SURGICAL AND ENDOSCOPIC PROCEDURES FOR WEIGHT LOSS IN THE MEDICARE POPULATION

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Disclosures

Ethicon EndoSurgery

Speaking honoraria / Consultant < $10,000

Medtronic

Speaking honoraria / Consultant <$10,000

Overview

- Obesity = disease
- Interventions
- Mechanisms
- Procedure outcomes
  - Durability
  - Safety
  - Survival
- Impact on comorbidities
  - Diabetes
  - Cancer
  - Cardiovascular disease
- Quality / Patient safety
- Newer treatments
  - VBLOC
  - Endoscopic treatments

Overview

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Obesity in America

Obesity is a chronic disease

World Obesity Federation Position Statement

Obesity: a chronic relapsing progressive disease process. A position statement of the World Obesity Federation

Received 6 March 2017; accepted 20 March 2017

Endocr Pract. 2014 September ; 20(9): 977–989. doi:10.4158/EP14280.PS.

The American Association of Clinical Endocrinologists and the American College of Endocrinology:

2014 ADVANCED FRAMEWORK FOR A NEW DIAGNOSIS OF OBESITY AS A CHRONIC DISEASE

W. Timothy Garvey, MD [Chair, AACE Obesity Scientific Committee], **Jeffrey I. Mechanick, MD, FACP, FACE, FACN, ECNU [President, AACE]**, and **Daniel Einhorn, MD, FACP, FACE [President, ACE]**

Obesity *Facts*
The European Journal of Obesity

Obes Facts 2015;8:342–349

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Clinical Information

Childhood Obesity Is a Chronic Disease Demanding Specific Health Care – a Position Statement from the Childhood Obesity Task Force (COTF) of the European Association for the Study of Obesity (EASO)

Nathalie J. Farpour-Lambert[a] Jennifer L. Baker[b, c] Maria Hassapidou[d]
Jens Christian Holm[e] Paulina Nowicka[f] Grace O'Malley[g] Ram Weiss[h]

American Medical Association 2013

Obesity Pathogenesis: An Endocrine Society Scientific Statement

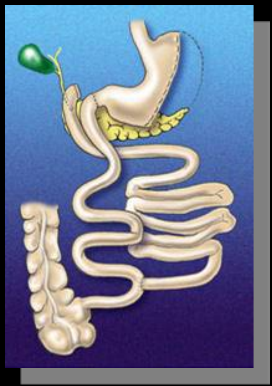
Michael W. Schwartz,[1] Randy J. Seeley,[2] Lori M. Zeltser,[3] Adam Drewnowski,[4] Eric Ravussin,[5] Leanne M. Redman,[5] and Rudolph L. Leibel[3,6]

ABSTRACT Obesity is among the most common and costly chronic disorders worldwide. Estimates suggest that in the United States obesity affects one-third of adults, accounts for up to one-third of total mortality, is concentrated among lower income groups, and increasingly affects children as well as adults. A lack of effective options for long-term weight reduction magnifies the enormity of this problem; individuals who successfully complete behavioral and dietary weight-loss programs eventually regain most of the lost weight. We included evidence from basic science, clinical, and epidemiological literature to assess current knowledge regarding mechanisms underlying excess body-fat accumulation, the biological defense of excess fat mass, and the tendency for lost weight to be regained. A major area of emphasis is the science of energy homeostasis, the biological process that maintains weight stability by actively matching energy intake to energy expenditure over time. Growing evidence suggests that obesity is a disorder of the energy homeostasis system, rather than simply arising from the passive accumulation of excess weight. We need to elucidate the mechanisms underlying this "upward setting" or "resetting" of the defended level of body-fat mass, whether inherited or acquired. The ongoing study of how genetic, developmental, and environmental forces affect the energy homeostasis system will help us better understand these mechanisms and are therefore a major focus of this statement. The scientific goal is to elucidate obesity pathogenesis so as to better inform treatment, public policy, advocacy, and awareness of obesity in ways that ultimately diminish its public health and economic consequences. *(Endocrine Reviews 38: 1 – 30, 2017)*

Various interventions / procedures for obesity and its comorbidities

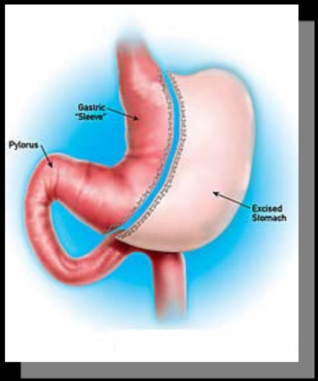
continuum of care

Spectrum of most common procedures

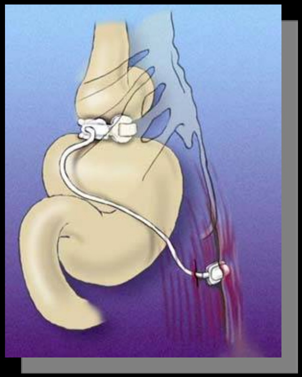


Biliopancreatic Diversion with Duodenal Switch

Roux-en-Y Gastric Bypass



Sleeve Gastrectomy



Adjustable Gastric Banding

Malabsorption → Restriction

More ← Weight Loss — Less

More — Risks → Less

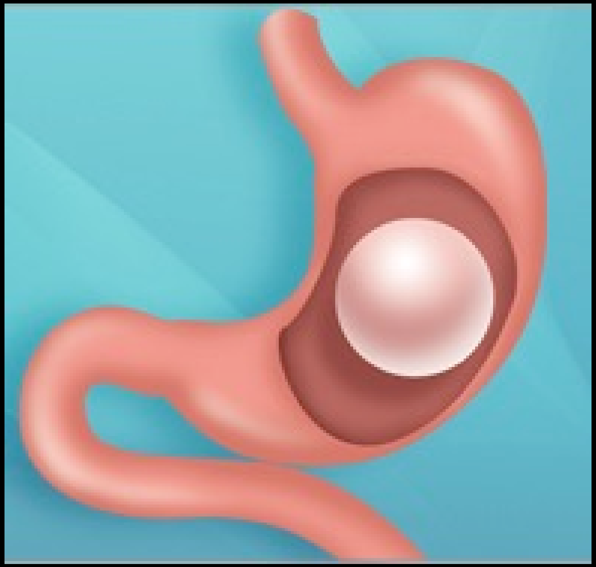
Obesity Care

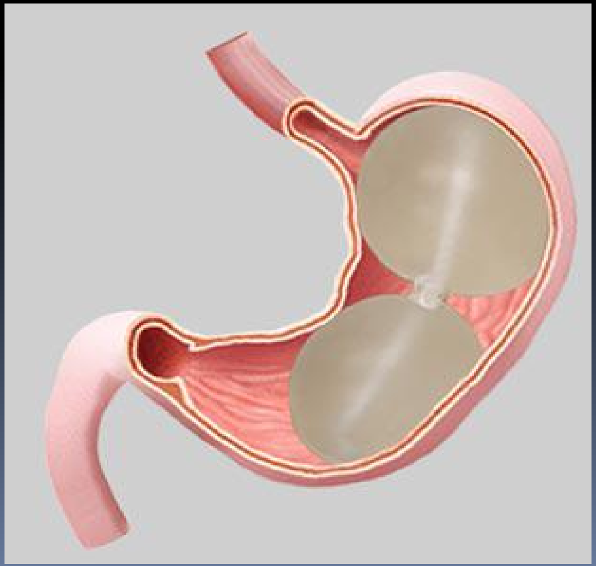
Treatment Options	**Diet, Rx and Lifestyle**		**Surgery**
BMI	25-30 kg/m^2	30-40 kg/m^2	>40 kg/m^2
% of US population	34.4%	26.2%	5.7%

