GROWING YOUR PRACTICE ADDING DIFFERENT INTERVENTIONS

Natan Zundel MD FACS FASMBS

Professor of Surgery University at Buffalo, NY

JNMC, Miami

Disclosures

Ethicon Endosurgery
Consultant/Speaker

Medtronic
Consultant/Speaker

Olympus
Consultant/ Speaker

Apolo
Advisory Board

GI Windows
Advisory Board

Advantage Bariatrics
Consultant

Sager
Advisory Board

LivsMed
Consultant

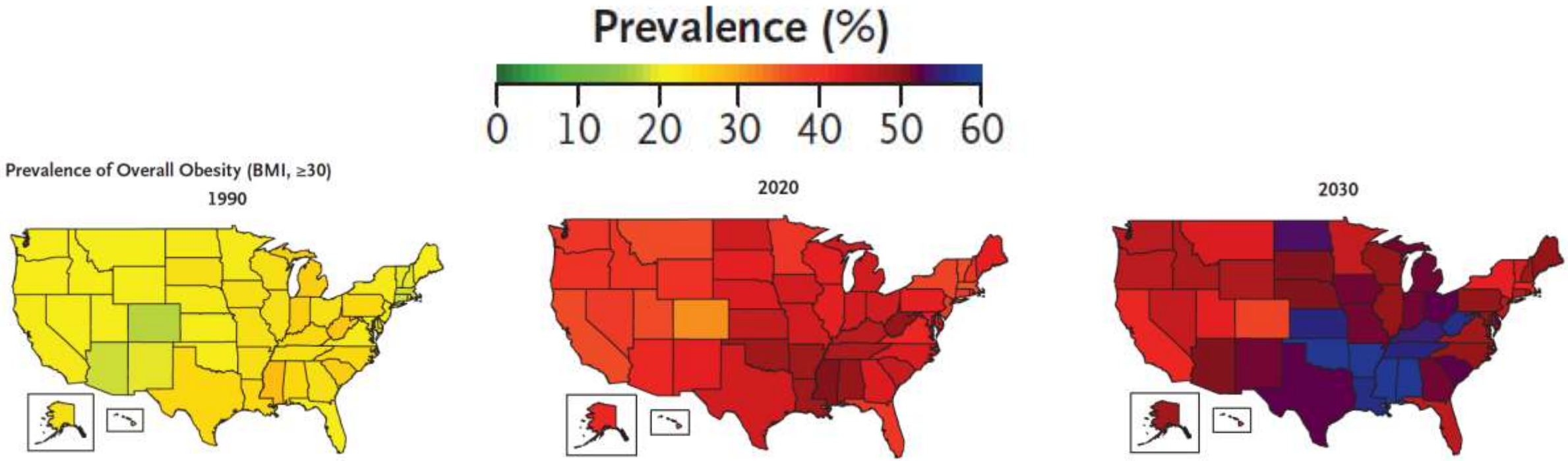
x

The NEW ENGLAND JOURNAL of MEDICINE

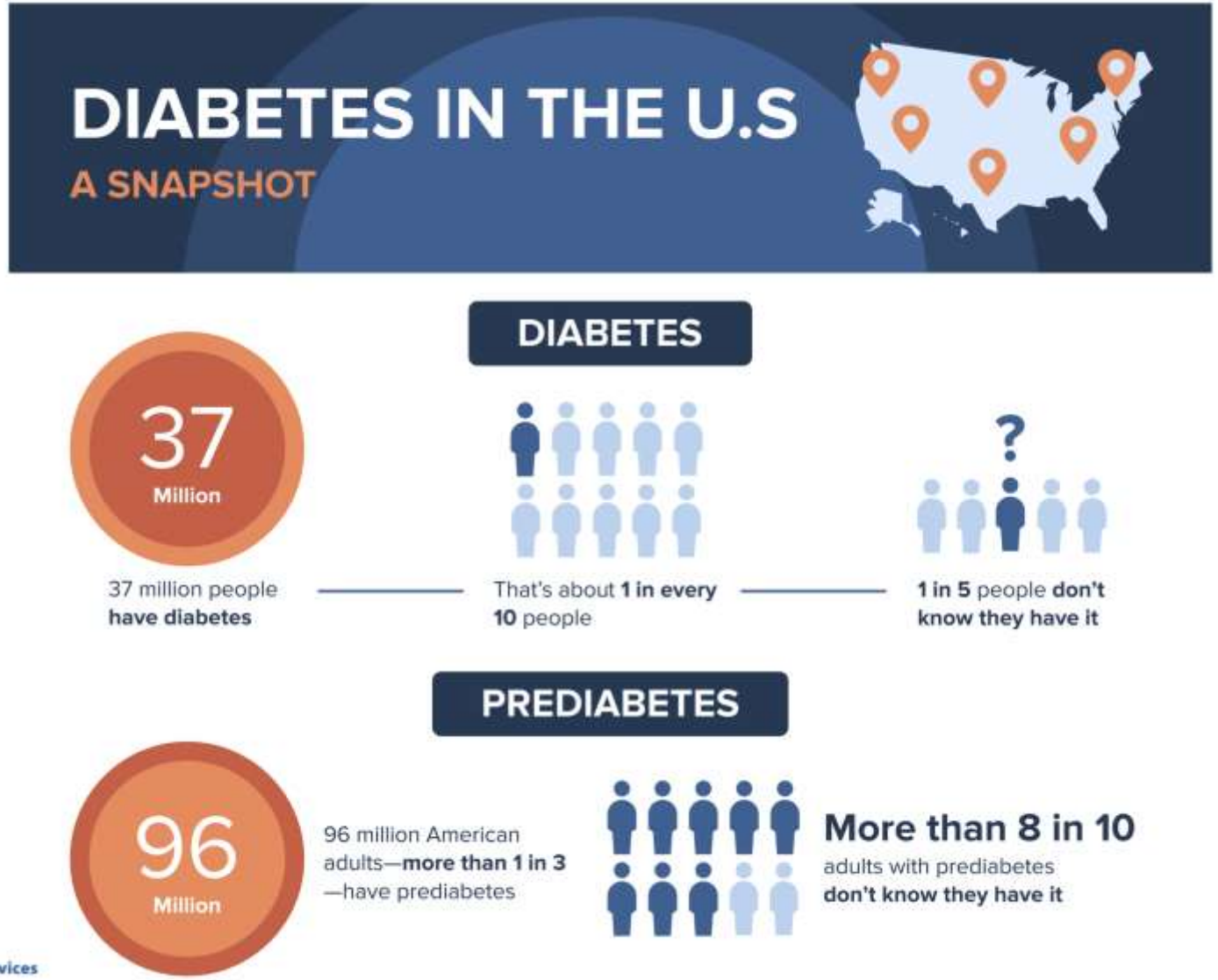
SPECIAL ARTICLE

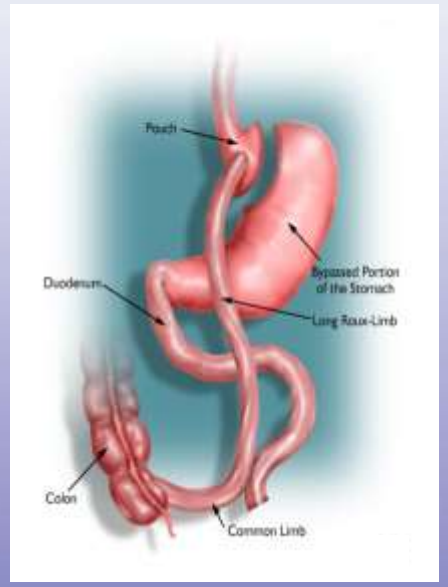
Projected U.S. State-Level Prevalence of Adult Obesity and Severe Obesity

Zachary J. Ward, M.P.H., Sara N. Bleich, Ph.D., Angie L. Cradock, Sc.D., Jessica L. Barrett, M.P.H., Catherine M. Giles, M.P.H., Chasmine Flax, M.P.H., Michael W. Long, Sc.D., and Steven L. Gortmaker, Ph.D.



Type 2 Diabetes: Broad Consequences + Unmet Needs





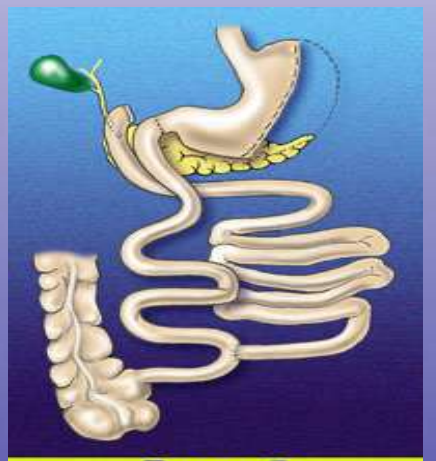


