



Breaking the Myths About Bariatric Surgery

Stacy A. Brethauer, MD, FACS

Professor of Surgery

The Ohio State University



THE OHIO STATE
UNIVERSITY

WEXNER MEDICAL CENTER

Disclosures

Medtronic
GI Windows

Speaker
Consultant

Obesity as a Disease

Definition of Chronic Disease

- A chronic disease is one lasting 3 months or more
- Chronic diseases generally cannot be prevented by vaccines or cured by medication, nor do they just disappear
- Eighty-eight percent of Americans over 65 years of age have at least one chronic health condition
- Health damaging behaviors - particularly tobacco use, lack of physical activity, and poor eating habits - are major contributors to the leading chronic diseases

Hypothetical Scenario

- Disease X
- Combination of genetic, environment, and lifestyle factors
- Chronic, slowly progressive over years
- Painless, asymptomatic for many years
- Eventually progresses to pain and organ failure
- Behavioral therapy successful < 1% of the time

Chronic Disease

- Medical treatment alone results in 5% improvement, rarely long-term remission
- Surgical treatment successful in >85% of cases
 - Mortality rate 0.2%
 - Cost-effective at 3 years
 - Improved work productivity
 - Improved long-term QOL
- Long-term remission of the primary disease and/or associated organ dysfunction in >75% of surgical patients
- 25% of patients will require additional treatment with medication or another operation
- 30-40% increase in life expectancy after surgical treatment

Chronic Disease

- Why wouldn't surgical treatment for this chronic disease be covered?
 - People don't consider it a disease
 - Perceived as a lifestyle choice only or due to lack of willpower
 - Years of bias and discrimination against Disease X in society, workplace, and medicine
- Why would other diseases like CAD, Cancers related to diet and smoking, organ failure (alcoholic cirrhosis, poorly controlled DM/HTN) requiring transplantation, etc...

AMA Recognizes Obesity a Disease

June 2013

- This resolution argued that obesity was a “multimetabolic and hormonal disease state” that leads to unfavorable outcomes like Type 2 diabetes and cardiovascular disease.
- “The suggestion that obesity is not a disease but rather a consequence of a chosen lifestyle exemplified by overeating and/or inactivity is equivalent to suggesting that lung cancer is not a disease because it was brought about by individual choice to smoke cigarettes,” the resolution said.

Does It Really Matter?

- No!
 - People that are well but have higher BMI will receive unnecessary treatment
 - Instantly categorizes one third of the population as sick
- Yes!
 - Takes Obesity out of the lifestyle arena and places it in the medical arena
 - “Medicalizing” a condition provides greater opportunity for coverage for that condition
 - Hopefully the beginning of the end of the bias and lack of understanding about obesity

What About Other Chronic Diseases?

No Problem..

- Cardiac Disease
- Hernias
- GERD
- Hypertension
- Joint Disease
- Cancer

Why Don't We Treat More Patients with Obesity?

- Denial
- Dollars
- Discrimination
- Fear
- Access

We Must Have a Cultural Change About How
Obesity is Perceived and Treated

Obesity in America

ASMBS /NORC Survey



John Morton MD FACS FASMBS

Stacy Brethauer MD FACS FASMBS

Samer Mattar MD FACS FASMBS

Raul Rosenthal FACS FASMBS

Roger Kissin PR and Media Consultant

KEY Findings from ASMBS/NORC survey

Growing Awareness of Risks of Obesity Itself

- **86% view obesity as a very high risk** to a person's overall health and
- 83% of Americans report that obesity is a very serious health problem

Risky and Complex, But Not a Disease for Most Americans

A slight majority views the **causes of obesity** as more complex than just lifestyle factors

- 54% view obesity resulting from many different genetic, environmental, and social factors
- 45% say it is a lifestyle choice resulting from a person's eating and exercise habits

State of Denial

- Only about **half of Americans consider themselves to be overweight (47%)**, significantly less than the numbers reported by CDC
- Most of those who meet the BMI criteria for obesity consider themselves to be overweight, **but not obese (89%)**
- **Four in 10 Americans who meet the BMI criteria for obesity have not talked with a doctor or health professional about their weight**

What is Considered Effective?

- Losing weight on one's own through diet and exercise is considered the **most effective** weight loss method (78%)
- Formal exercise programs (72%) and losing weight with the help of a doctor (68%) are considered the second and third most effective methods
- This is followed by one-on-one dietary counseling (61%), **weight loss surgery (59%)**, and formal weight loss programs (53%)
- Meal replacements (32%), Prescription medications (26%), Dietary supplements (22%) are considered less effective

What is Considered Safe?

- When it comes to the **safety of weight loss surgery**, there is no consensus of opinion:
 - 30% say the method is very safe or safe
 - **36% say it is unsafe or very unsafe**
 - 30% say it is neither safe nor unsafe

What is Considered Safe?

- Prescription medications and dietary supplements both receive low ratings for safety, with just 17% of Americans rating these methods as very safe or safe

Summary

There appears to be an overestimation of the safety and effectiveness of diets and an underestimation of other proven methods of weight loss

Summary

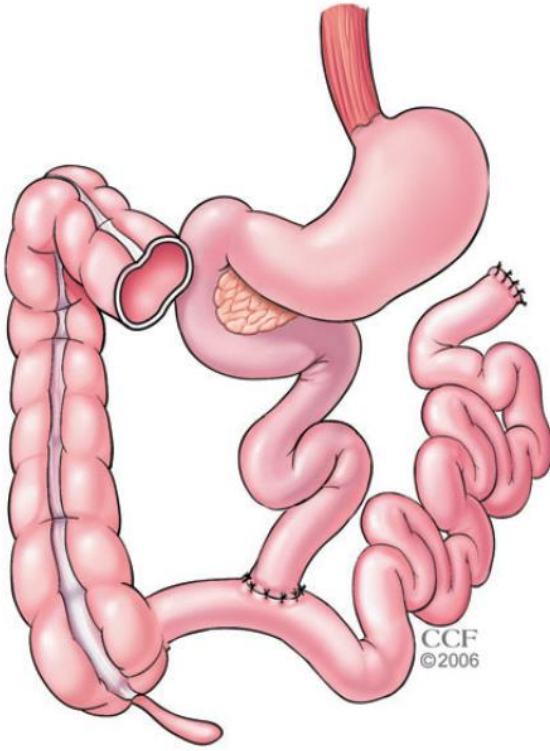
- Relatively **few people turn to the medical community** for help with obesity
- Significant amount of **denial exists among people with obesity**, despite their knowledge of its risks and its impact on their lives

Current Practice of Bariatric Surgery

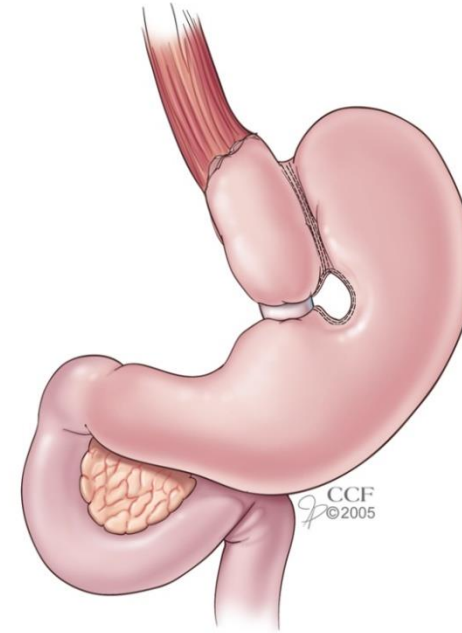
History of Bariatric Surgery

1952	First gastrointestinal operation to reduce weight by Henrikson in Sweden
1954	First gastrointestinal bypass procedure by Kremen and Linner in Minnesota
1963	First series of bariatric surgery patients reported by Payne
1967	Mason and Ito devise the loop gastric bypass
1977	Griffen publishes results of modification to a Roux-en-Y gastric bypass
1978	Scopinaro introduces the biliopancreatic diversion
1980	Vertical Banded Gastroplasty
1983	ASBS founded in Iowa City
1985	First adjustable gastric band reported
1991	NIH consensus conference held on bariatric surgery
1992	First minimally invasive bariatric procedure (non-adjustable band)
1993	First laparoscopic RYGB by Wittgrove
1995	IFSO founded
1998	First laparoscopic BPD/DS by Gagner
2005	ASBS accredits first bariatric Center of Excellence
2007	ASBS changes name to ASMBS
2007	1 st Diabetes Surgery Summit held in Rome
2012	MBSAQIP formed from ASMBS and ACS programs
2013	AMA recognizes obesity as a disease
2015	2 nd Diabetes Surgery Summit
2016	International Diabetes Surgery Guidelines Published