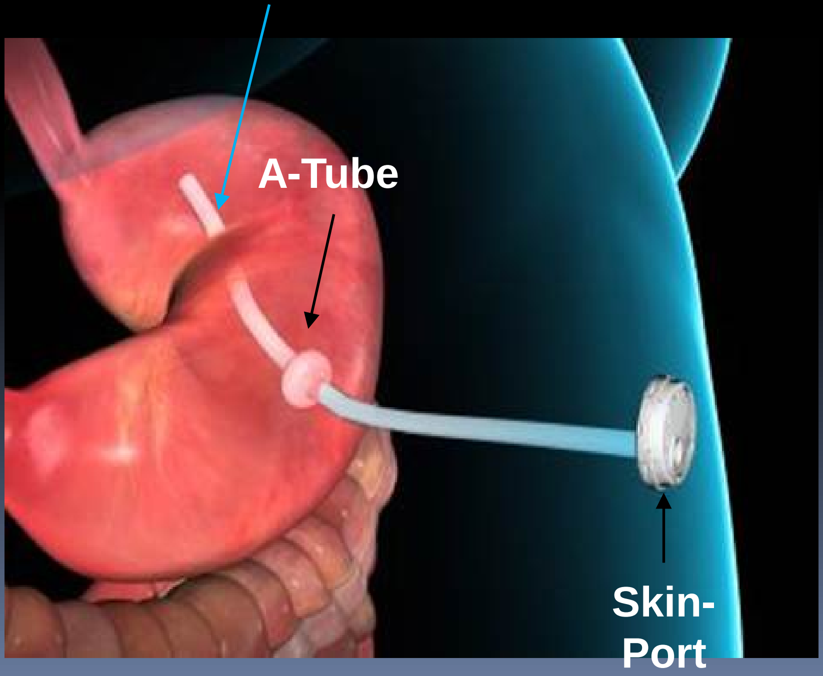
Treatment Gap

JAMA 2010;303:235-41

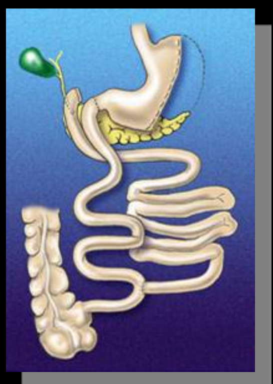
Newer FDA approved interventions





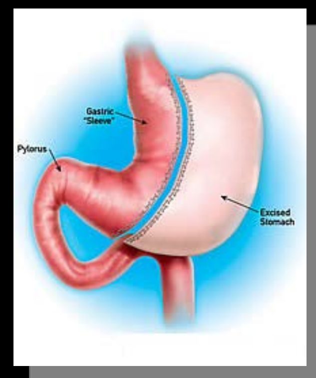


Spectrum of most common procedures

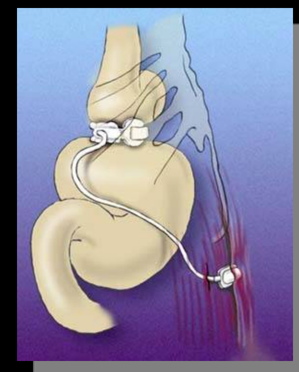


Biliopancreatic Diversion with Duodenal Switch

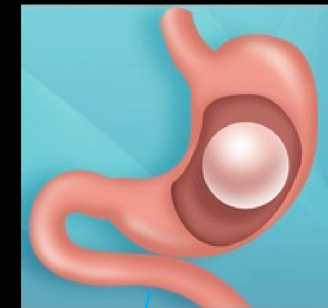
Roux-en-Y Gastric Bypass

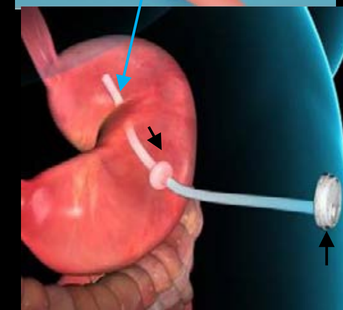


Sleeve Gastrectomy



Adjustable Gastric Banding





IGB
Aspireassist
VBLOC

More — Risks — Less

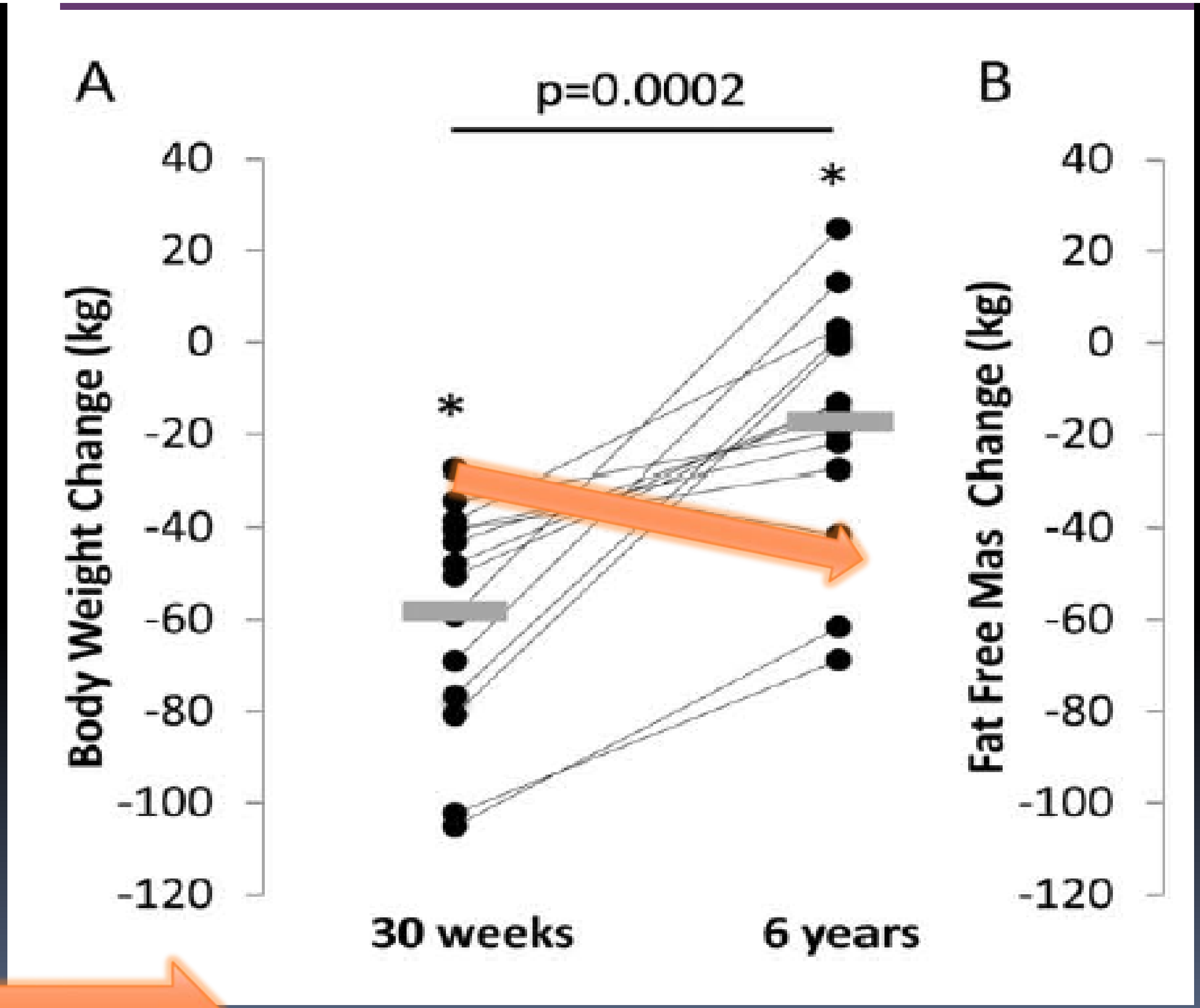
More — Weight Loss — Less

How? Mechanisms of GI procedures

- Restriction / malabsorption- classic terms
- Metabolic and physiologic mechanisms
  - GLP-1
  - Ghrelin
  - PYY
  - GIP
  - Amylin
  - CCK
  - Bile acids
- Preserved energy expenditure
- Microbiome

Persistent Metabolic Adaptation 6 Years After "The Biggest Loser" Competition

Erin Fothergill[1], Juen Guo[1], Lilian Howard[1], Jennifer C. Kerns[2], Nicolas D. Knuth[3], Robert Brychta[1], Kong Y. Chen[1], Monica C. Skarulis[1], Mary Walter[1], Peter J. Walter[1], and Kevin D. Hall[1]



Bariatric Surgery

Bariatric Surgery Evolution from the Malabsorptive to the Hormonal Era

OBES SURG (2012) 22:827–831

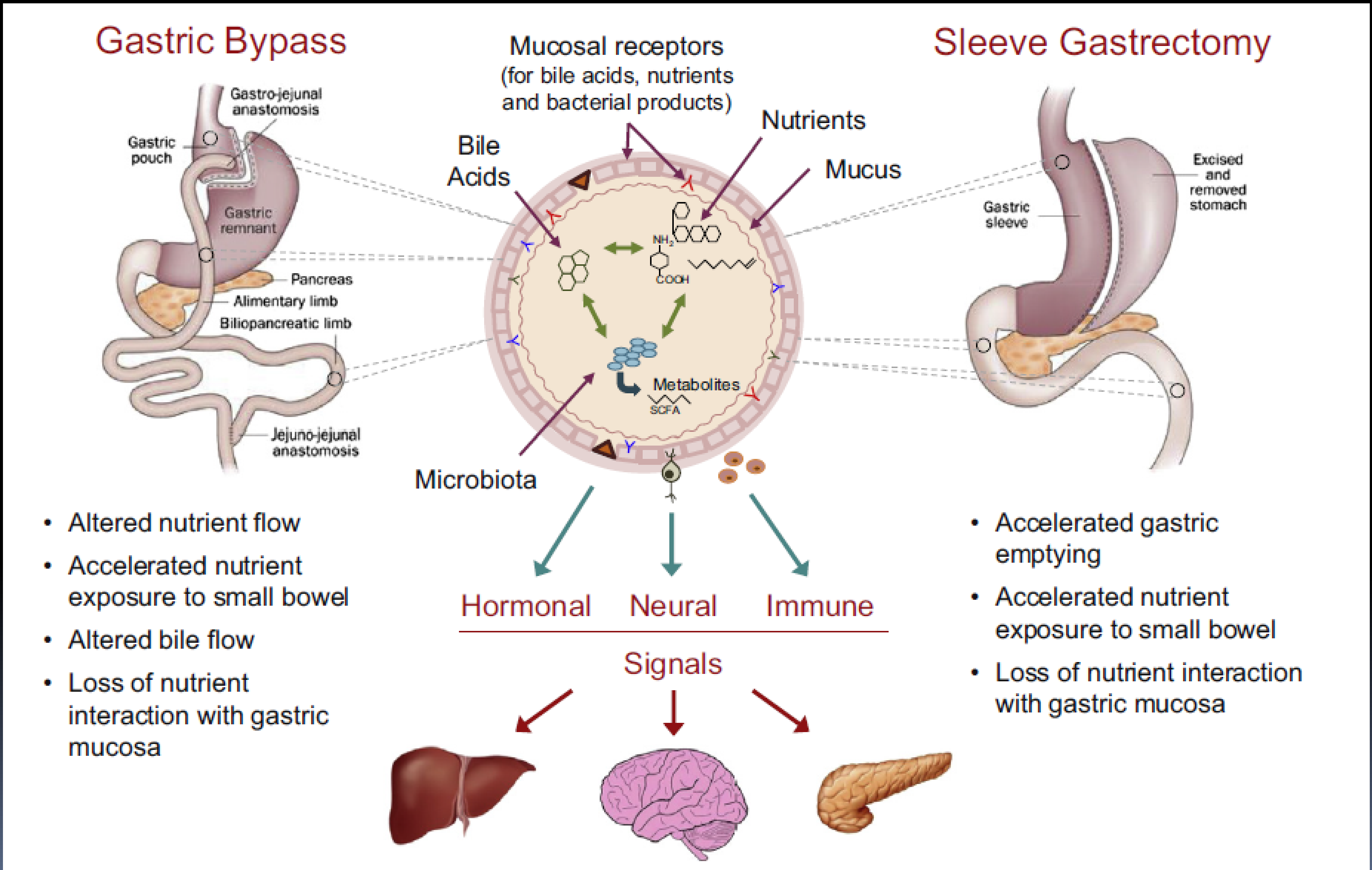
Ehab Akkary

Table 2 Advantages of hormonal bariatric procedures

	Secreted from	Acts on	Effect on satiety	Roux-Y gastric bypass	DS/BPD	Sleeve gastrectomy	Adjustable gastric band
Ghrelin	Fundus	V, BS, HT	↓	↓	↓	↓	↑
GLP-1	L cells	V, BS, HT	↑	↑	↑	↑	No Δ
GIP	K cells	β-cells	?	↓ or no Δ	↓ or no Δ	↑	No Δ
PYY	L cells	V, BS, HT	↑	↑	↑	↑	No Δ
Pancreatic polypeptide	F cells	V, BS	↑	↑	↑	↑	?
Amylin	B cells	BS, HT	↑	↓	?	↑	No Δ
CCK	I cells	V, BS, HT	↑	No Δ	?	↑	?
Oxyntomodulin	L cells	HT	↑	↑	?	?	?