FIGURE 5
BILIOPANCREATIC DIVERSION (BPD) WITH DUODENAL SWITCH (HESS/MARCEAU)

SP4569V01

PRIMARIES

METABOLIC

REVISIONS

ASMBS/ IFSO Updated Position Statement to address this disease sooner

Major updates to 1991 National Institutes of Health guidelines for bariatric surgery

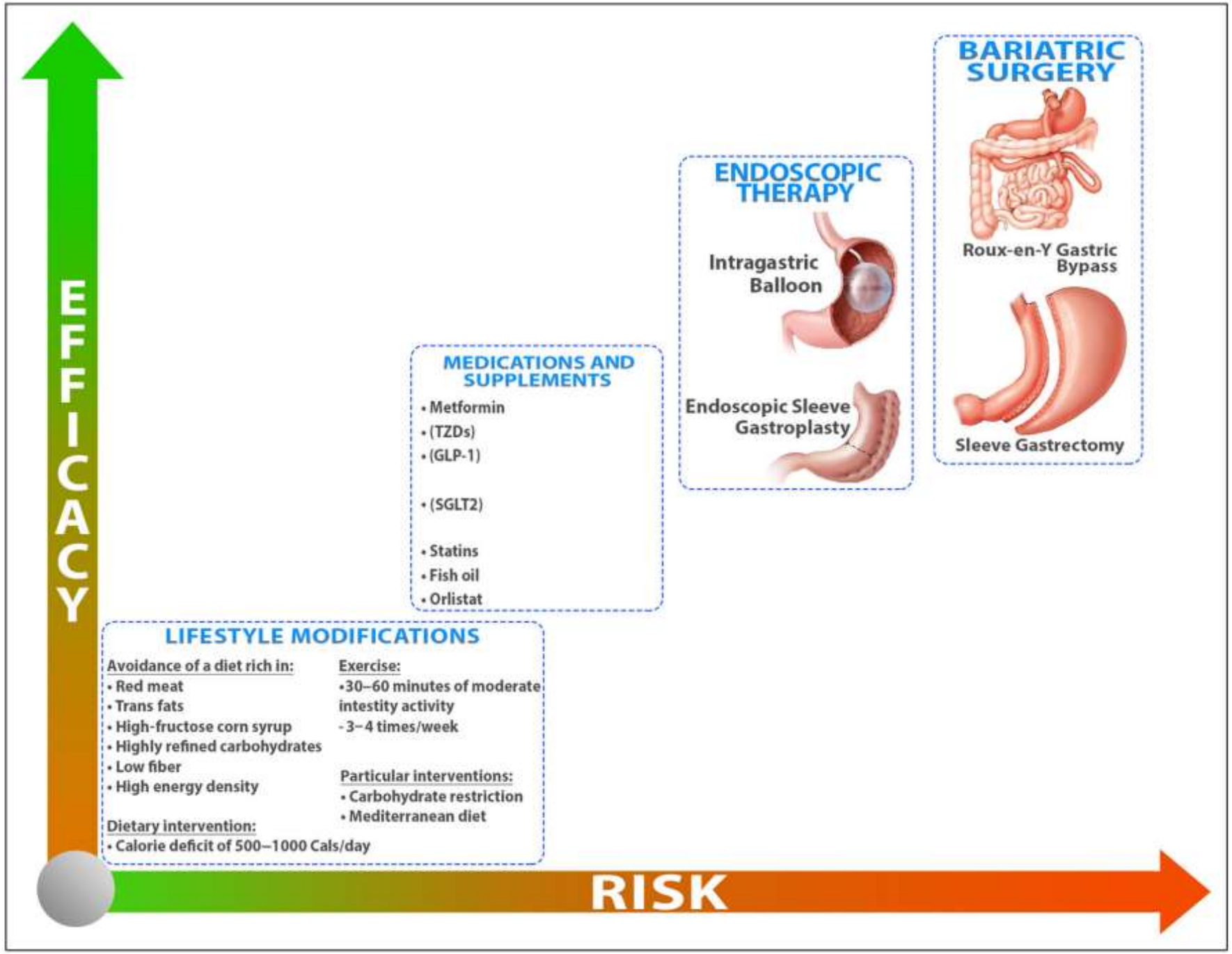
- Metabolic and bariatric surgery (MBS) is recommended for individuals with a body mass index (BMI) $\geq$35 kg/m^2, regardless of presence, absence, or severity of co-morbidities.
- MBS should be considered for individuals with metabolic disease and BMI of 30-34.9 kg/m^2.
- BMI thresholds should be adjusted in the Asian population such that a BMI $\geq$25 kg/m^2 suggests clinical obesity, and individuals with BMI $\geq$27.5 kg/m^2 should be offered MBS.
- Long-term results of MBS consistently demonstrate safety and efficacy.
- Appropriately selected children and adolescents should be considered for MBS.