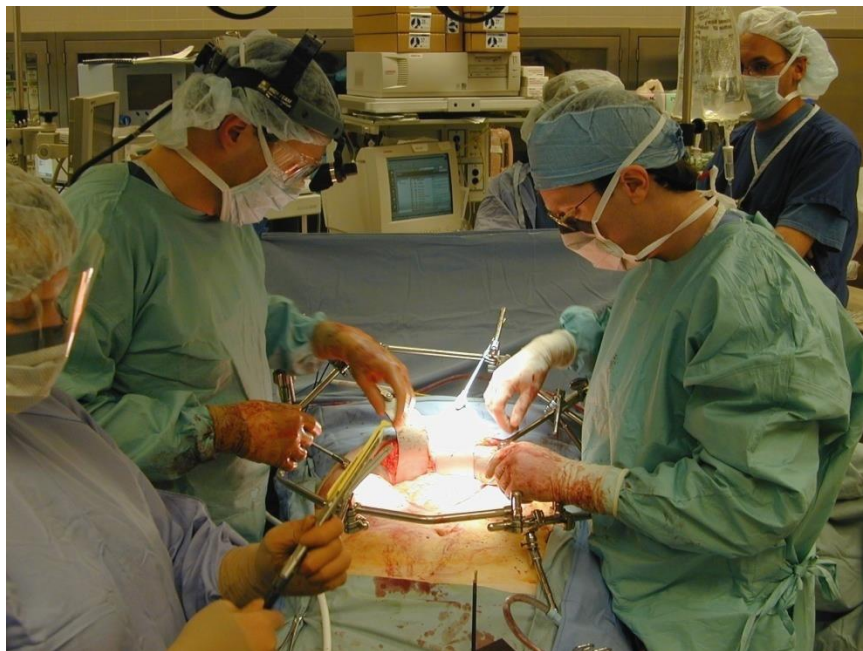
Bariatric Surgery Historical Perspective



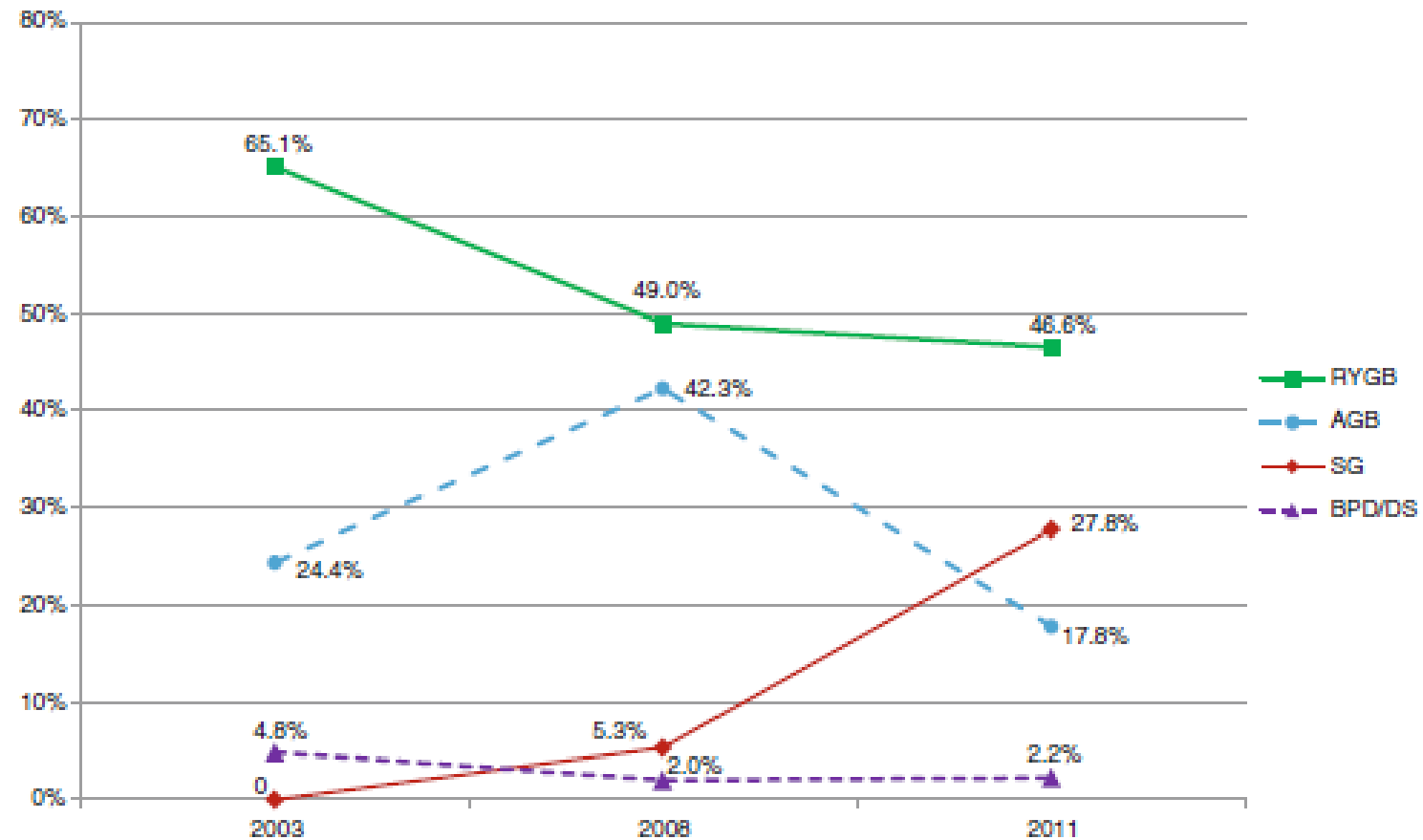
Jejunioileal Bypass (JIB)



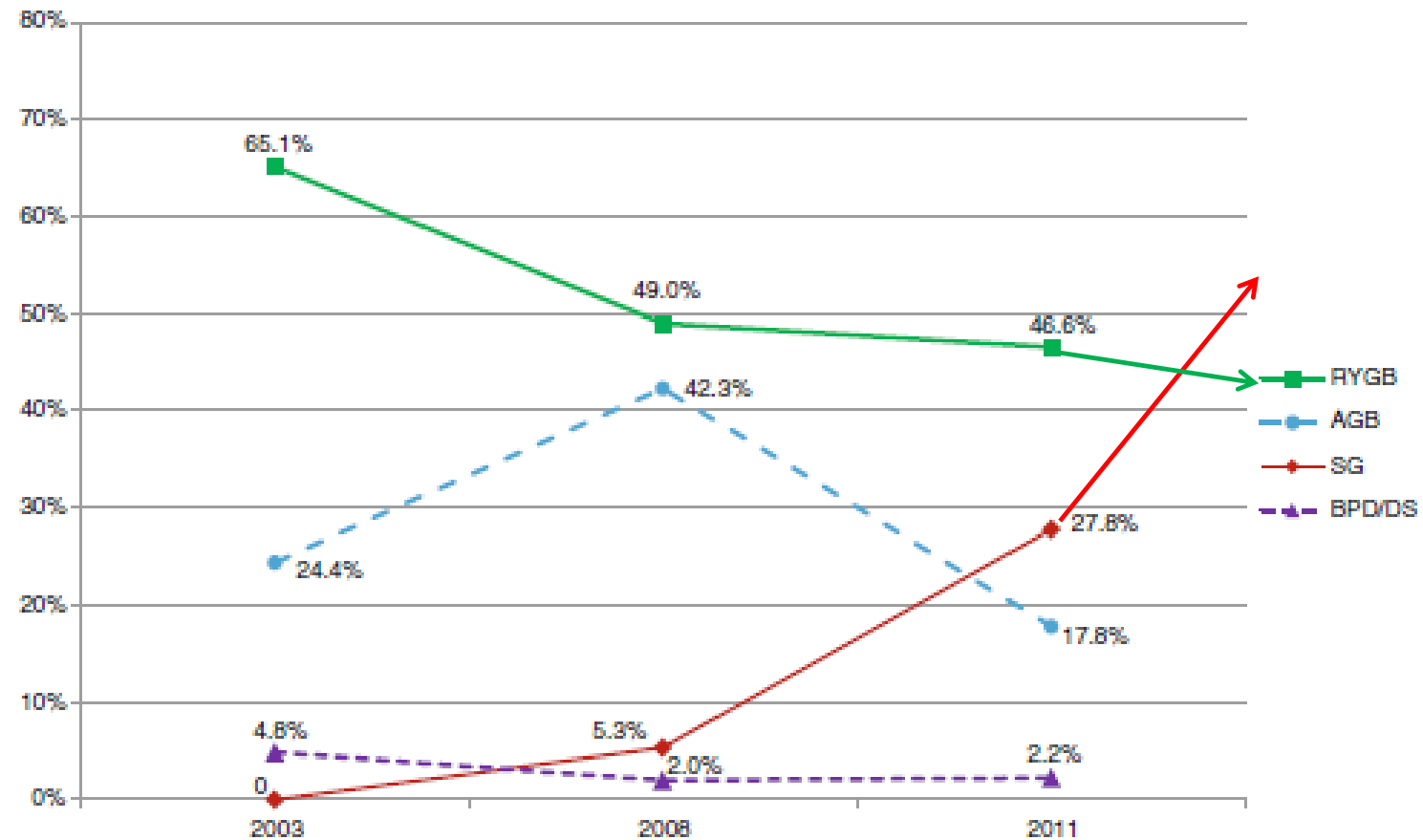
Vertical Banded Gastroplasty (VBG)



Bariatric Surgery Worldwide



Bariatric Surgery Worldwide



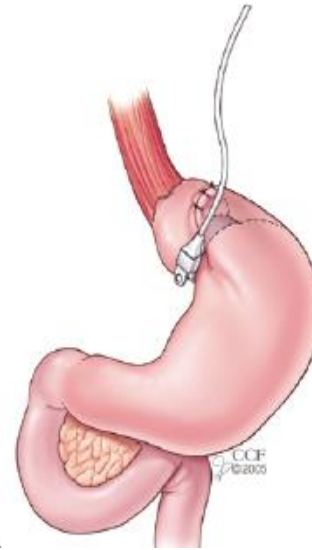
Bariatric/Metabolic Surgery 2019



20%



75%



3%



2%

Bariatric Surgery is Risky

History of COEs in Bariatric Surgery

- 2005 CMS requirement for Centers of Excellence
- ASMBS formed Surgical Review Corporation
- ACS formed Bariatric Surgery Network
- The two programs combined into MBSAQIP in 2012
- 2013 CMS removed requirement of accreditation for coverage

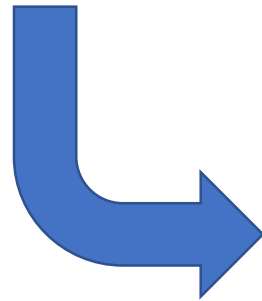
A joint initiative...



AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:
Highest Standards, Better Outcomes*

100+years



Started in 2006; ~125
centers

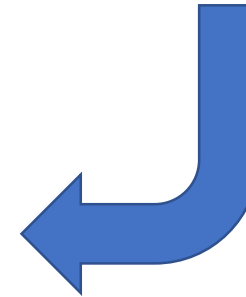


**Started in 2012
>800 centers**



ASMBS

American Society for
Metabolic & Bariatric Surgery

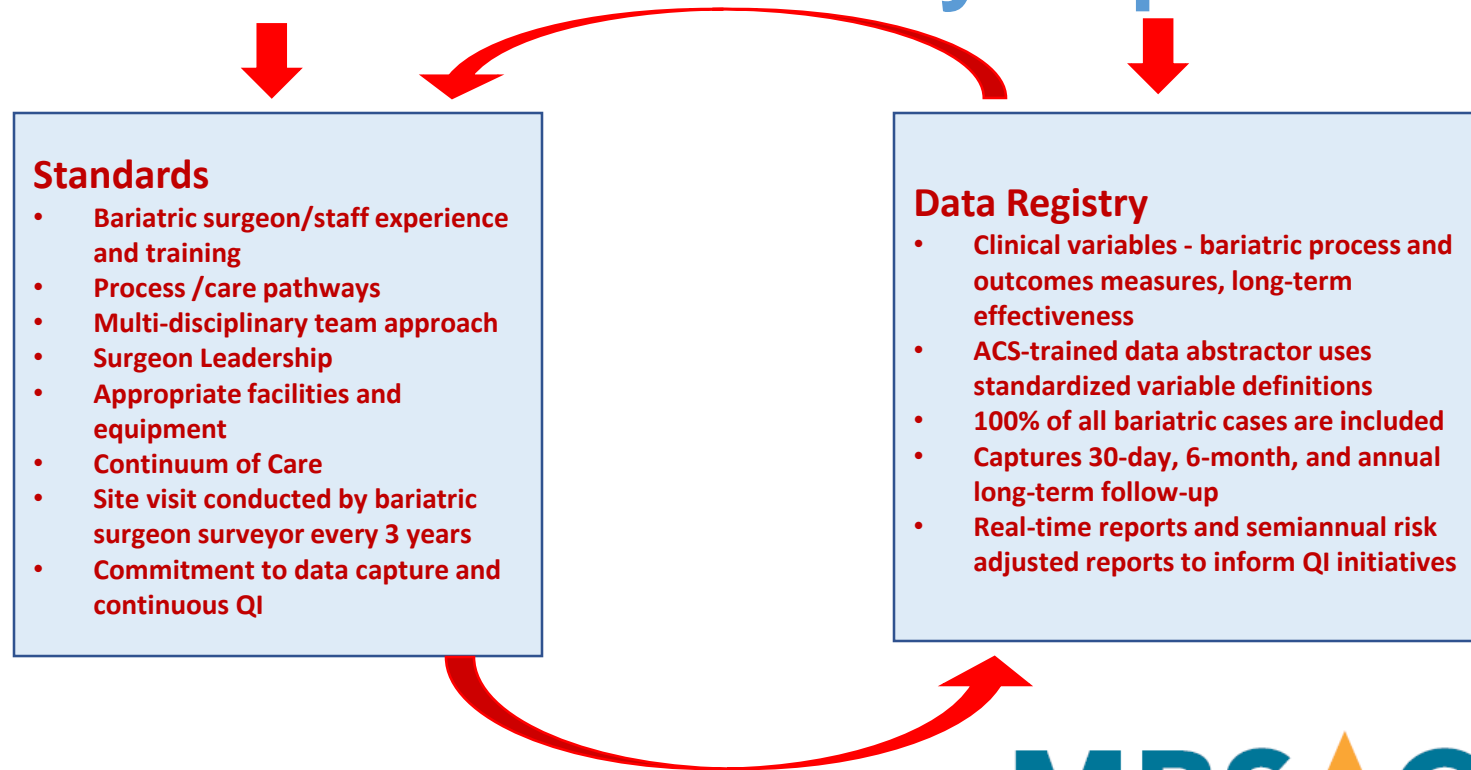


Started in 2005; ~600
centers

MBSAQIP

Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

Accreditation + Quality Improvement



CURRENT ENROLLMENT

- There are **845** Centers participating in the MBSAQIP
 - **755** MBSAQIP Accredited
 - 226 new since MBSAQIP rollout in September 2014*
 - includes **49** states, Washington DC, Puerto Rico, and Canada
 - Alaska coming soon
 - **30** Data Collection Only
 - **1** International Data Collection Center
 - **59** Initial Applications in Process
 - **291** Site Visits in CY 2016

MBSAQIP

Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

	PROCEDURE							
	Band		Bypass		Sleeve		Balloon Insertion	
	Overall	Age >= 65	Overall	Age >= 65	Overall	Age >= 65	Overall	Age >= 65
N*	1339	65	41401	2302	121211	6232	608	23
Mean # comorbidities	1.6	3.2	2.3	3.7	1.8	3.3	0.9	2.0
Outcome (%)								
Mortality	0.1	0.0	0.1	0.1	0.1	0.3	0.0	0.0
Morbidity	1.0	3.1	3.5	5.9	1.7	2.7	0.5	4.4
All Occurrences Morbidity	2.7	7.7	8.5	11.8	3.8	5.2	3.6	17.4
Serious Event	1.1	4.6	3.8	6.3	1.7	2.9	1.2	4.4
Leak	0.0	0.0	0.4	0.7	0.2	0.1	0.0	0.0
Bleeding	0.2	1.5	1.6	2.9	0.7	1.3	0.2	0.0
SSI	0.5	0.0	1.3	1.9	0.4	0.3	0.0	0.0
All Cause Reoperation	0.8	3.1	2.2	3.2	0.8	1.1	2.0	0.0
Related Reoperation	0.8	3.1	1.8	2.7	0.6	0.8	0.8	0.0
All Cause Intervention	0.8	0.0	2.0	2.3	0.7	0.7	13.2	17.4
Related Intervention	0.7	0.0	1.7	1.7	0.5	0.4	4.0	13.0
All Cause Readmission	2.1	4.6	5.8	7.7	2.8	3.6	2.6	13.0
Related Readmission	1.5	4.6	4.6	5.7	2.0	2.2	2.0	8.7

*Cases performed in CY 2018

Patients Regain Their Weight

Long-Term Outcomes

Vertical sleeve gastrectomy

38 published peer reviewed studies
with ≥ 5 year follow up

Follow up available in 2,248 patients

%EWL/EBMIL range from 37.1 to 86

*Source: Update of the Sleeve gastrectomy
ASMBS position statement (SOARD in press)*

Gastric Bypass \geq 5 yr Follow-up

- 38 peer reviewed case series published within past 5 years (2012-2017)
- Range 50-72 % EWL / EBMIL
- Range 19.1 – 35.4 % TWL
- Follow up range from 5 to 14 years post op