V vagus, *BS* brain stem, *HT* hypothalamus

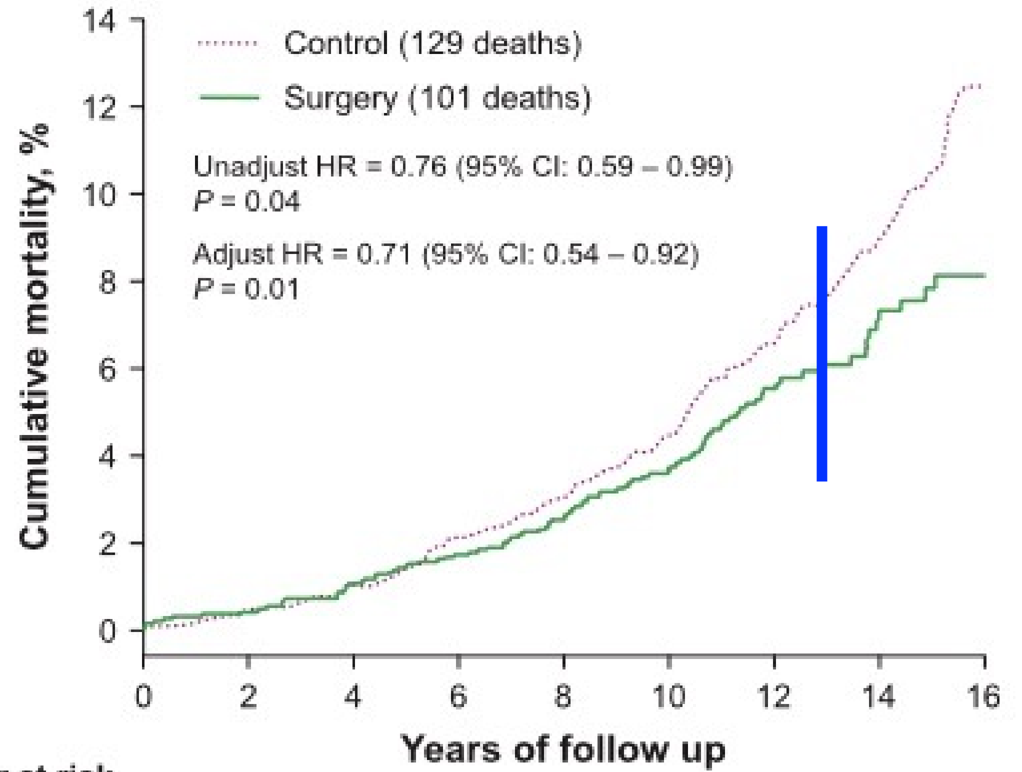
Kaplan GI Endosc Clin N Am 2017



Outcome data:
morbidity
longterm outcomes
(durability)

Bariatric surgery provides a longterm survival benefit

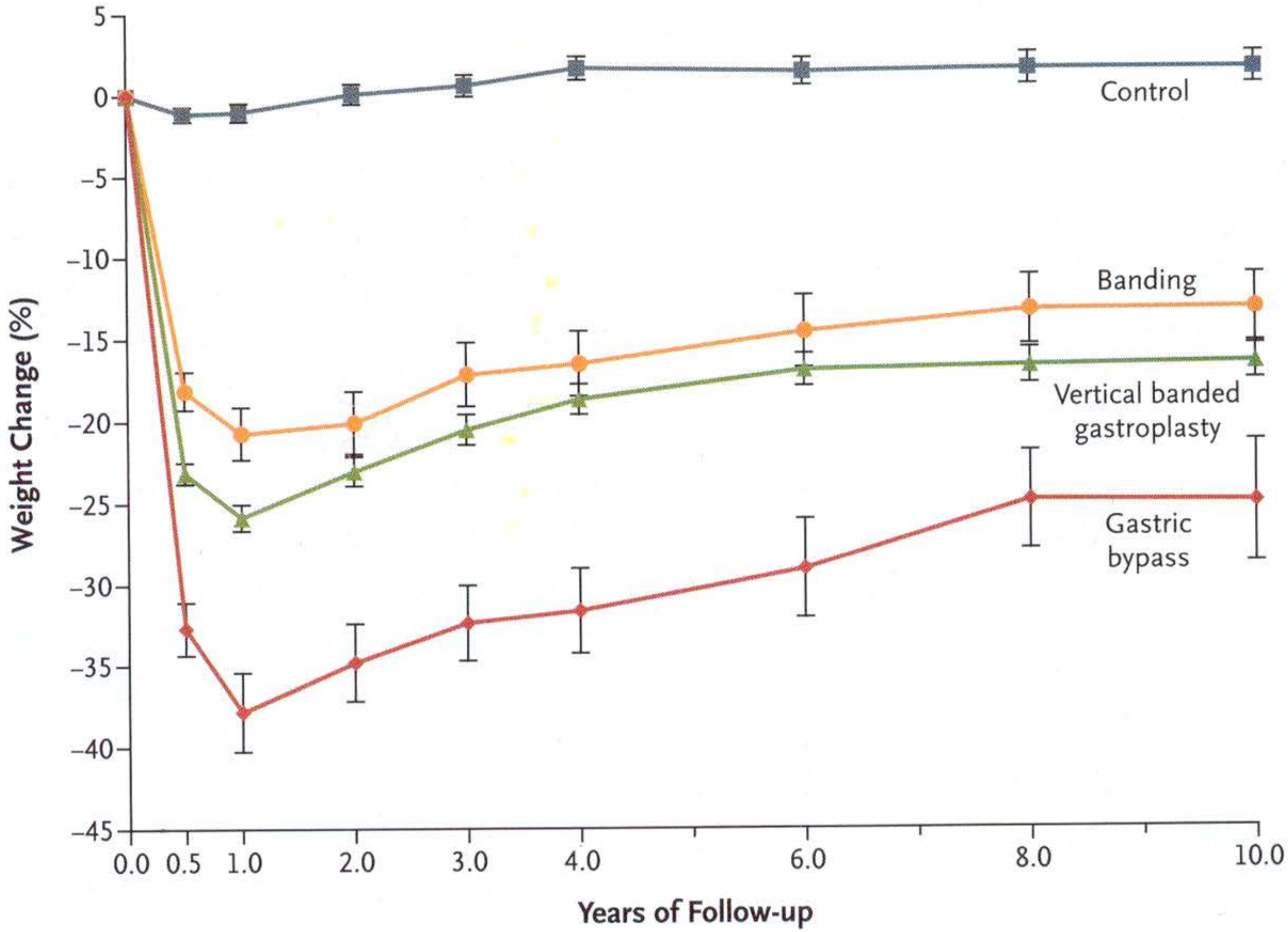
Sjostrom L. **Review of the key results from the Swedish Obese Subjects (SOS) trial - a prospective controlled intervention study of bariatric surgery.** J Intern Med 2013;273:219–34.



Number at risk

Surgery	2010	2001	1987	1821	1590	1260	760	422	169
Control	2037	2027	2016	1842	1455	1174	749	422	156

SOS Study: Ten-year results



No. of Subjects

	0.0	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0
Control	627	585	594	587	577	563	542	535	627
Banding	156	150	154	153	149	150	147	144	156
Vertical banded gastroplasty	451	438	438	438	429	417	412	401	451
Gastric bypass	34	34	34	34	33	32	32	29	34

Sjöström L, Lindroos AK, Peltonen M et al. N Engl J Med. 2004;351:2683

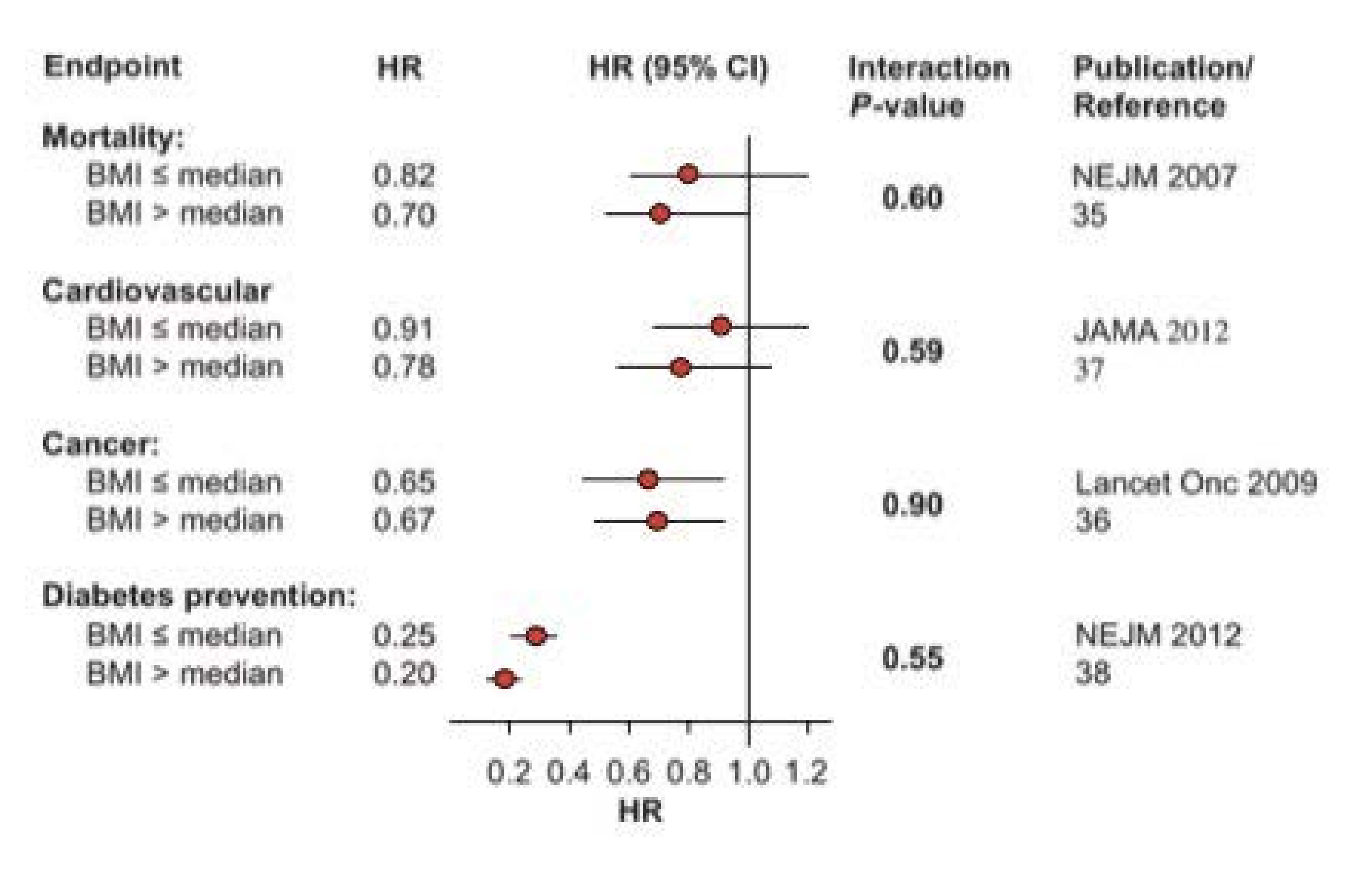
The SOS Study:
Incidence of co-morbidities