(Surg Obes Relat Dis 2022;■:1–12.)

Keywords: Obesity; Metabolic and bariatric surgery; IFSO; ASMBS; Criteria; Indications

- **The obesity rate for adults in America is 42%**
- **Obesity rate in children is now 20%**
- **Revisions are now the fastest growing bariatric intervention.**

Eisenberg, D., et al 2022 American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and MetabolicDisorders (IFSO): Indications for Metabolic and Bariatric Surgery., SOARD 10-2022


EFFICACY
RISK
LIFESTYLE MODIFICATIONS
Avoidance of a diet rich in:
• Red meat
• Trans fats
• High-fructose corn syrup
• Highly refined carbohydrates
• Low fiber
• High energy density
Dietary intervention:
• Calorie deficit of 500–1000 Cals/day
Exercise:
•30–60 minutes of moderate intestity activity
- 3–4 times/week
Particular interventions:
• Carbohydrate restriction
• Mediterranean diet
MEDICATIONS AND SUPPLEMENTS
• Metformin
• (TZDs)
• (GLP-1)
• (SGLT2)
• Statins
• Fish oil
• Orlistat
ENDOSCOPIC THERAPY
Intragastric Balloon
Endoscopic Sleeve Gastroplasty
BARIATRIC SURGERY
Roux-en-Y Gastric Bypass
Sleeve Gastrectomy