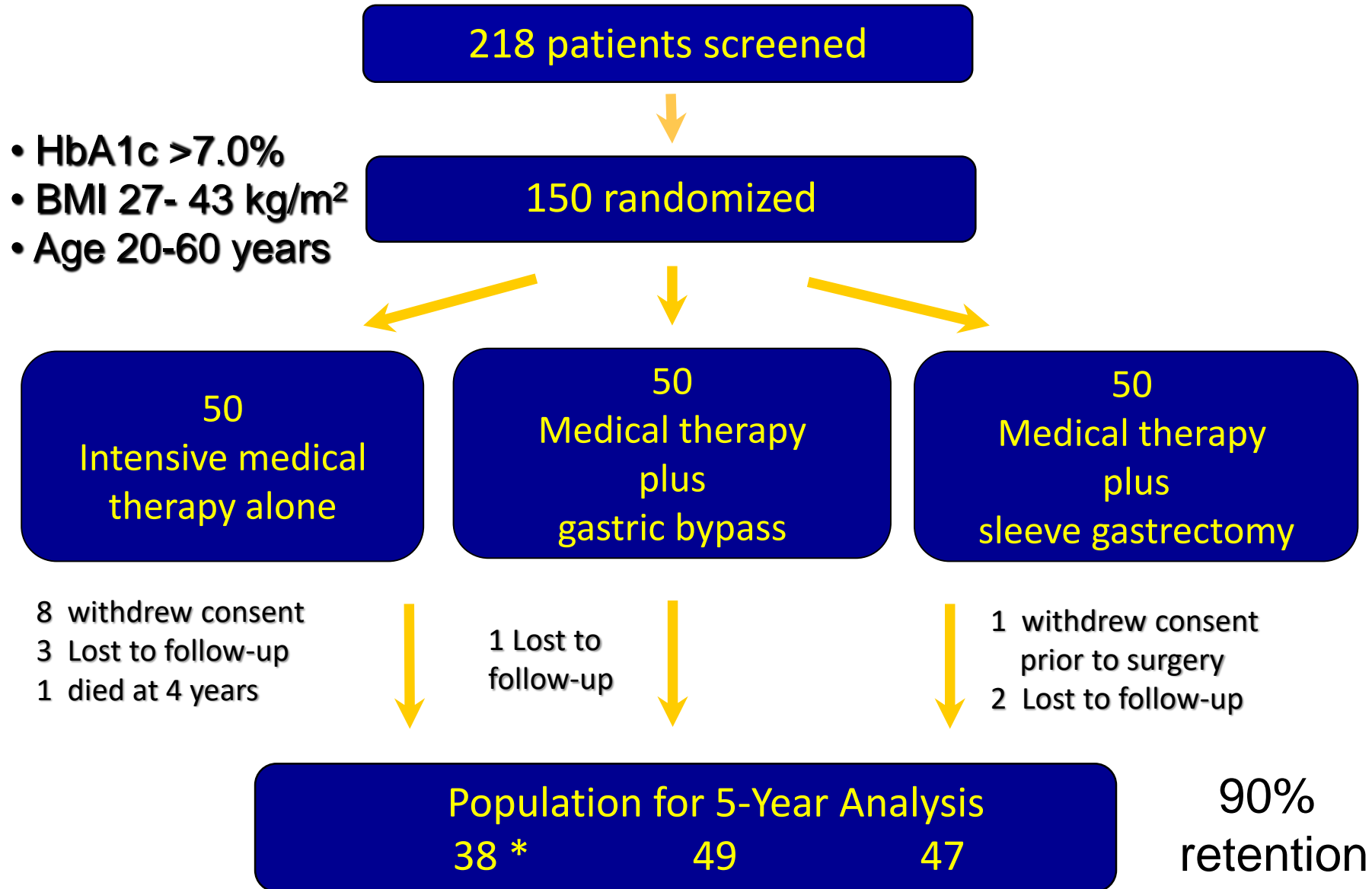
Duodenal switch

- 14 studies \geq 5 year follow up
- 3,763 patients followed from 5 to 20 years
- %EWL from 63.7 to 93.7 reported
- Subset of super obese BMI>50 reported %EWL > 64

Bariatric or Metabolic?

- Weight loss independent effects of surgery
- Earlier intervention = Better remission rates
- Predictors of lower remission or recurrent diabetes:
 - T2DM > 10 years
 - Insulin use at time of surgery
 - Long-term weight gain

STAMPEDE Trial: Flow of Patients



* 2 patients crossed over to surgery, 1 SG patient converted to RYGB

Baseline Characteristics

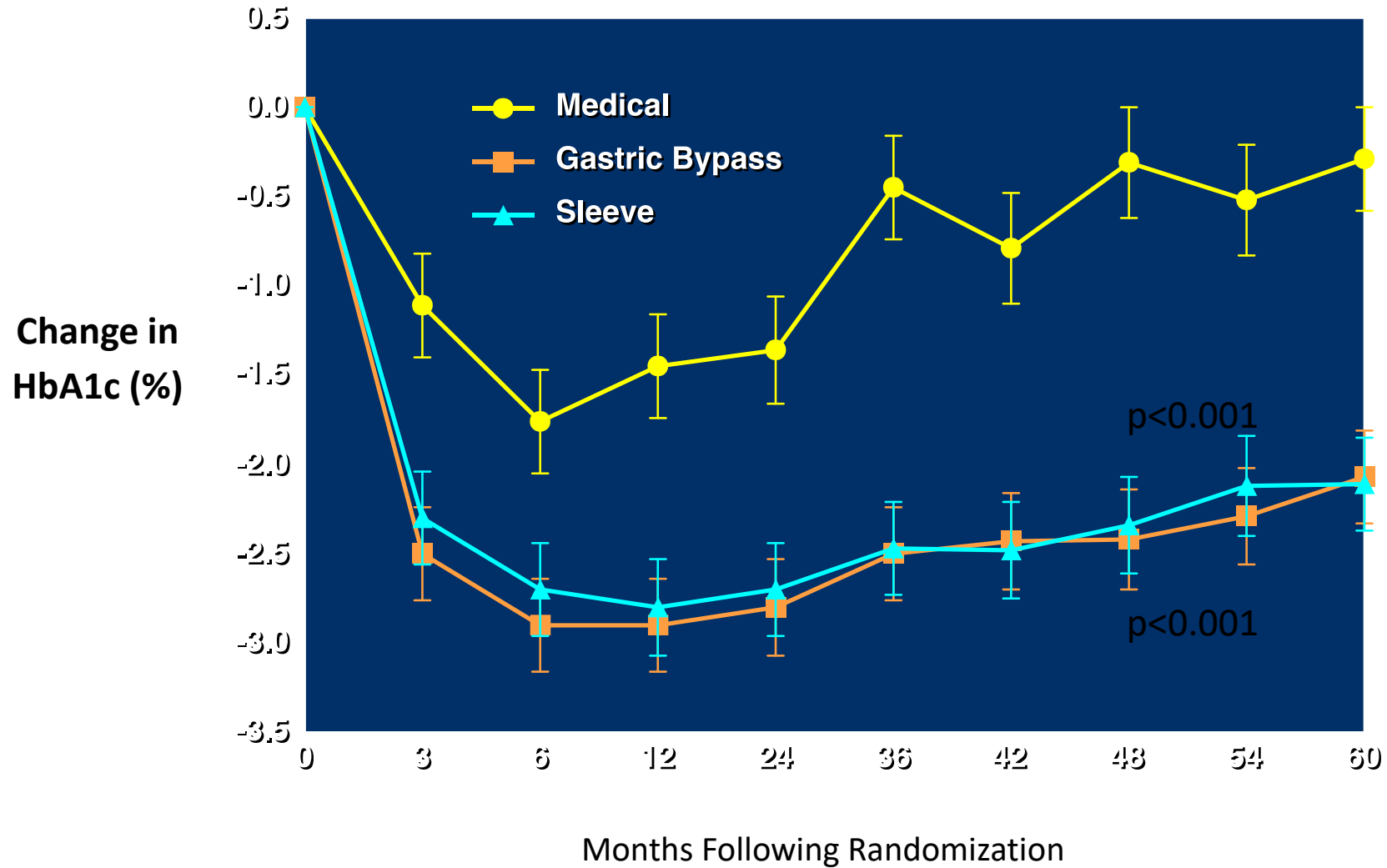
Parameter	Medical Therapy (n=38)	Bypass (n=49)	Sleeve (n=47)
Age (yrs)	50.2	48.2	48.1
Females	66%	57%	77%
Duration of diabetes (yrs)	8.8	8.2	8.3
HbA1c (%)	8.8	9.3	9.5
Body Mass Index (kg/m ²)	36.4	37.0	36.0
≥ 3 diabetes medications	61%	53%	47%
Insulin use	53%	47%	45%