	Control	Surgery
Diabetes	24	7*
HTN	49	41
Hyperuricemia	28	17*
Hypertriglyceridemia	27	17*
Hypercholesterolemia	27	30

*** P<0.001 (all others NS)**

Sjöström L, Lindroos AK, Peltonen M et al. N Engl J Med. 2004;351:2683

Sjostrom L. Review of the key results from the Swedish Obese Subjects (SOS) trial - a prospective controlled intervention study of bariatric surgery. J Intern Med 2013;273:219–34.



Outcomes independent of BMI

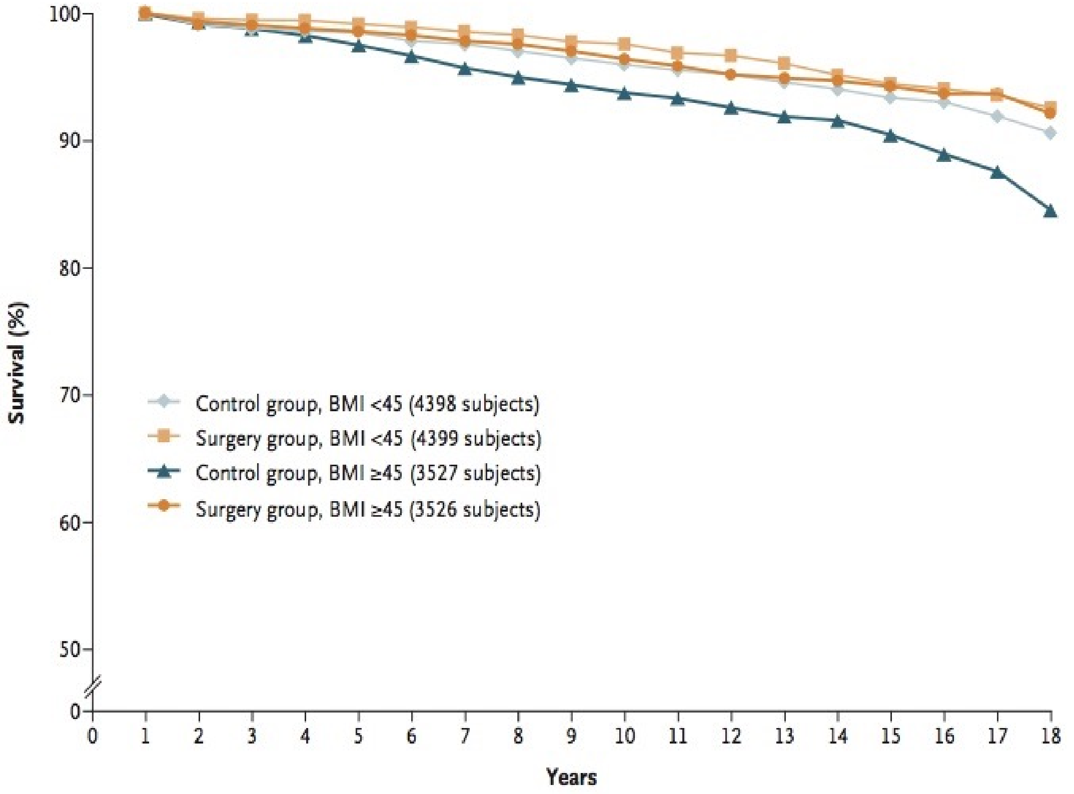
Christou NV, Sampalis JS, Liberman M, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. Ann Surg 2004;240: 416-23.

89% reduction in death after a mean f/u of 2.6 years

Flum DR, Dellinger EP. Impact of gastric bypass operation on survival a population-based analysis. J Am Coll Surg 2004;199:543-51.

- 33% reduction in death after a mean f/u of 4.4 years

Adams TD, Gress RE, Smith SC, Halverson RC, Simper SC, Rosamond WD, Lamonte MJ, Stroup AM, Hunt SC. **Long-term mortality after gastric bypass surgery.** N Engl J Med. 2007



No. of Deaths

Control group	41	66	85	117	153	176	199	219	234	244	259	271	281	294	302	310	318	327
Surgery group	42	54	62	74	86	102	113	132	141	159	169	182	192	202	206	210	213	213

Figure 2. Survival According to BMI in the Surgery Group and the Control Group.
The body-mass index (BMI) is the weight in kilograms divided by the square of the height in meters.

7925 pts
F/U: 7.1 years

Adjusted Mortality:
p<0.001 ↓40%

p=0.006 CAD: ↓56%
p=0.005 DM: ↓92%
p<0.001 Cancer: ↓60%

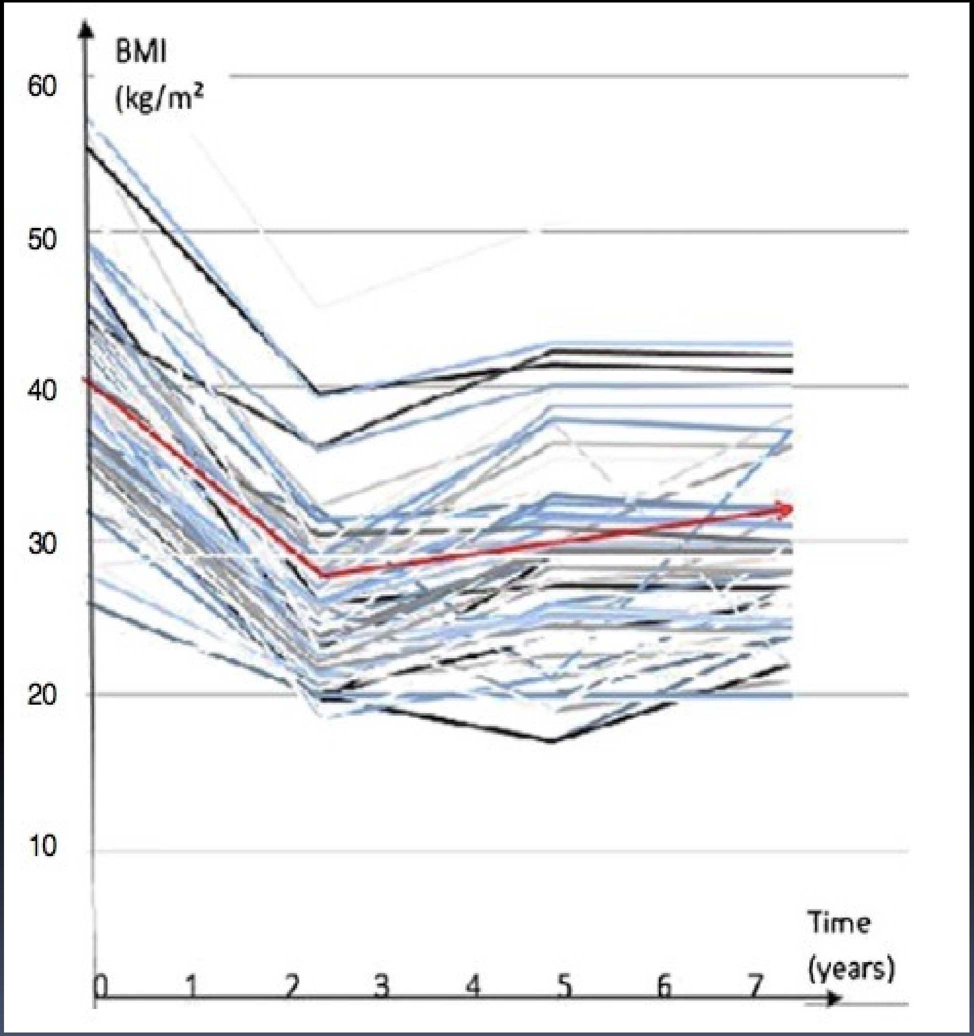
Weight loss / comorbidity outcomes of commonly performed surgical procedures in longterm follow-up

Gastric bypass $\geq$ 5 yr follow-up Recently published data

- 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

ASMBS position statement on durability of bariatric surgery procedures (in preparation, 2017)

Himpens J, Verbrugghe A, Cadière GB, Everaerts W, Greve JW. Long-term results of laparoscopic Roux-en-Y Gastric bypass: evaluation after 9 years. Obes Surg. 2012