PRIMARIES

METABOLIC

REVISIONS

ENDOSCOPIC

LETS BE SMART ABOUT IT

PRIMARIES

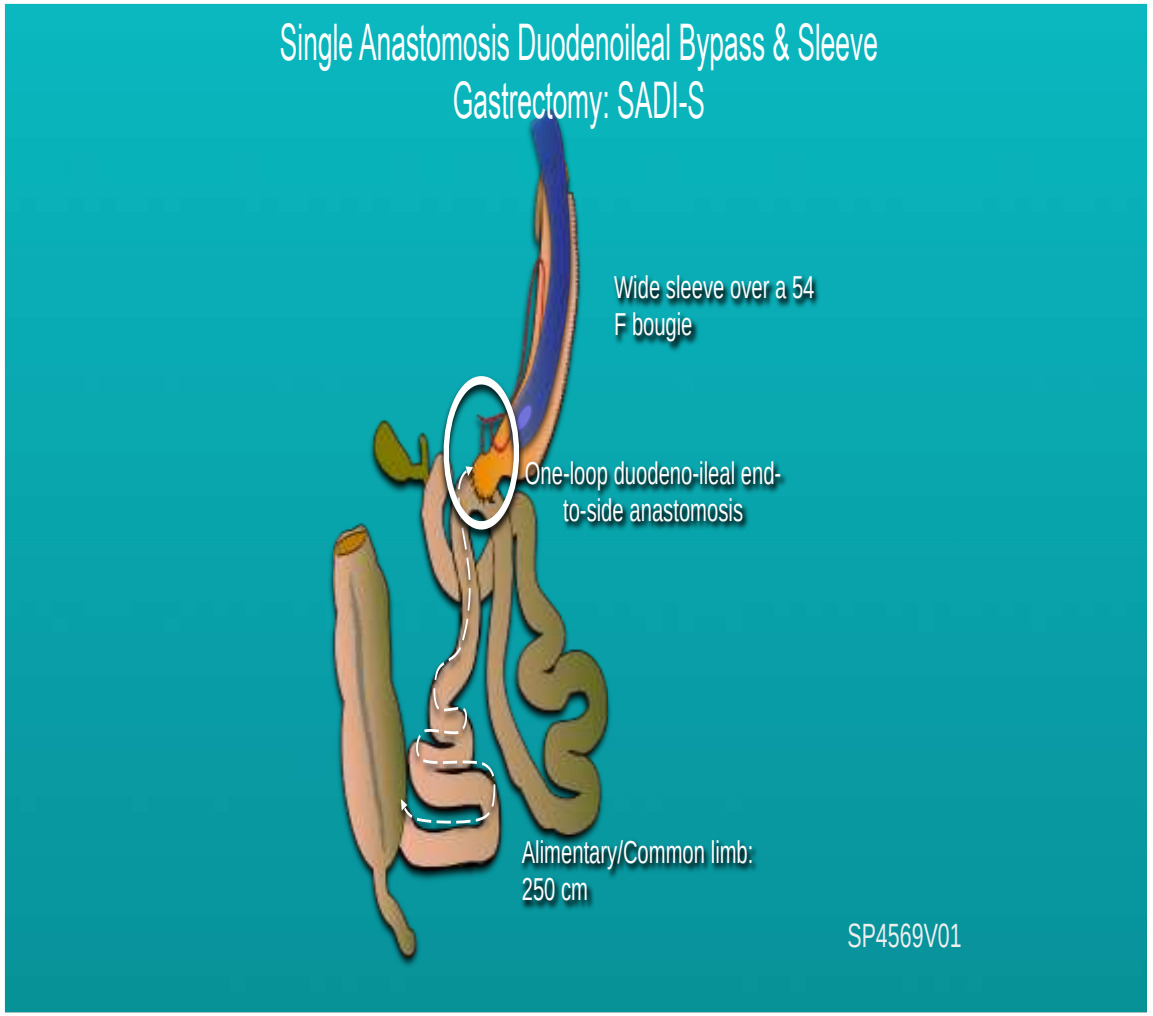
METABOLIC

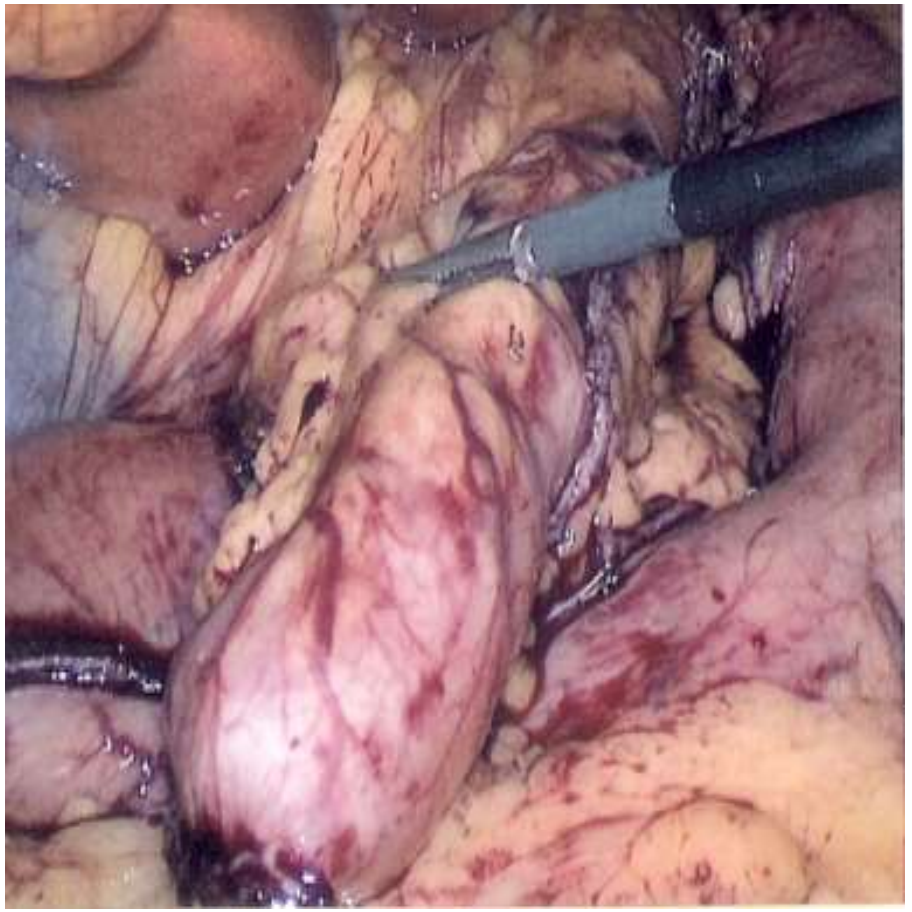
+. MEDICATIONS

REVISIONS

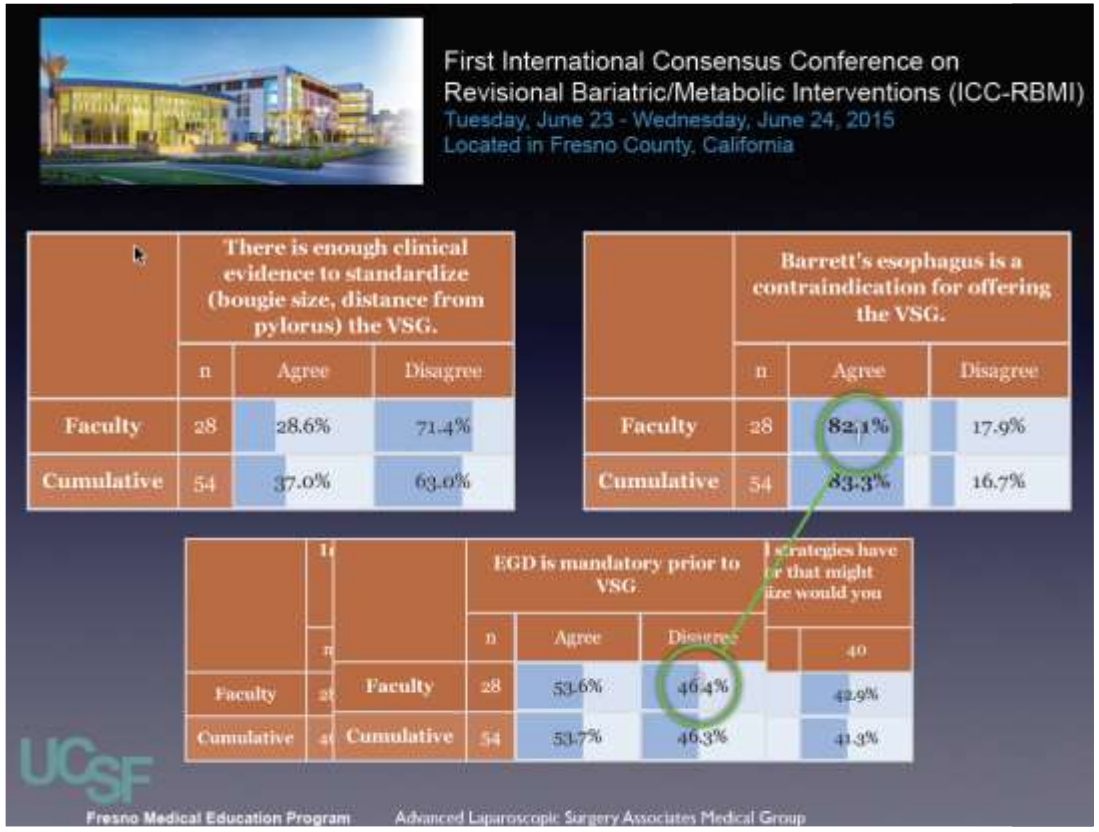
ENDOSCOPIC

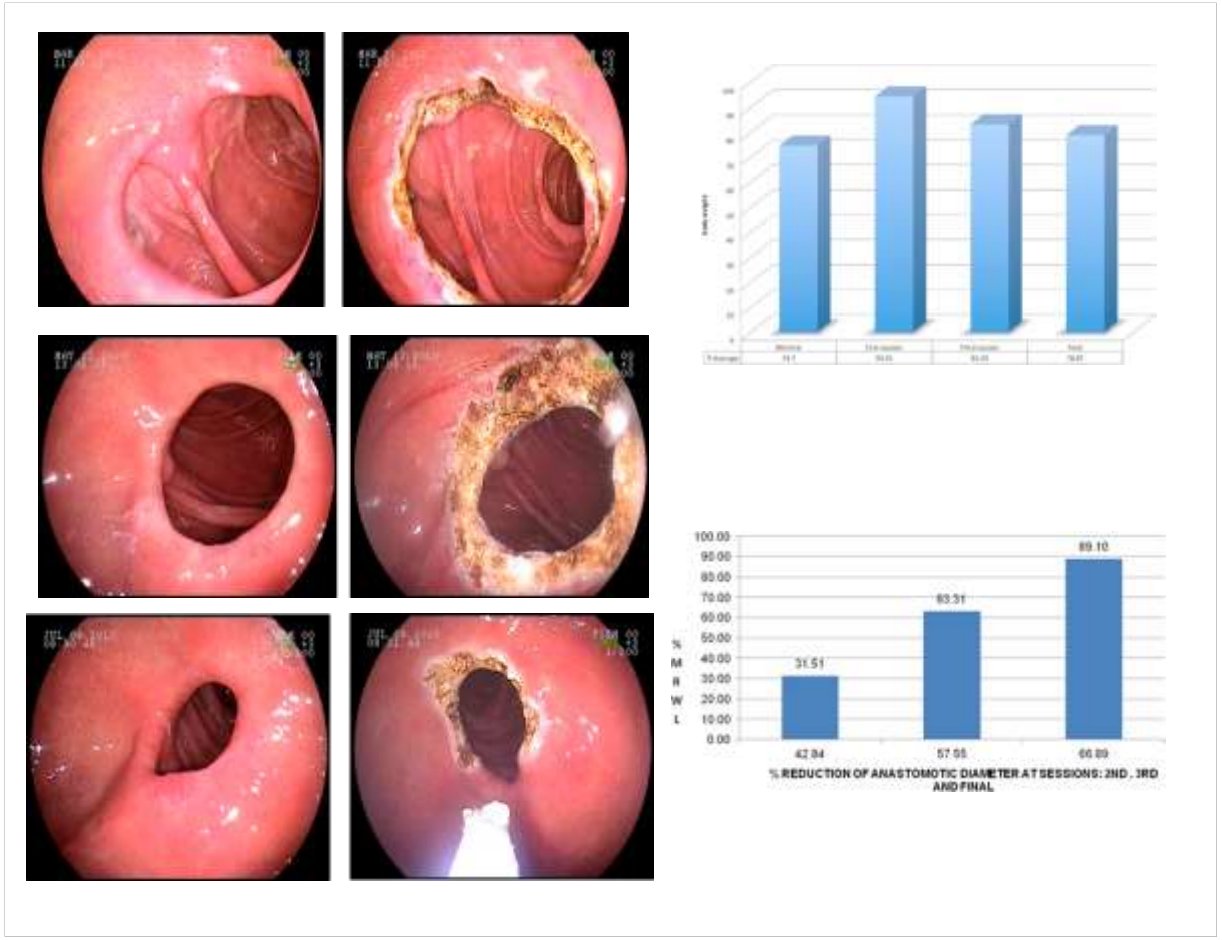
PRIMARIES AND / OR METABOLIC





REVISIONS


First International Consensus Conference on Revisional Bariatric/Metabolic Interventions (ICC-RBMI)
Tuesday, June 23 - Wednesday, June 24, 2015
Located in Fresno County, California
There is enough clinical evidence to standardize (bougie size, distance from pylorus) the VSG.
n Agree Disagree
Faculty 28 28.6% 71.4%
Cumulative 54 37.0% 63.0%
Barrett's esophagus is a contraindication for offering the VSG.
n Agree Disagree
Faculty 28 82.1% 17.9%
Cumulative 54 83.3% 16.7%
EGD is mandatory prior to VSG
n Agree Disagree
Faculty 28 53.6% 46.4%
Cumulative 54 53.7% 46.3%
42.9%
41.3%
UCSF
Fresno Medical Education Program
Advanced Laparoscopic Surgery Associates Medical Group


31.51
83.31
89.10
% REDUCTION OF ANASTOMOTIC DIAMETER AT SESSIONS: 2ND , 3RD AND FINAL

OTHER SOCIETIES


WHITE PAPER

A pat ay to endoscopic bariatric therapies

ASGE/ASMBS Task Force on Endoscopic Bariatric Therapy: Gregory G Ginsberg, Bipan Chand, Gregory A Cote, Ramsey M Dallal, Steven A Edmundowicz, Ninh T Nguyen, Aurora Pryor, Christopher C Thompson

TABLE 2. Reported weight loss at 12-24 months†

Intervention	Weight loss
Lifestyle interventions (24 months) (Diet, counseling, exercise)[54]	4 kg (2%-9% total body weight)
Medical therapy (12 months)[13]	3-5 kg (2%-9% total body weight)
Laparoscopic gastric banding (12 months)[36]	47.5% EWL
Gastroplasty (12 months)[14,15]	68% EWL
RYGB (12 months)[14,15]	62% EWL

NEJM, New England Journal of Medicine; *RYGB*, Roux-en-Y gastric bypass; *EWL*, percent of excess weight loss.
†Values extrapolated from representative clinical trials of each intervention class.