Primary and Secondary Endpoints at 5 Years

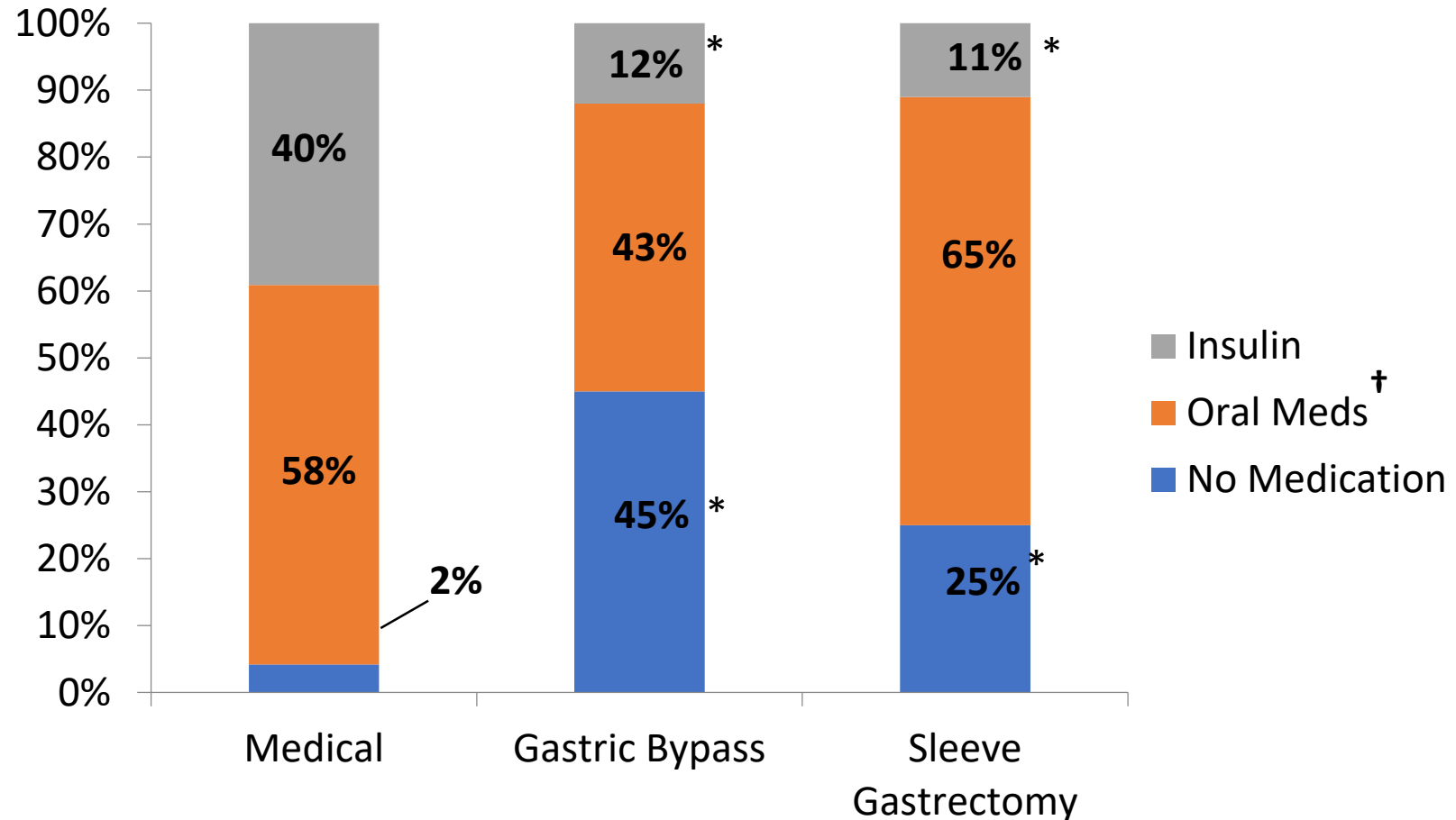
Parameter	Medical Therapy (n=38)	Bypass (n=49)	Sleeve (n=47)	P Value ¹	P Value ²
HbA1c ≤ 6%	5%	29%	23%	0.005	0.02
HbA1c ≤ 6% (without DM meds)	0%	22%	15%	0.002	0.02
HbA1c ≤ 7%	21%	51%	49%	0.004	0.008
Median change in FPG (mg/dL)	-14	-72	-49	<0.001	0.01
Relapse of glycemic control	80%	40%	50%	0.16	0.34
% change in HDL	+7	+32	+30	0.003	0.008
Median % change in TG	-8	-40	-29	0.01	0.02