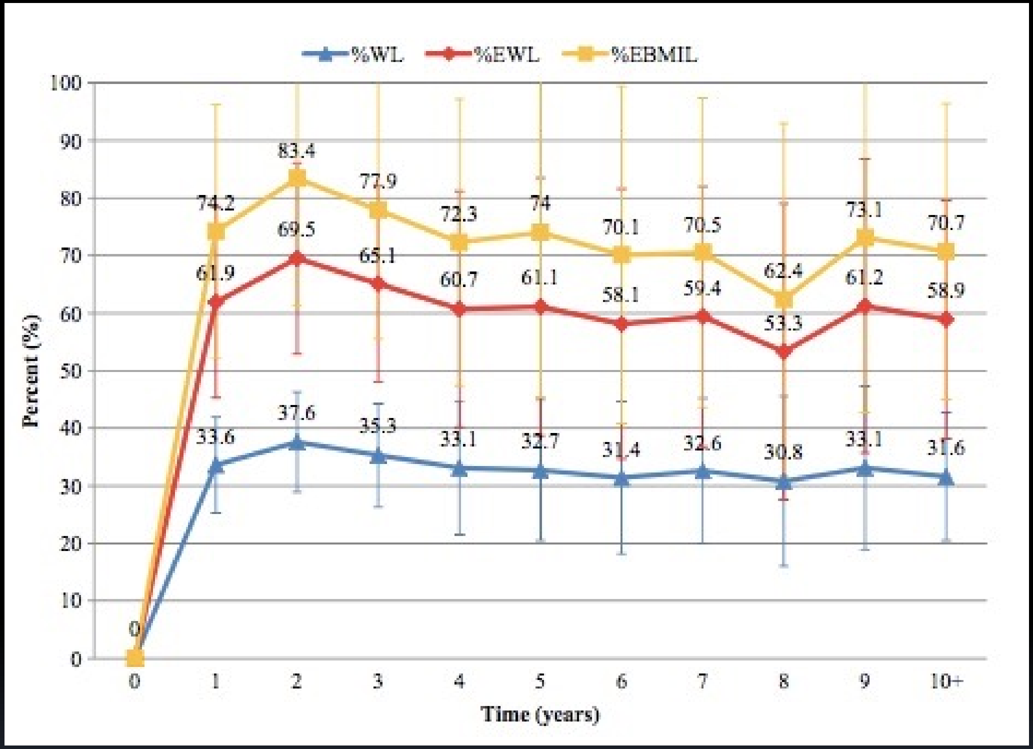
%EBMIL: 56.2

DM 2 Resolution: 80%

New-onset DM 2: 27.9%

"No link between weight regain and new-onset DM II"

Obeid, Nabeel R. et al. Long-term outcomes after Roux-en-Y gastric bypass: 10- to 13-year data Surgery for Obesity and Related Diseases 2015

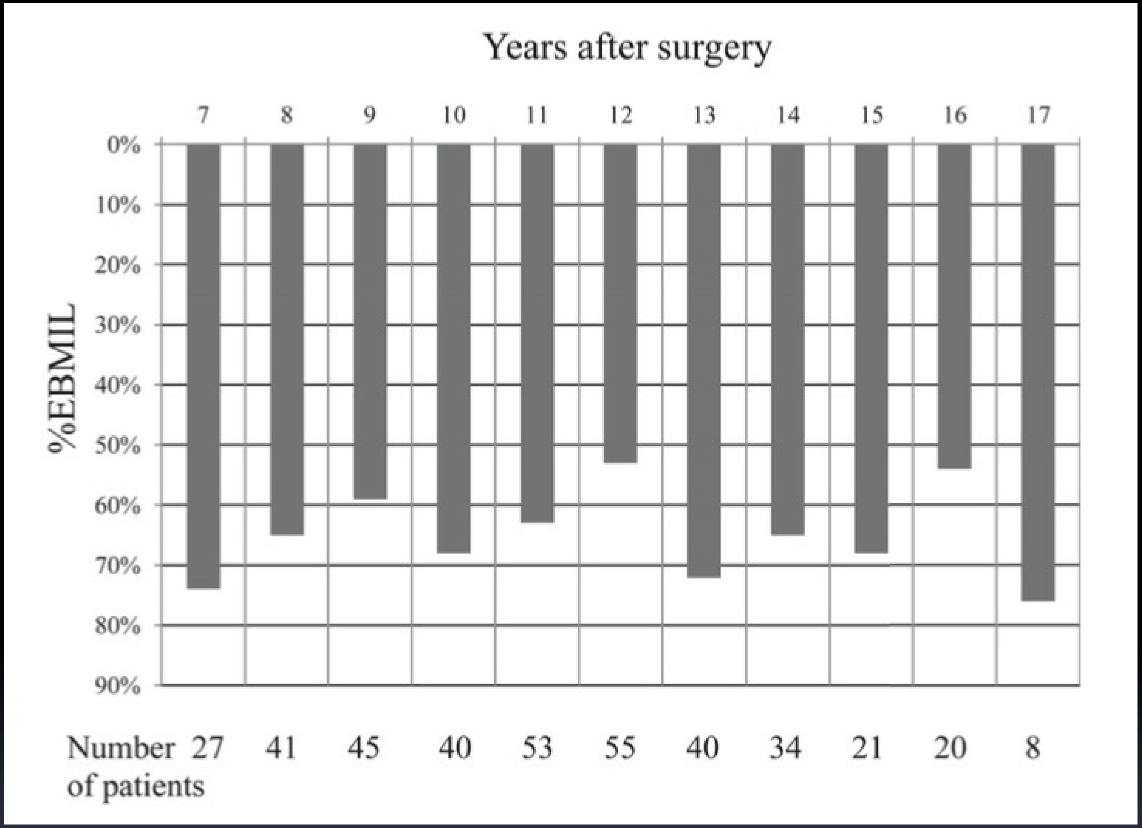


134 patients
@10+ years

58.9% EWL

DM: 58%
Dyslipidemia: 46%
HTN: 46%

Edholm D, Svensson F, Naslund I, Karlsson F, Rask E, Sundbom M. **Long-term results 11 years after primary gastric bypass in 384 patients.** SOARD 2013.



DM: 72%
TG: 62%

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)

Author/ publication year)	Country	F/u yrs	Number of eligible pts	Weight loss at 1-2 yrs	Weight loss (at end of f/u)	Diabetes Resolution	Criteria used by the authors
Brethauer (2013)	USA	5	23	49.7±32.5	49.5±24.9%	9%	EWL%
Sieber (2014)	Switzerland	5	54	61.5±23.4%	57.4% ±24.7%	85% at 5y	EBMIL%
Musella (2014)	Italy	5	102	61.4%	68.1%	_	EWL%
Pok (2016)	Taiwan	5	61	76%	72.6%	_	EWL%
Braghetto (2012)	Chile	5	60	84.8%	57.3%	_	EWL%
Del Genio (2016)	Italy	5	36	_	56%	_	EWL%
Ruiz-Tovar (2016)	Spain	5	47	81.8%	78.7%	69.2% at 5y	EWL%
Weiner (2007)	Germany	5	8	_	40%	14% at 1y	EBMIL%
Perrone (2016)	Italy	5	161	75%	78.8±23.5	_	EBMIL%
Keren (2016)	Israel	5	123	_	49.1 %± 19.6 % 45.3 %±19.5 %*	78.12%	EBMIL% EWL%*
Alexandrou (2015)	Greece	5	25	65.2±6.1	56.4 6 5.8%	66% at 5y	EWL%
Lemanu (2015)	New Zealand	5	55	56%	40%	42.9% at 5y	EWL%
Kehagias (2013)	Greece	5	21	79.2%	57.6%	100% at 5y	EWL%
Rawlins (2013)	USA	5	49	_	86%	100% at 5 y	EWL%
Boza (2014)	Chile	5	112	88%	62.9%	40% at 5y	EWL%
Zhang (2014)	China	5	26	73.9%	63.2±24.5 %	88.9% at 5 y	EWL%
Catheline (2013)	France	5	45	54.4%	53.7%	61.5% at 5 y	EWL%
Saif (2012)	USA	5	30	58.5%	46.1%	_	EBMIL%
Abbatini (2013)	Italy	5	13	_	55.9 ±20.5	76.9% at 5 y	EWL%
Van Rutte (2014)	Netherland	5	19	68.4%	58.3%	_	EWL%

Bohdjalian (2010)	Austria	5	21	57.5±4.5%	55.0±6.8%		EWL%
Lim (2014)	USA	5	14	64.7%	57.4%	_	EWL%
Golomb (2015)	Israel	5	39	76.8%	56.1%	20% at 5 y	EWL%
D'Hondt (2011)	Belgium	6	23	81.51%	55.9±25.55%	50%	EWL%
Himpens (2010)	Belgium	6	30	_	53.3%	_	EWL%
Casella (2016)	Italy	6	148	70.4%	67.3%	83.8% at 6 y	EWL%
Aridi (2016)	Lebanon	7	14	_	76.6%± 21%	37.5% at 5 y	EWL%
Abdellatif (2014)	Egypt	7	519	53%	57%	69% at 3 y	EWL%
Hirth (2015)	USA	7	14	_	59.6 ±89.9%	33% at 7 y	EWL%
Gadiot (2017)	Netherland	8	26	_	53.9%	68% at 5 y	EBMIL%
Alvarenga ** (2016)	USA	8		86±22.3%	52±9.2%		EWL%
Sarela (2012)	UK	8	13	76%	69%	_	EWL%
Eid (2012)	USA	8	21	_	46%	37.1%	EWL%
Noel (2017)	UAE	8	116	81%	67%	43.4%	EBMIL%
Felsenreich (2016)	Austria	10	32	71±25%	53±25%	_	EWL%
Arman (2014)	Belgium	11	47	_	62.5%	_	EBMIL%
Zachariah (2013)	China	5	6	72.39±16.00	63.71 ± 20.08	66.6% at 5 y	EWL%
Prevot (2013)	France	5	95	_	46±26	_	EWL%

