8 L/min 55 W, q8-12 weeks, mean 1.8 sessions/pt
- TORe: interrupted or pursestring

Jirapinyo P, et al. DDW

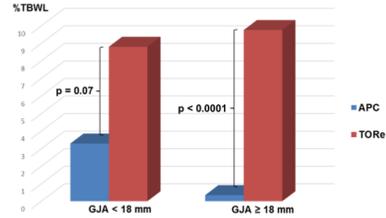
APC or Suturing?

| | APC (N = 68) | TORe (N = 244) | P-value |
|---------------------------------------|-----------------|-------------------|---------|
| Absolute weight loss (kg) (mean ± SD) | 3.3 ± 15.2 | 10.9 ± 11.4 | <0.0001 |
| % TBWL (%) (mean ± SD) | 1.9 ± 7.5 | 9.7 ± 9.3 | <0.0001 |

Jirapinyo P, et al. DDW

APC or Suturing?

6 Month Efficacy of APC versus TORe at Different GJA Sizes



Jirapinyo P, et al. DDW

Novel Therapy

- NozNoz
- 12 hours/day x 2 weeks then discard
- Inhibits smell without compromising breathing
- Wellness device not medical
- 65 obese pts on hypocaloric diet
 - Significant reduction in weight, BMI c/w controls
 - Reduced insulin levels
 - Reduced consumption of sweets



Dicker D, et al. ECO 2018

Conclusions

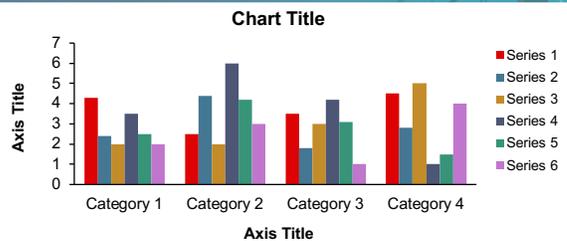
- EBTs are established as viable weight loss/ metabolic therapies
- IGB, ESG, Aspiration therapy currently available as part of a multidisciplinary approach
- DMR, adjustable balloon, plication devices coming soon
- Stay tuned for more novel devices/techniques!

Sample Table

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|------|------|------|------|
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| Text | Text | Text | Text |
| Text | Text | Text | Text |

Sample Footer

Sample Chart



Sample Footer