THRESHOLD FOR PRIMARY ENDOSCOPIC THERAPY:

25% minimum EWL at 12 months

15% EWL over control at 12 months

low rate of SAEs

SUMMARY STATEMENTS

- Obesity: a major health problem, associated with substantial morbidity and cost, is increasing world-wide
- Life-style & medical therapies for obesity have limited benefit
- Operative therapy for obesity is effective but at considerable cost, limited patient applicability, and with substantial risks
- EBTs may have various roles in treatment of obesity epidemic, including primary therapy, early intervention, bridge therapy, and metabolic therapy
- EBTs will have varying degrees of intensity, durability, and repeatability and should be evaluated based on intent of therapy and overall risk/benefit

Source: 2011 ASGE and ASMBS Task Force

What we have:

Orbera Intragastric Balloon

GLOBAL PUBLICATIONS

>525 Publications: including longer term follow-up

>32K Participants studied in clinical trials

Bariatric Revisions (TORe/ LSG)

GLOBAL PUBLICATIONS

>130 Publications: including follow-up to 5 years

>3,000 Participants studied in Revision clinical trials

Endoscopic Sleeve Gastroplasty

GLOBAL PUBLICATIONS

>200 Publications: including follow-up to 5 years

>10,000 Participants studied in ESG clinical trials

Neto MG, et al. Brazilian Intragastric Balloon Consensus Statement (BIBC): practical guidelines based on experience of over 40,000 cases. Surg Obes Relat Dis. 2018 Feb;14(2):151-159, Sa1938 Seven-year outcomes of transoral outlet reduction (tore) for the treatment of weight regain following roux-en-y gastric bypass, DDW 2021 (Publication in process, Sharaiha RZ, et al. Five-Year Outcomes of Endoscopic Sleeve Gastroplasty for the Treatment of Obesity. Clin Gastroenterol Hepatol. 2021 May;19(5):1051-1057

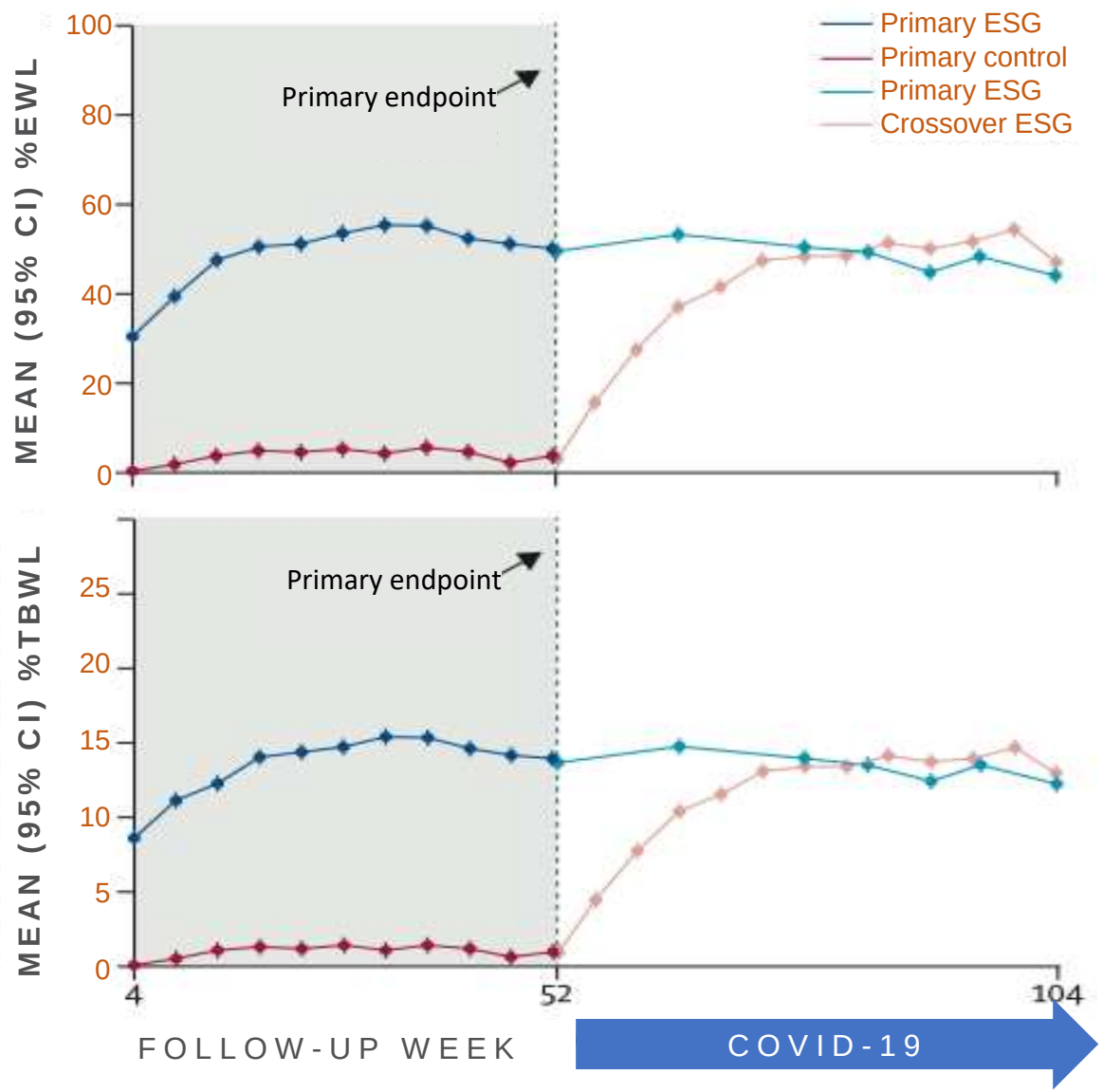
MERIT Results: Efficacy & Durability

49% ± 32%, target 25%

45% delta vs lifestyle [95% CI 39 – 51]; target 15%

77% responder rate ≥ 25% EWL

16% ± 7% TBWL among responders; 11% > control



MERIT Results: Safety

✓ Met primary safety endpoint

2%

SAE rate among all ESG completers n=150
All recovered

SAE Grade III Clavien-Dindo, ZERO grade IV or V

Peri-Gastric Abscess	**Upper GI Bleed**	**Malnutrition**
Endoscopy	Endoscopy	Endoscopic Reversal
Antibiotics	No transfusion	

6 patients (4%) hospitalized for conservative management of accommodative symptoms

MERIT Results: METABOLIC TOO ?? Significant Impact on Comorbidities

ESG compared to standard of care

	ESG		SoC		p
	Improve	Worsen	Improve	Worsen	
Diabetes Mellitus Type II (DMII)	92%	0%	15%	44%	<0.001
Metabolic Syndrome + NAFLD + Inflammation	83%	0%	35%	38%	<0.001
Hypertension (HTN)	67%	6%	40%	23%	=0.01

diabetes mellitus type II (DMII)