¹ Gastric Bypass vs Medical Therapy; ² Sleeve vs Medical Therapy

Change in HbA1c Over 5 Years



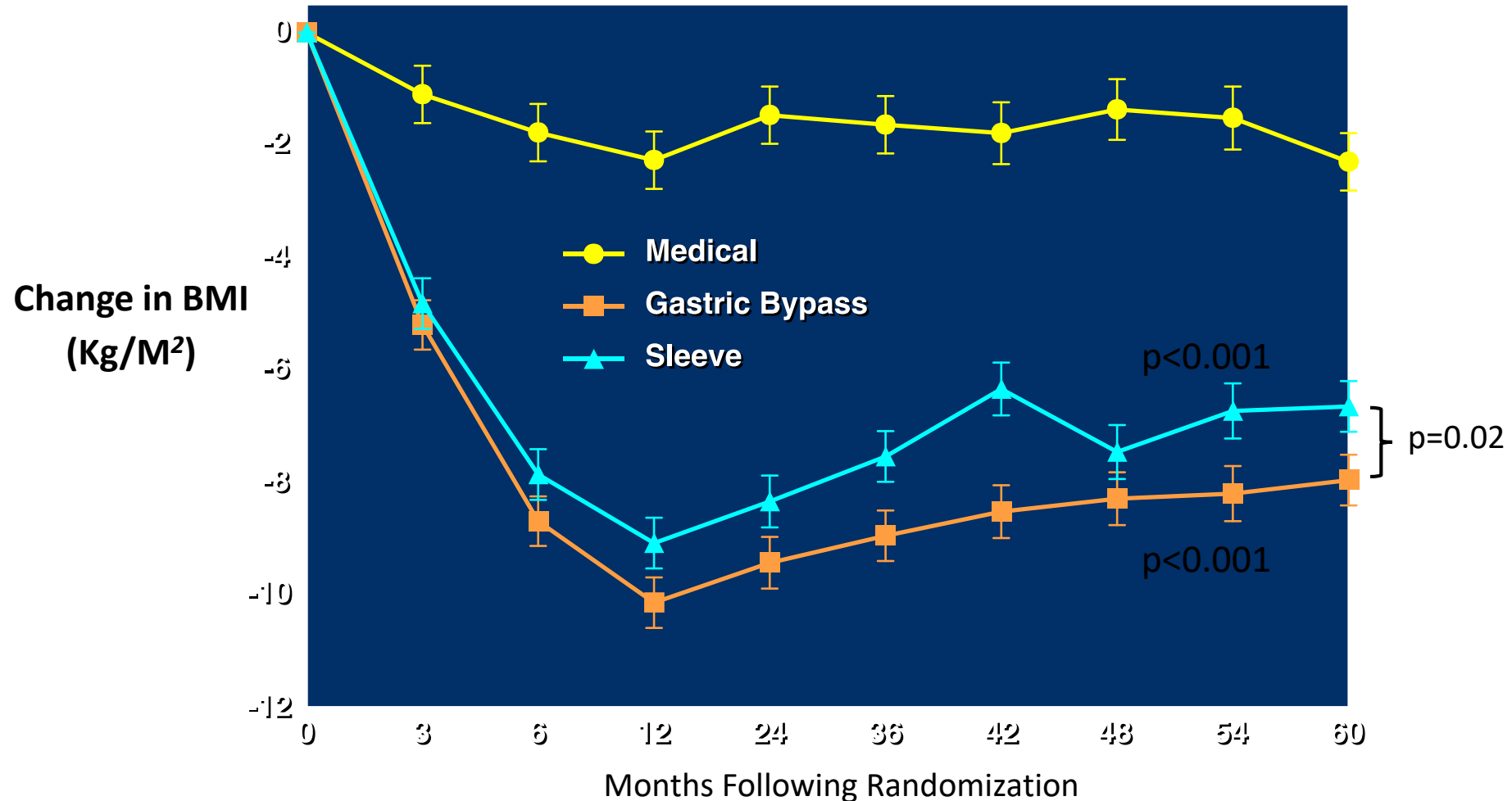
Diabetes Medications at 5 Years



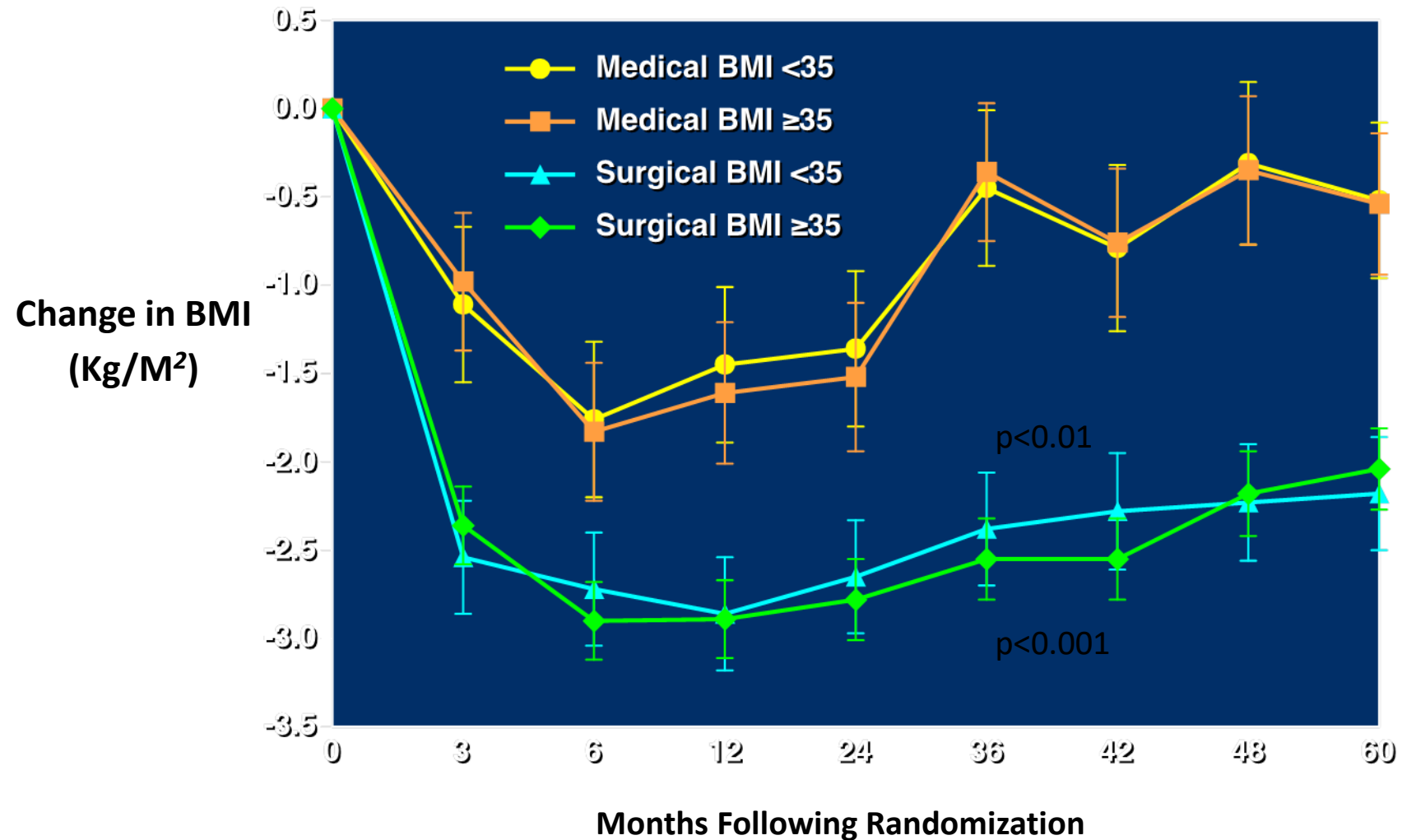
* P<0.05 compared to medical therapy

† Includes injectables such as GLP-1 agonists

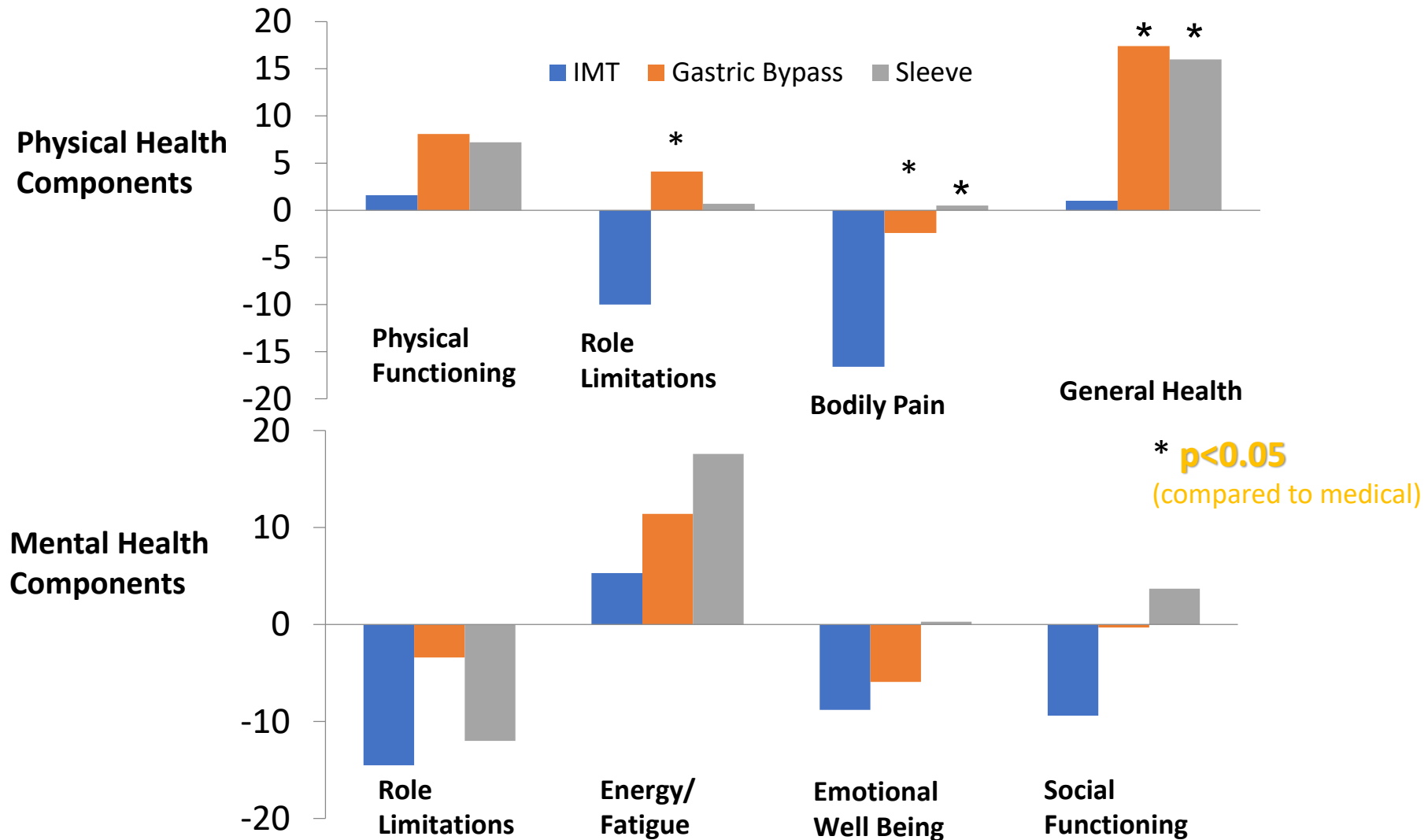
Change in Body Mass Index Over 5 years



Change in HbA1c According BMI Over 5 Years



Change in Quality of Life Measures at 5 Years (RAND-36)