Adjustable gastric banding LAGB

RCT

- LAGB vs gastric bypass
- LAGB vs medical therapy

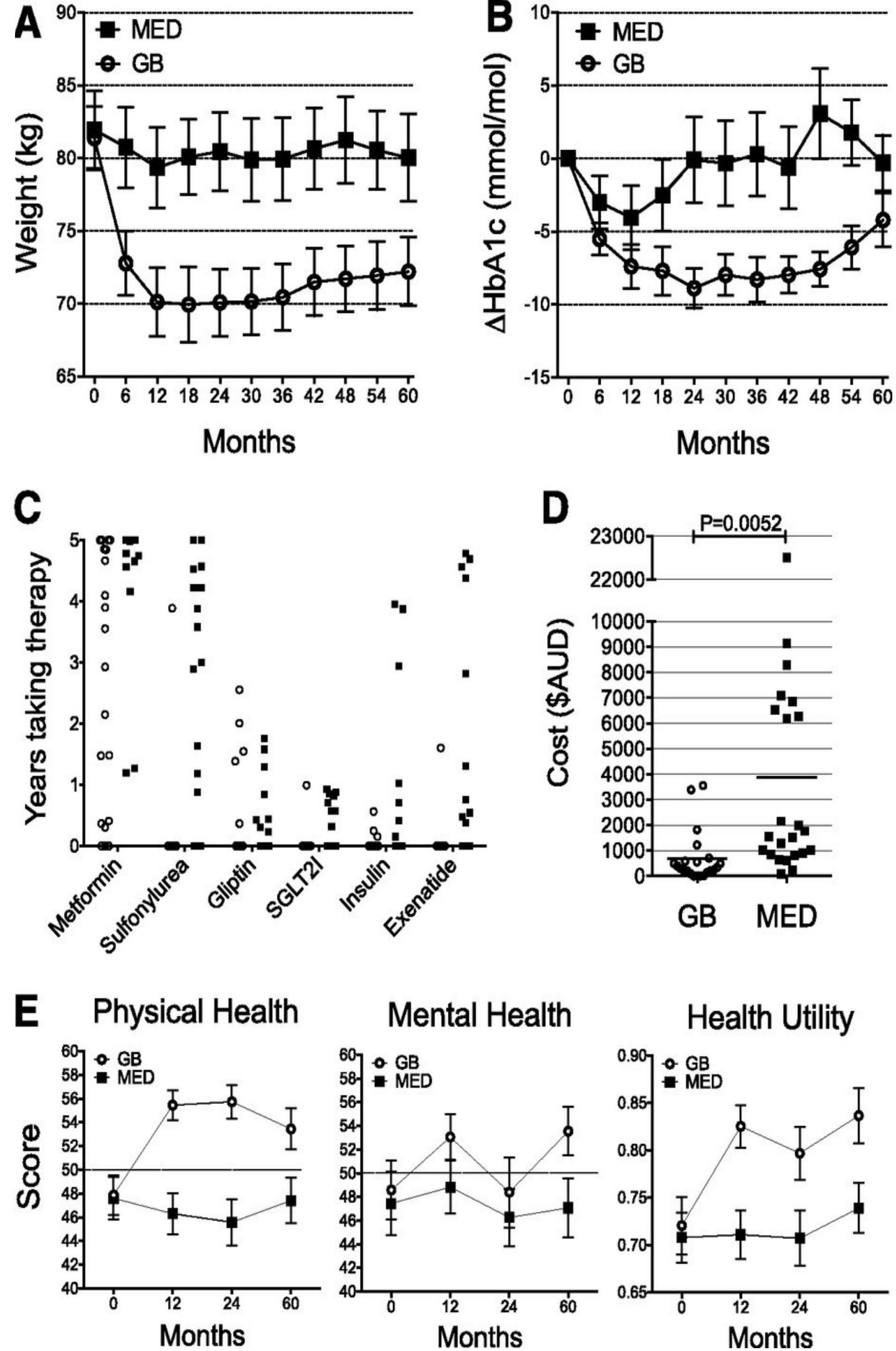
10 year follow up studies

- 17 studies

Five-Year Outcomes of a Randomized Trial of Gastric Band Surgery in Overweight but Not Obese People With Type 2 Diabetes

Diabetes Care 2017;40:e44–e45 | DOI: 10.2337/dc16-2149

John M. Wentworth,[1,2,3] Paul Burton,[1] Cheryl Laurie,[1] Wendy A. Brown,[1] and Paul E. O'Brien[1]



ELSEVIER
Surgery for Obesity and Related Diseases 9 (2013) 405–416

Original article

Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 10-year results of a prospective, randomized trial

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Abstract

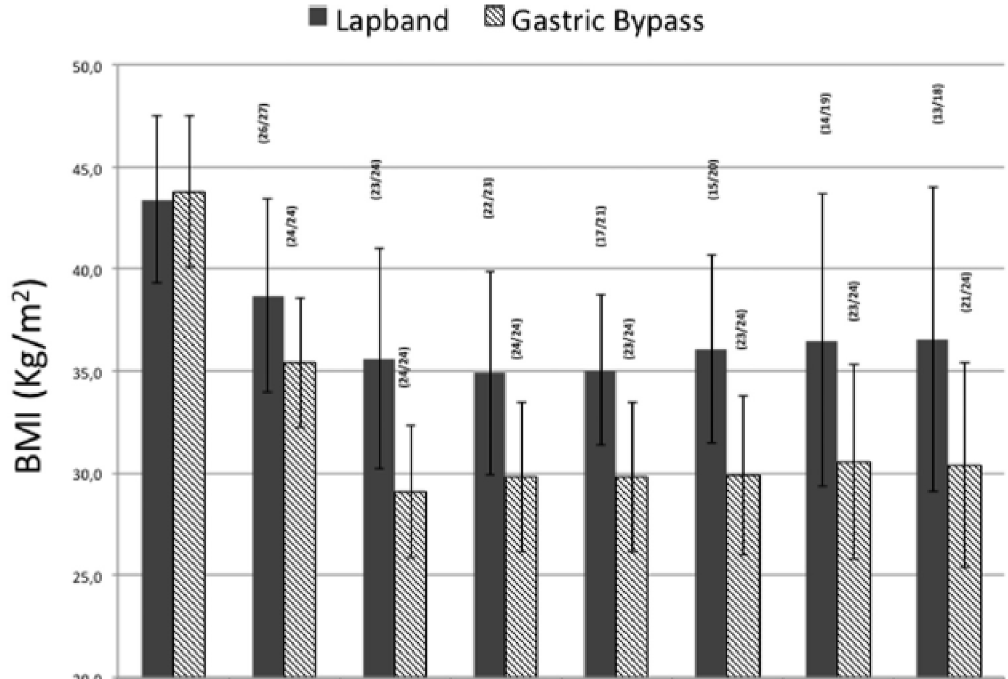
Background: There are few studies of long-term outcomes for either laparoscopic adjustable gastric banding (LAGB) or laparoscopic Roux-en-Y gastric bypass (LRYGB). The objective of this study was to compare outcomes of patients randomly assigned to undergo LAGB or LRYGB at 10 years.

Methods: LAGB, using the pars flaccida technique, and standard LRYGB were performed. From January 2000 to November 2000, 51 patients (mean age 34.0 ± 8.9 years; range 20–49) were randomly allocated to undergo either LAGB (n = 27, 5 men and 22 women; mean age 33.3 years; mean weight 120 kg; mean body mass index [BMI] 43.4 kg/m^2) or LRYGB (n = 24, 4 men and 20 women; mean age 34.7; mean weight 120 kg; mean BMI 43.8 kg/m^2). Data on complications, reoperations, weight, BMI, percentage of excess weight loss, and co-morbidities were collected yearly. The data were analyzed using Student's *t* test and Fisher's exact test, with $P < .05$ considered significant.

Results: Five patients in the LAGB group and 3 patients in the LRYGB group were lost to follow-up. No patient died. Conversion to laparotomy was performed in 1 (4.2%) of 24 LRYGB patients. Reoperations were required in 9 (40.9%) of 22 LAGB patients and in 6 (28.6%) of the 21 LRYGB patients. At 10-year follow-up, the LRYGB patients had a greater percentage of mean excess weight loss than did the LAGB patients (69 ± 29% versus 46 ± 27%; $P = .03$).

Conclusion: LRYGB was superior to LAGB in term of excess weight loss results (76.2% versus 46.2%) at 10 years. However, LRYGB exposes patients to higher early complication rates than LAGB (8.3% versus 0%) and potentially lethal long-term surgical complications (internal hernia and bowel obstruction rate: 4.7%). (Surg Obes Relat Dis 2013;9:405–416.)

Keywords: Lap-Band; Gastric bypass; Long term weight loss; Prospective; randomized study



Months	Pre-op	12	36	60	84	96	108	120
Lapband	43,4	38,7	35,6	34,9	35,0	36,1	36,5	36,5
Gastric Bypass	43,8	35,4	29,1	29,8	29,8	29,9	30,6	30,4

Fig. 1. Comparison of body mass index (BMI) between laparoscopic adjustable gastric banding (LAGB) and laparoscopic gastric bypass (LRYGB) group during 10 years of follow-up ($P = .003$ at 10 years). In brackets: n° of patients present at follow-up/n° of eligible patients.

Table 2
Late surgical complications and reoperations

Group	Complication	Presentation time	Treatment	Hospital stay
LAGB	GPD	24 mo	Band removal	2 d
	GPD	36 mo	Band removal	3 d
	GPD	64 mo	Band removal	4 d
	GPD	84 mo	Band removal	4 d
	Band erosion	72 mo	Band removal	7 d
	Untreatable reflux symptoms	115 mo	Band removal, hiatal hernia repair	5 d
LRYGB	Internal hernia	15 mo	Intestinal resection	11 d
	Gallstones	64 mo	Cholecystectomy	4 d
	Gallstones	80 mo	Cholecystectomy	4 d
	Gallstones	102 mo	Cholecystectomy	4 d
	Gallstones	120 mo	Cholecystectomy	3 d
	Incisional hernia on trocar site	115 mo	Incisional hernia repair	4 d

GPD = gastric pouch dilation; LAGB = laparoscopic adjustable gastric banding; LRYGB = laparoscopic roux-en-y gastric bypass.

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Original article

Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 10-year results of a prospective, randomized trial

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Received November 5, 2013; accepted November 30, 2013

- LRYGB was superior to LAGB in term of excess weight loss results
  - (76.2% versus 46.2%) at 10 years
- LRYGB exposes patients to higher early complication rates than LAGB
  - (8.3% versus 0%)
- LRYGB risk includes potentially lethal long-term surgical complications
  - (internal hernia and bowel obstruction in 4.7%)