	Improve ESG	Worsen (SoC)	p
HOMA-IR	-3 (SD 6.354)	+1.35 (SD 3.2)	P=0.01
HgA1c (Diabetics)	-0.87 (SD 1.1)	+0.39 (SD 0.7)	P<0.001
HgA1c (baseline>7)	-1.77 (SD 0.755)	+0.16 (SD 0.635)	p<0.001

metabolic syndrome + NAFLD + inflammation

	Improve ESG	Worsen (SoC)	p
Hepatic Steatosis Index (HSII)	-2.24 (SD 3.075)	-0.61 (SD 3.409)	P=0.01
CRP	-1.78 (SD 4.04)	+0.51 (SD 3.525)	P<0.01
Waist/ Hip Ratio (% Change)	-2.91 (SD 8.5188)	-0.36 (SD 7.2852)	P=0.02

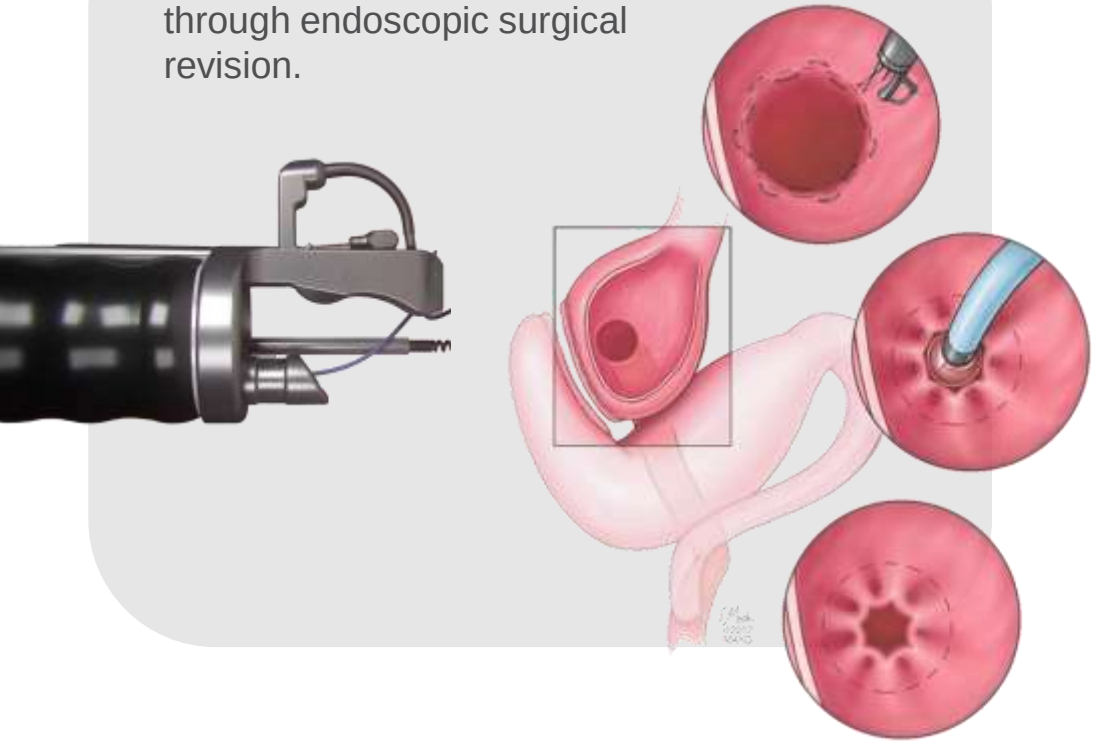
MARKET AUTHORIZATION

The FDA authorized for marketing the Apollo ESG & Revise Systems, the **first FDA-authorized systems for endoscopic sleeve gastroplasty**, a minimally invasive procedure **to facilitate weight loss**. It is intended for adults with obesity (BMI 30-50 kg/m^2) who have not been able to lose weight or maintain weight loss through more conservative measures such as diet and exercise.

TM

Equipping physicians with an efficacious, less invasive solution for revision surgery

Anatomically-driven weight regain following gastric bypass surgery can be corrected through endoscopic surgical revision.



REVISION CANDIDATES

1.4M U.S. adults received a gastric bypass or gastric sleeve procedure between 2011 and 2019[1]

~28% of adult bariatric surgery patients undergo revision surgery[2]

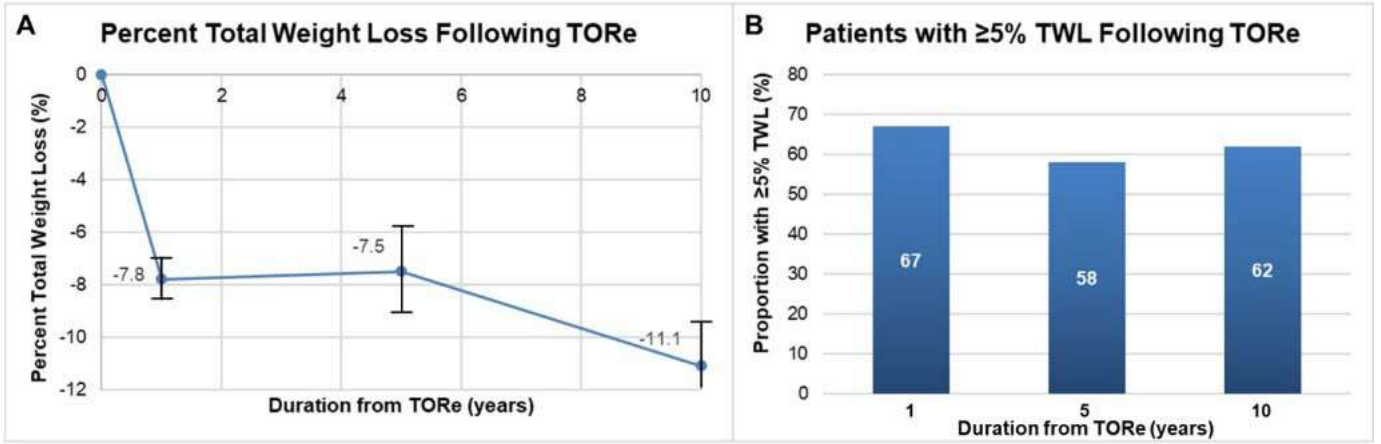
fastest growing segment of bariatric surgery market[3]

1. American Society for Metabolic and Endobariatric Surgery | 2. Hjorth S, Näslund I, Andersson-Assarsson JC, et al. Reoperations After Bariatric Surgery in 26 Years of Follow-up of the Swedish Obese Subjects Study. *JAMA Surg.* 2019;154(4):319–326. doi:10.1001/jamasurg.2018.5084. | 3. ASMBS. Estimates of bariatric surgery numbers, 2011-2020.