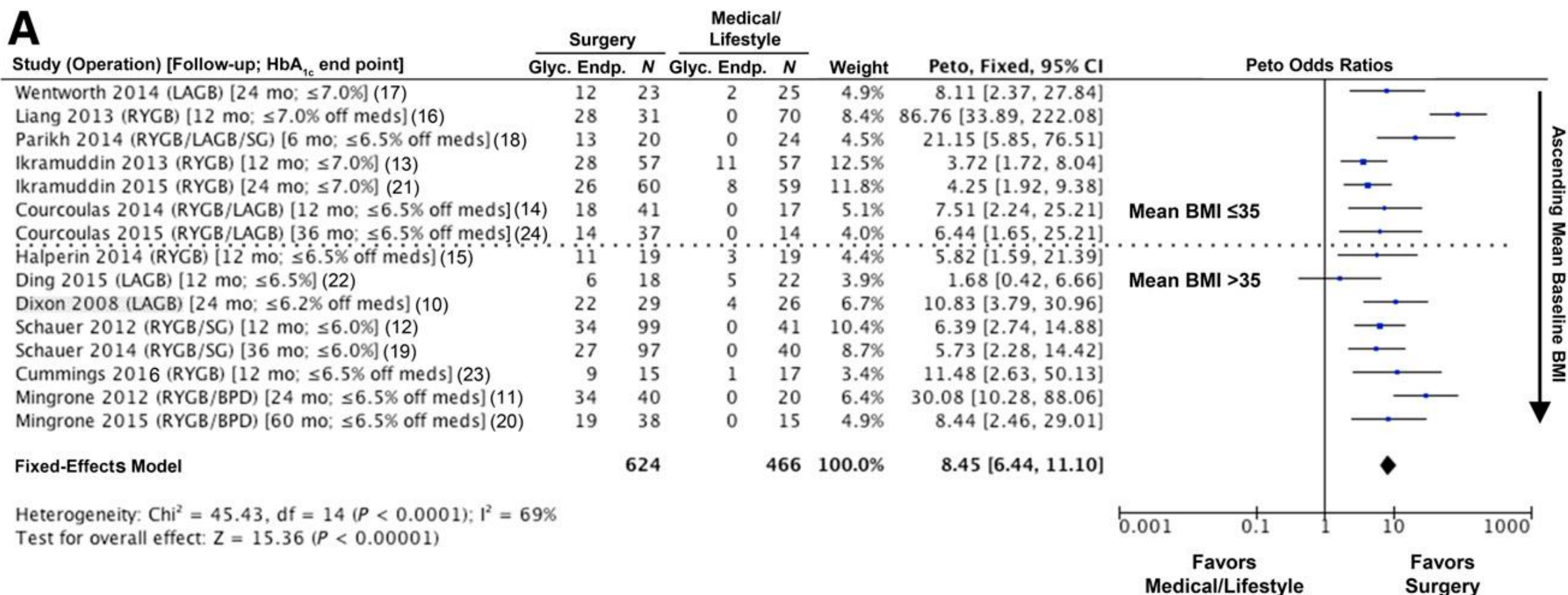
History



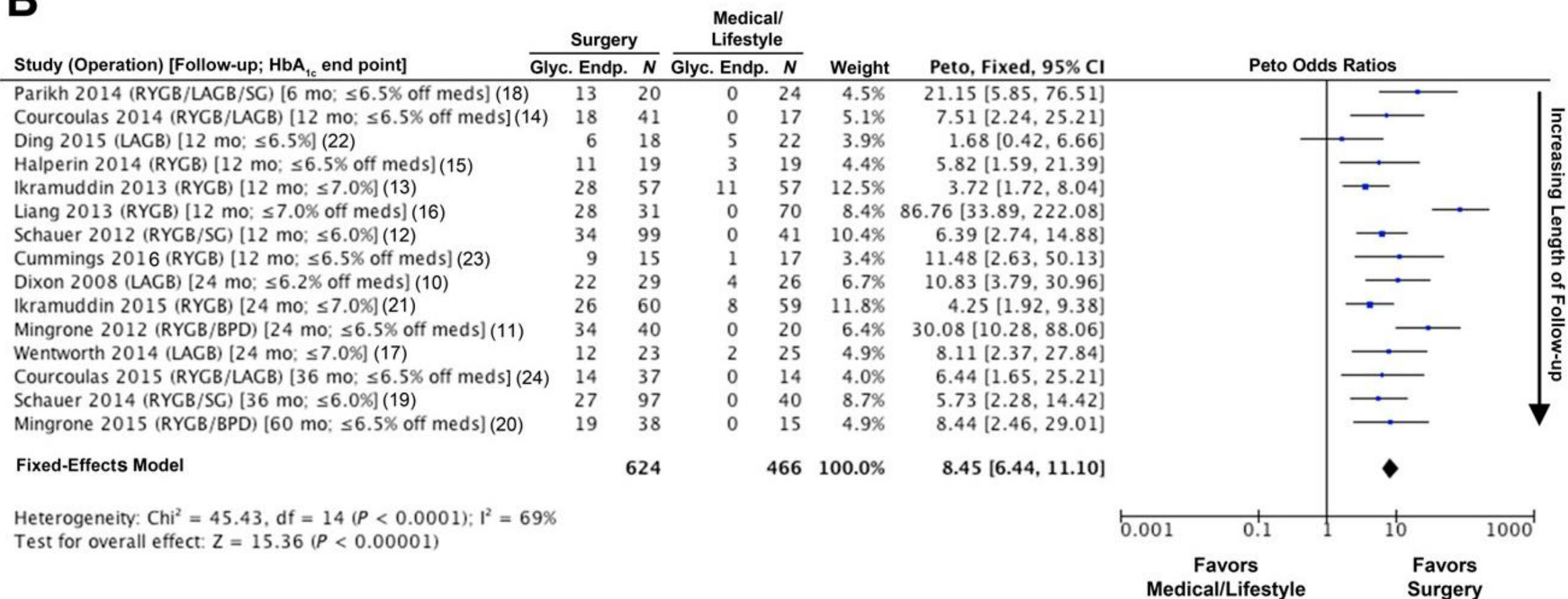
- DSS-I held in Rome 2007
- 2008-present: Emphasis on metabolic effects and mechanisms of our operations
- First mention of surgery in ADA guidelines was in 2009: “..may be considered”
- 2009-present: 11 RCT’s for metabolic procedures
- 2015: DSS-11 in London



A



B



3RD WORLD CONGRESS
ON INTERVENTIONAL
THERAPIES FOR
TYPE 2 DIABETES



2ND DIABETES
SURGERY SUMMIT
DSS-II

Earn up to
15 CME
Credits

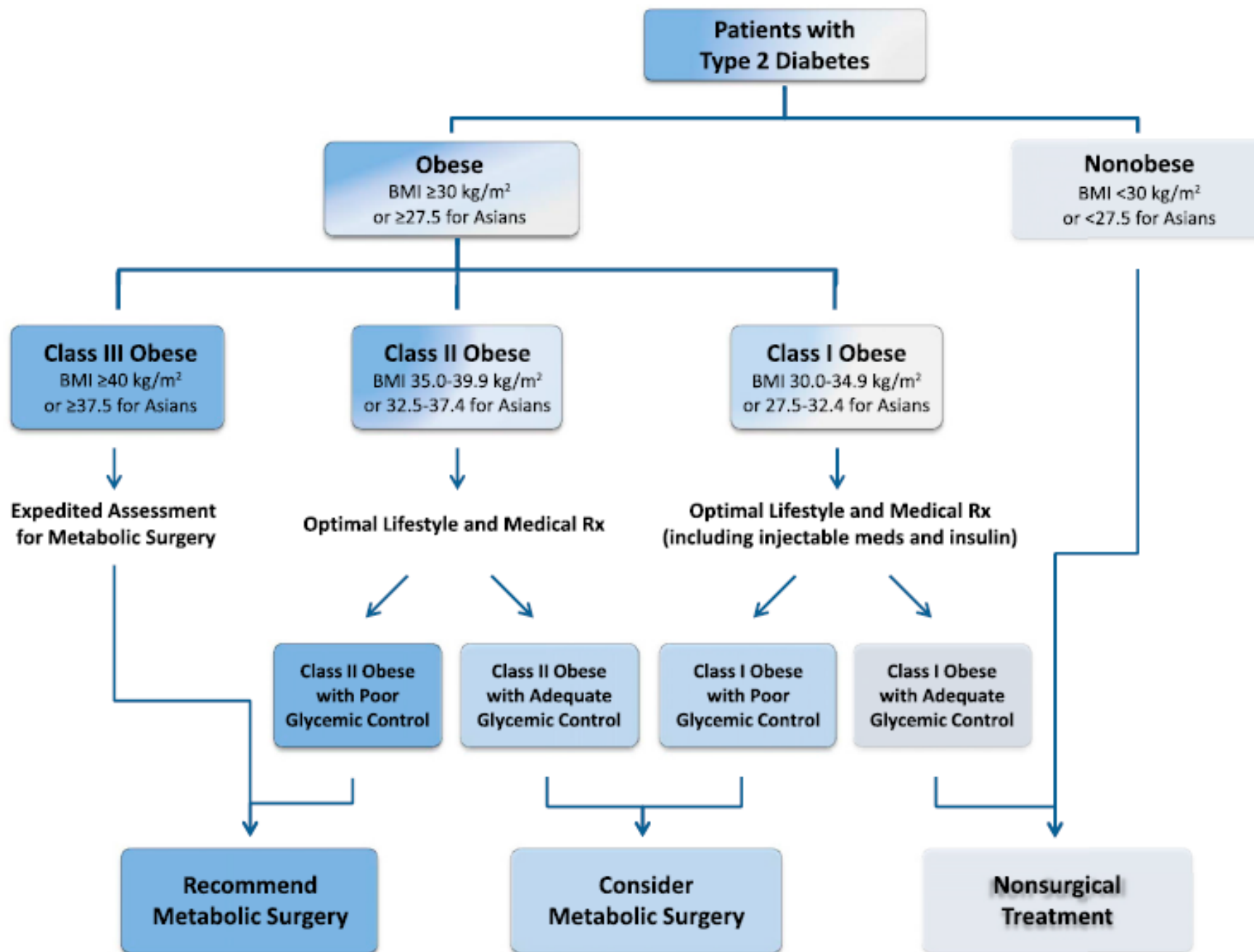


September 28-30, 2015 | London, UK



Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations

Francesco Rubino¹[↑](#), David M. Nathan²[↑](#), Robert H. Eckel³[↑](#), Philip R. Schauer⁴[↑](#), K. George M.M. Alberti⁵[↑](#), Paul Z. Zimmet⁶[↑](#), Stefano Del Prato⁷[↑](#), Linong Ji⁸[↑](#), Shaukat M. Sadikot⁹[↑](#), William H. Herman¹⁰[↑](#), Stephanie A. Amiel¹[↑](#), Lee M. Kaplan²[↑](#), Gaspar Taroncher-Oldenburg¹¹[↑](#) and David E. Cummings¹²[↑](#) on behalf of the Delegates of the 2nd Diabetes Surgery Summit^{*}[↑](#)



The Future of Obesity Treatment

- Endoscopic therapy
- Combined therapy
 - Surgery + Endoscopy
 - Surgery + Medication
 - Endoscopy + Medication
- Neuromodulation
- Gene therapy

Endoluminal Duodenal-Jejunal Liner

- Targets duodenum
- Reproducible
- Some mechanisms are known
- Targets a comorbidity



Revita procedure

Duodenal Mucosal Resurfacing

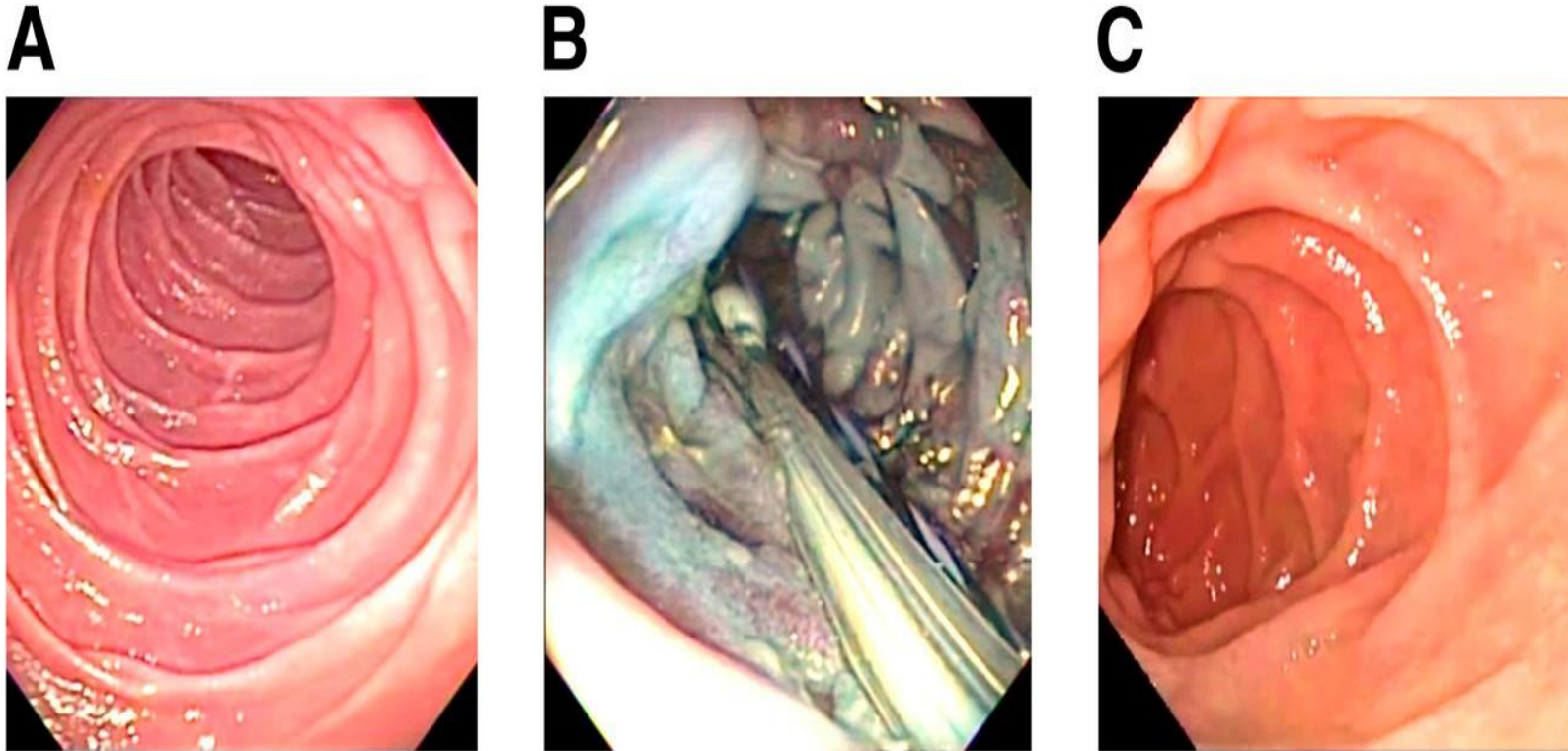
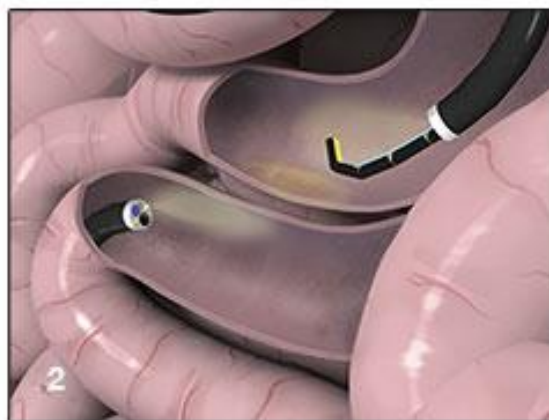