Review article

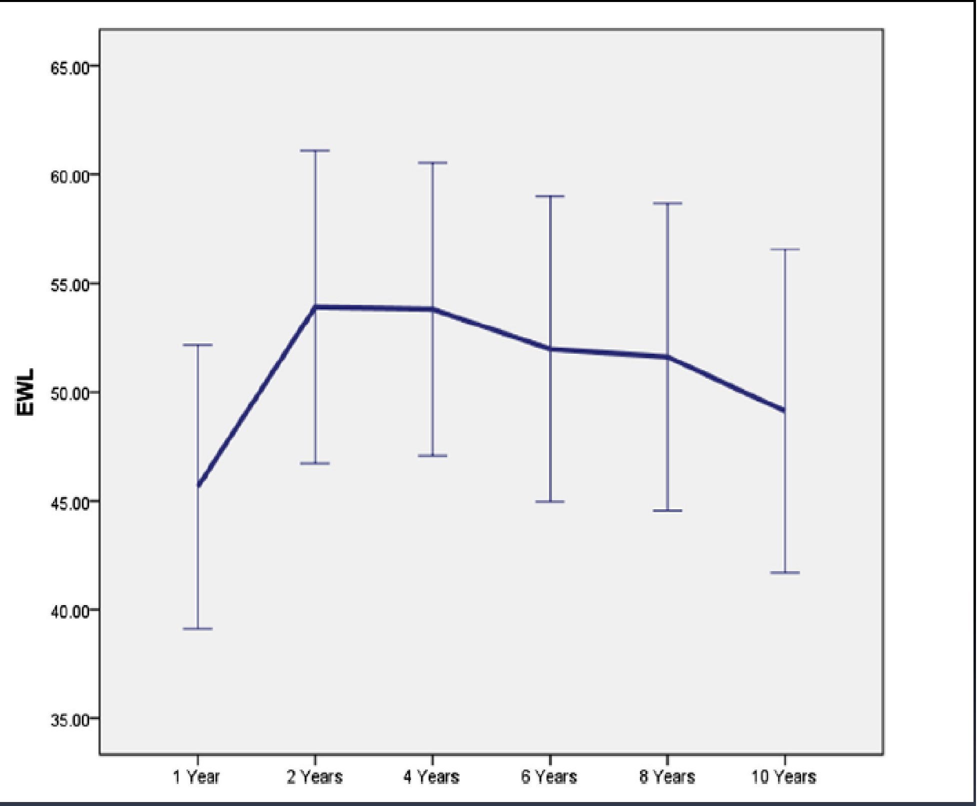
Long-term complications requiring reoperations after laparoscopic adjustable gastric banding: a systematic review

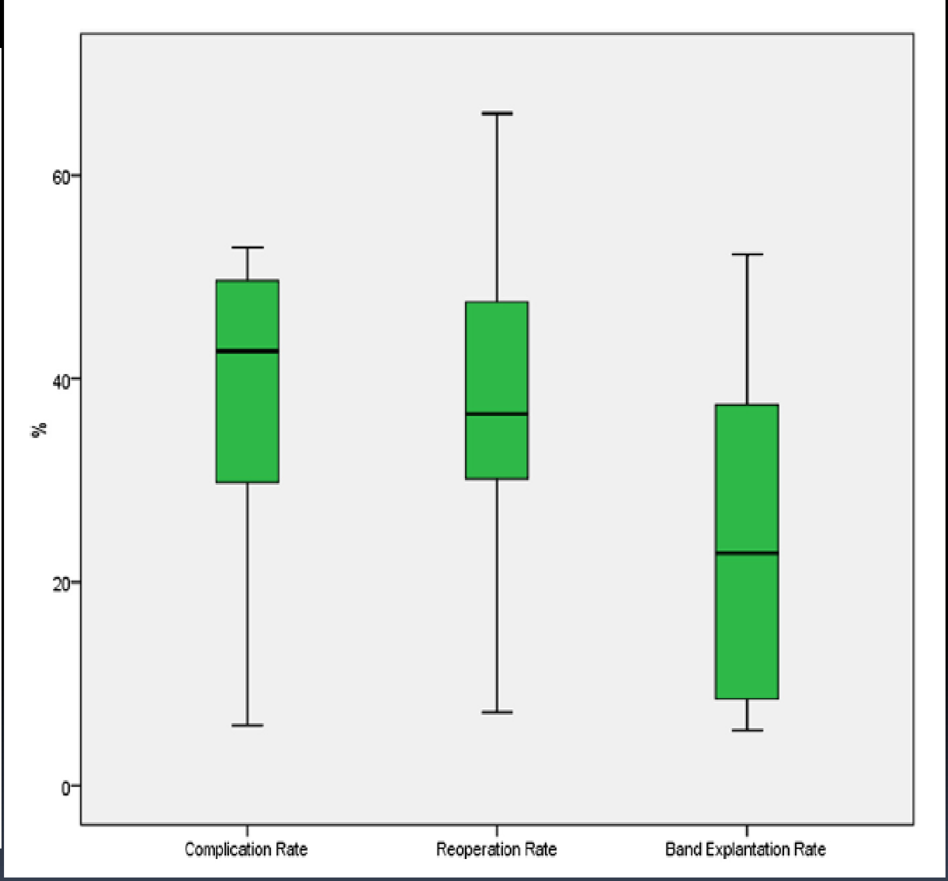
Xiaojun Shen, M.D., Ph.D., Xin Zhang, M.D., Ph.D., Jianwei Bi, M.D., Ph.D., Kai Yin, M.D., Ph.D.*

Department of General Surgery, Changhai Hospital, Second Military Medical University, Shanghai, China

Surgery for Obesity and Related Diseases 11 (2015) 956–964

LAGB. A PubMed search was conducted through October 31, 2014, for relevant studies that included minimal 10-year follow-up data for LAGB patients. The defined outcomes of interest were weight loss outcomes, long-term complications, and reoperations. Seventeen studies, including 2 randomized controlled trials and 15 observational studies, were identified involving a total of 9706 LAGB patients, of which 8215 patients (84.6%) were followed up and 1974 patients (20.3%) were available 10 years after LAGB. The follow-up data indicated that the mean percentage of excess weight loss at 10 years after LAGB was 49.1% ± 13.1% and the median long-term complication rate and reoperation rate for the LAGB patients were 42.7% (5.9%–52.9%) and 36.5% (7.2%–66.1%), respectively. At the end of long-term follow-up, approximately 22.9% (5.4%–54.0%) of the LAGB patients had their bands removed and the commonest reason was complications. In conclusion, long-term adverse events are important and remarkable for LAGB patients. The role of LAGB in bariatric surgery is worthy of further appraisal, by comparing with other types of bariatric procedures, because of the limited high-quality evidence. (Surg Obes Relat Dis 2015;11:956–964.)





Means with 95% CI

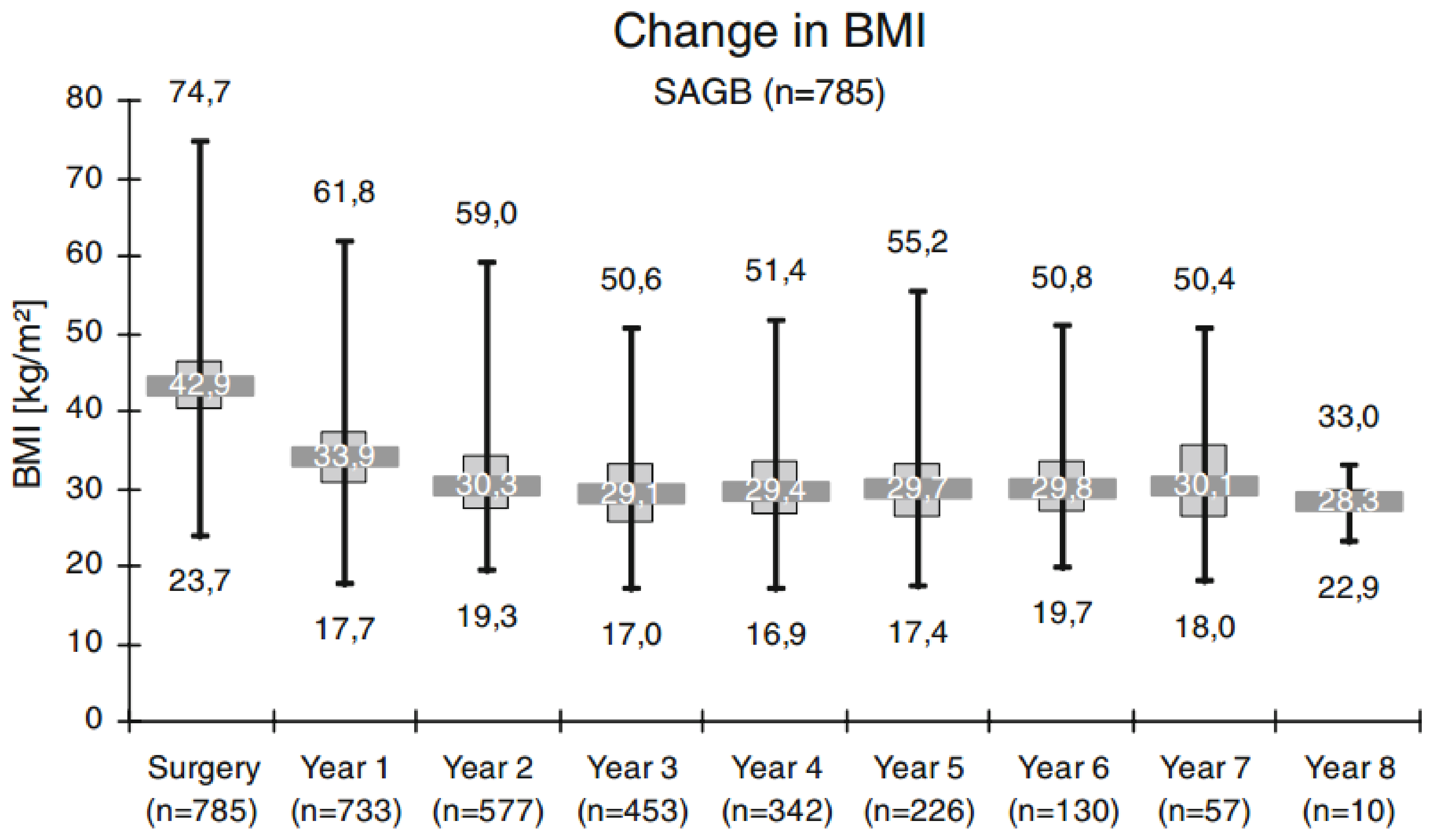
Medians
Green bars are 25th and 75th percentiles
Whisker lines are minimum to maximum range of all data

Surgery for Obesity and Related Diseases 11 (2015) 956–964

Results and Complications after Swedish Adjustable Gastric Banding—10 Years Experience

Reinhard P. Mittermair · Sabine Obermüller · Alexander Perathoner · Michael Sieb · Franz Aigner · Raimund Margreiter

Obes Surg. 2009;19:1639-41.



Complications Obes Surg. 2009;19:1639.