TORe Long-Term Follow Up

- 50 patients eligible for 10-year F/U
- 11.2±14.5% TBWL+
- 9.8±16.2% TBWL*
- 74% Interrupted suture pattern
- 26% Purse-string suture pattern
- Presented at Digestive Disease Week 2023

Characteristics	N = 50
Age (years)	49 ± 11
Female sex (n (%))	40 (80)
Pre-RYGB weight (kg)	152 ± 34
Nadir weight (kg)	90 ± 22
Weight at the time of TORe (kg)	117 ± 28
BMI at the time of TORe (kg/m^2)	41.8 ± 10.5
Amount of weight regain (% from maximal lost weight)	43.9 ± 26.3
Duration from RYGB to TORe (years)	7 ± 3
Pre-TORe GJA diameter (mm)	25 ± 6
Pre-TORe pouch length (cm)	5 ± 2

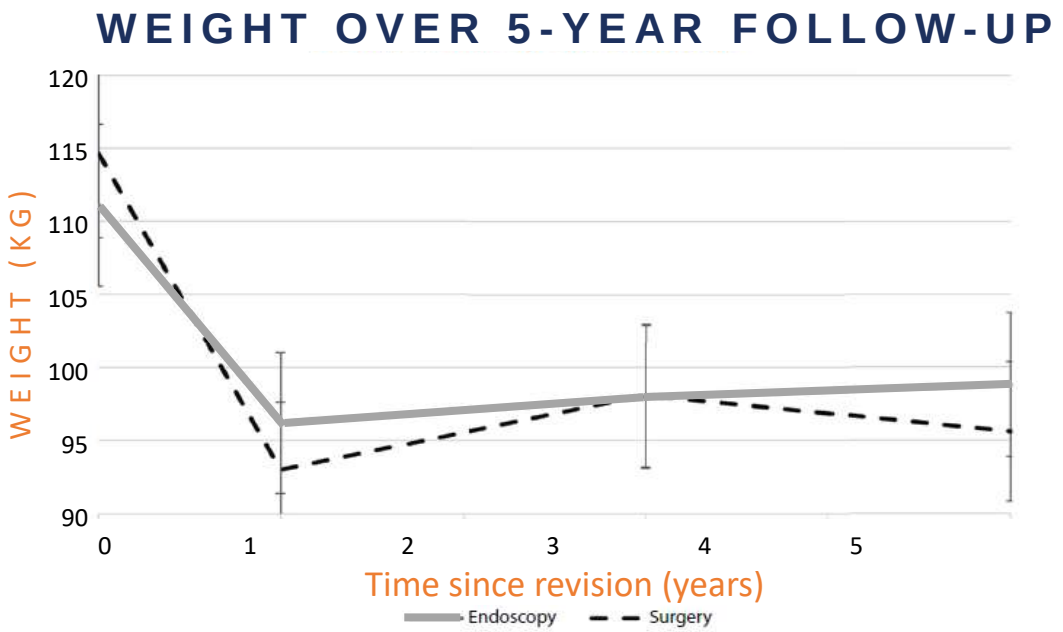


+All 50 patients included

*All patients on pharmacotherapy (10) & those having undergone surgical intervention (3)

5-Yr Study: Endoscopic v. Surgical Revisions

Peer-reviewed Brigham & Women's study demonstrated **equivalent efficacy** & **improved safety profile**



	ENDO (n=31)	SURGICAL (n=31)	p
Efficacy at 5 years	**11.5%** TBWL	**13.1%** TBWL	0.67
Adverse events	**6.5%**	**29.0%**	0.04
Safety profile	**0%** SAE rate	**19.4%** SAE rate	0.024

Dolan, et al; Endoscopic versus surgical gastrojejunal revision for weight gain in Roux-en-Y gastric bypass patients: 5-year safety and efficacy comparison. Gastrointestinal Endoscopy. 2021.

ESG Can Benefit Practices

Surgeon's experience: integration of ESG procedure had a significant impact on practice

469 New patient consults driven to practice over 2-year period after initiating ESG

65% Total conversion rate (304 procedures)
- 42% ESG (197 procedures)
- 23% LSG (107 procedures)

24% TBWL @ 12 months for the patients that were treated with ESG

Top 10 Paper at IFSO 2022

"Millions of people are stuck in the disease of obesity but feel that surgery is too extreme for them. We need more tools to fight obesity."

BRANDON VANDERWEL, MD

Publication in Process

VanderWel, Brandon. Endoscopic Sleeve Gastroplasty Complements a Bariatric Surgery Practice. 2022 Top 10 Paper at the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) 2022 World Congress. 2022.

GROWING YOUR PRACTICE ADDING DIFFERENT INTERVENTIONS

AS LONG AS:

THEY ARE SAFE AND EFFECTIVE

THEY ARE SUPPORTED FOR OUR SOCIETY

WE HAVE THE PROPER TRAINING

WE WILL GROW OUR PRACTICE WITH A BETTER MENU, BETTER RESULTS AND MULTIDISCIPLINARY APPROACH

PRACTICES THAT DO ALL

MAY OFFER BETTER INDIVIDUAL APPROACH TO ALL THE DIFFERENT ISSUES OF OUR PATIENTS

CAN YOU MENTION THE DIFFERENCE??

CAN YOU MENTION THE DIFFERENCE??

AND YES. NEW PROCEDURES/INTERVENTIONS/COMBINED APPROACHES ARE A GREAT MARKETING TOOL

THANKS