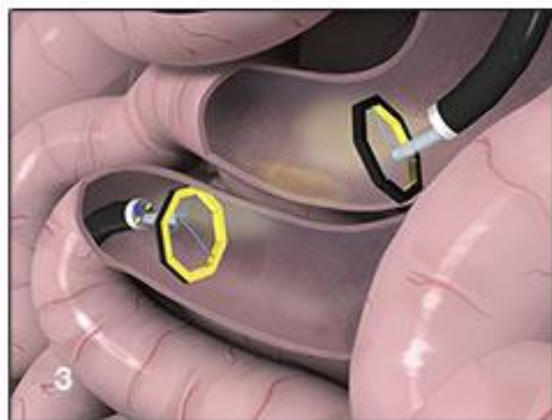
Figure 1 — The duodenal mucosa prior to DMR (A), immediately after hydrothermal ablation (B), and 1 month after the procedure (C) as seen during follow-up endoscopy.



Two standard endoscopes are used to access the small bowel



Self-forming magnets are deployed from the working channel of each endoscope



The devices are connected to create a compression anastomosis



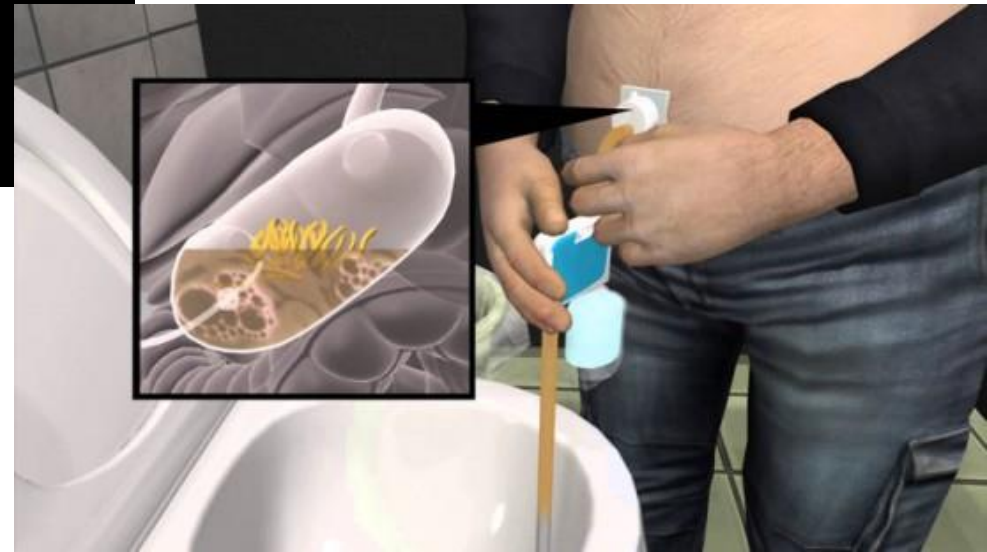
When the anastomosis is fully formed, the devices are passed

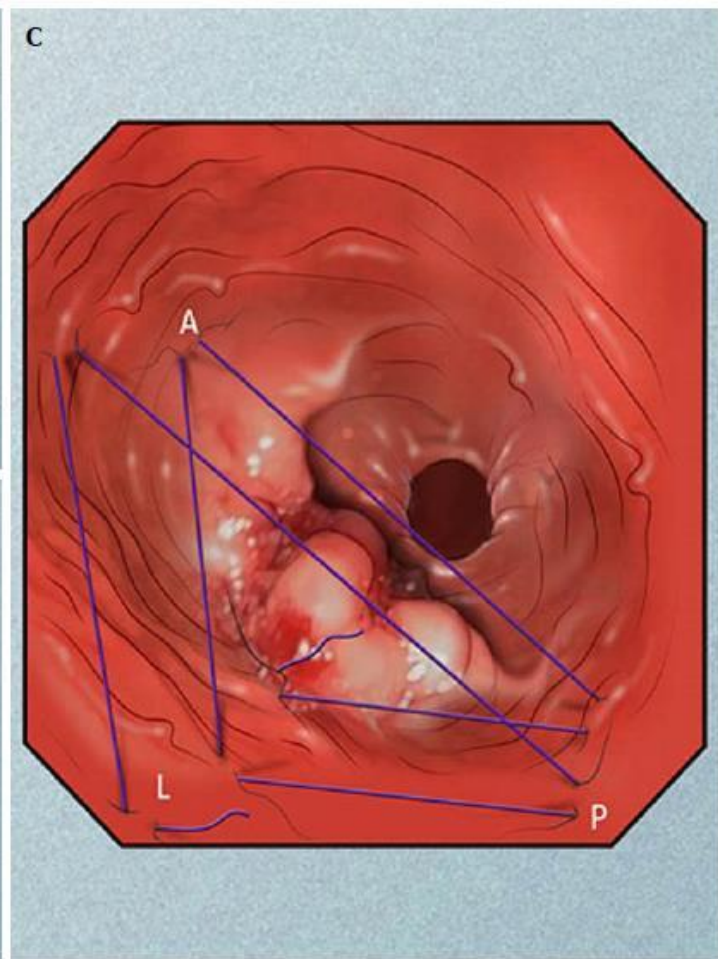
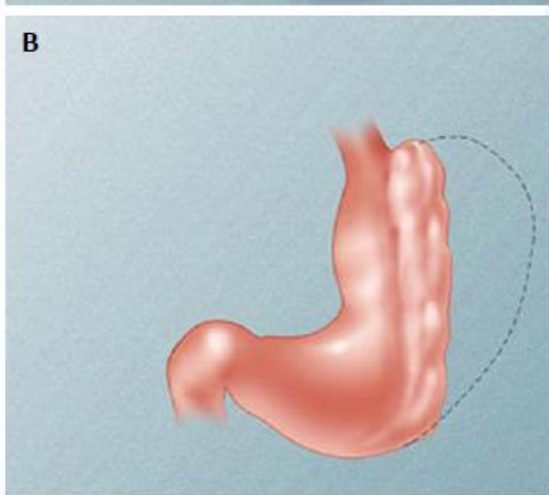
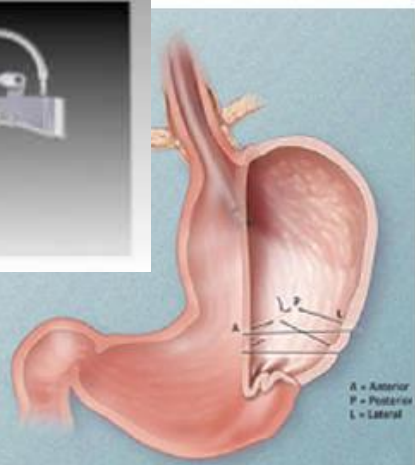


A treatment path is created, by-passing a portion of the small

Introducing the

ASPIRE Assist™
ASPIRATION THERAPY SYSTEM





Intragastric Balloon



Summary

- Bariatric surgery has a checkered past
- Currently perceived as a subspecialty in general surgery
- We are treating a chronic disease that is not perceived as such by most physicians or lay people
- Current procedures are safe, effective, and durable
- Re-intervention may be required for recurrent disease
- Adjuvant or combination therapy is often warranted
- Many endoluminal options are emerging and some have promise

Thank You



wexnermedical.osu.edu