Table 2 Complications among 785 SAGB patients

Complication		Number, *n*	Percent of the 396 patients with complications (%)	Percent of all 785 patients (%)
1	Esophagitis	226	57.07	28.79
2	Pouch dilation	120	30.30	15.29
3	Esophageal dilation	98	24.75	12.48
4	Port problems	86	21.71	10.96
	-Port disconnection	45	11.36	5.73
	-Port infection	19	4.80	2.42
	-Port dislocation	14	3.54	1.78
	-Port pain	7	1.76	0.89
	-Skin maceration	1	0.25	0.13
5	Band migration	51	7.41	6.50
6	Band leakage	50	7.27	6.37
7	Incisional hernia	16	4.04	2.04
8	Esophageal stenosis	11	2.78	1.40
9	Wound infection	7	1.77	0.89
10	Band infection	6	1.51	0.76
11	Gastric perforation–pouch necrosis	4	1.01	0.51
12	Gastric fistula	3	0.76	0.38
13	Abdominal abscess	3	0.76	0.38
14	Gastric bleeding	2	0.51	0.25
15	Pneumonia	2	0.51	0.25
16	Mental disorder	2	0.51	0.25
17	Complicating subcutaneous tube	1	0.25	0.13
	Total	688		

Reoperations *Obes Surg*. 2009;19:1639.

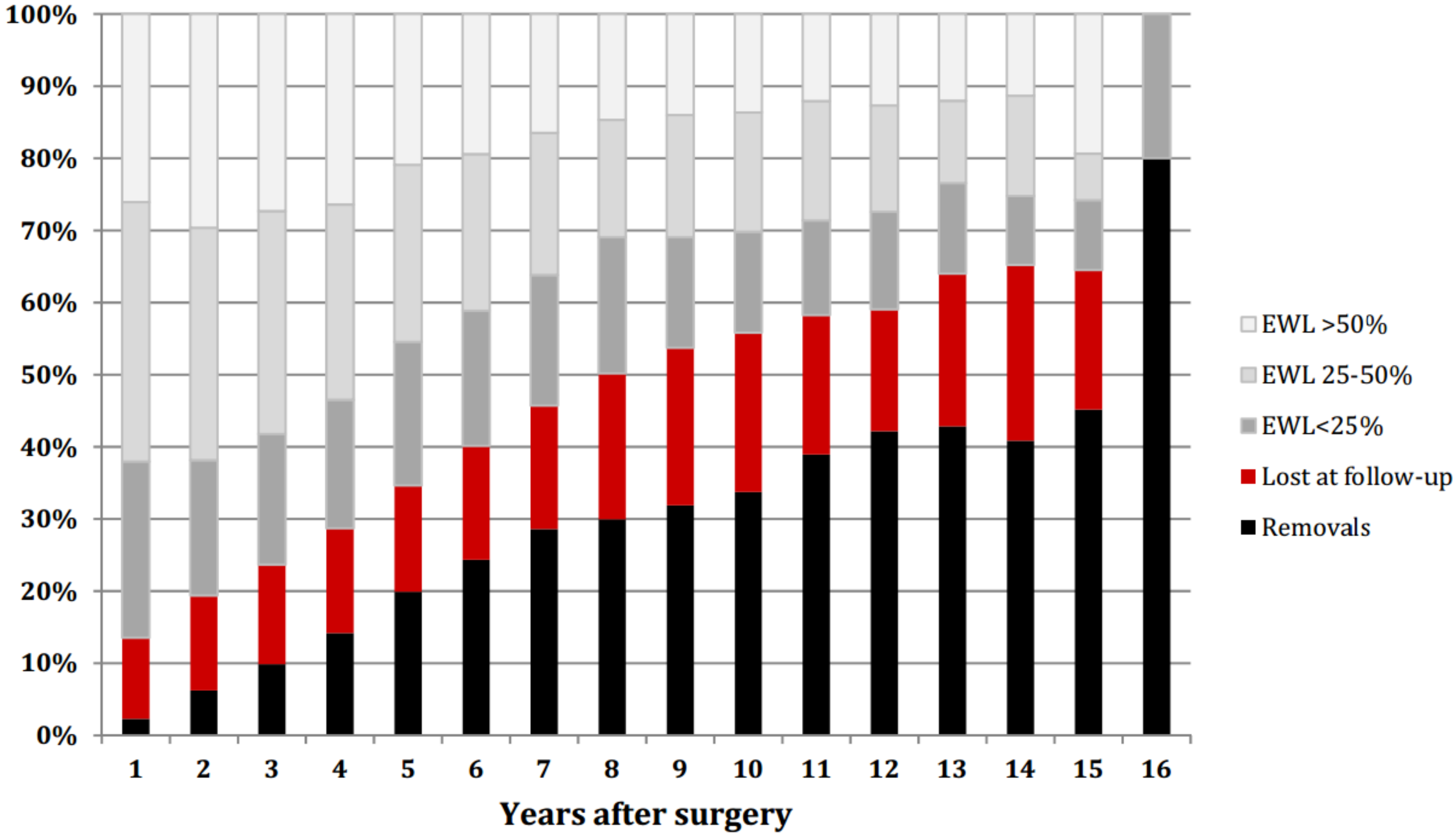
Table 3 Reoperations among 785 SAGB patients

Complication		Number	Number of reoperations, *n*	Percent of all 785 patients (%)
1	Pouch dilation	120	48	6.11
2	Esophageal dilation	98	6	0.76
3	Port problems	86	71	9.04
4	Band migration	51	44	5.61
5	Band leakage	50	46	5.86
6	Incisional hernia	16	13	1.66
7	Esophageal stenosis	11	3	0.38
8	Wound infection	7	3	0.38
9	Band infection	6	5	0.64
10	Gastric perforation–pouch necrosis	4	4	0.51
11	Gastric fistula	3	3	0.38
12	Abdominal abscess	3	2	0.25
13	Mental disorder	2	2	0.25
14	Complicating subcutaneous tube	1	1	0.13
	Total	688	251	31.97

Long-Term Outcomes of the Laparoscopic Adjustable Gastric Banding: Weight Loss and Removal Rate. A Single Center Experience on 301 Patients with a Minimum Follow-Up of 10 years

Obes Surg. 2017;27:889-95

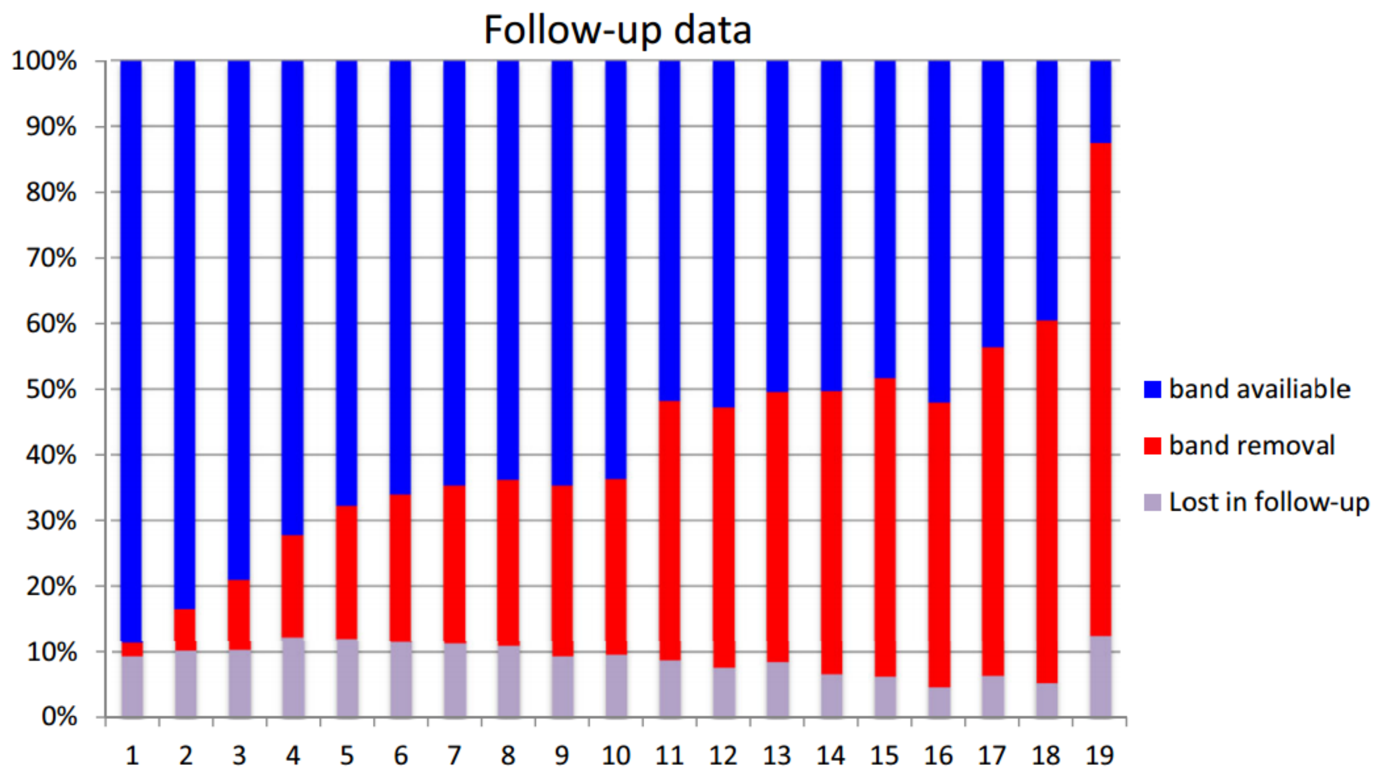
Sergio Carandina[1] · Malek Tabbara[1] · Leila Galiay[1] · Claude Polliand[1] · Daniel Azoulay[2] · Christophe Barrat[1] · Andrea Lazzati[2]



Long-Term Results After Laparoscopic Adjustable Gastric Banding for Morbid Obesity: 18-Year Follow-Up in a Single University Unit

Obes Surg. 2017;27:630-40.

K. Arapis[1] · P. Tammaro[1] · L. Ribeiro Parenti[1] · A.L. Pelletier[2] · D. Chosidow[1] · M. Kousouri[1] · C. Magnan[3] · B. Hansel[4] · J.P. Marmuse[1]



Eligible patients	897	897	897	897	897	897	897	897	813	794	723	668	552	376	257	150	78	38	8
Patients losti n follow-up	75	85	90	97	95	92	90	87	75	69	59	52	44	28	16	11	7	2	1
Available patients (number)	822	812	807	800	802	805	807	810	738	718	664	616	508	348	241	139	71	36	7
Available patients (percentage)	91.6	90.5	89.9	89.1	89.4	89.7	89.9	90.3	90.7	90.4	91.8	92.2	92.0	92.5	93.7	92.6	91	94.7	87.5

Long-Term Results After Laparoscopic Adjustable Gastric Banding for Morbid Obesity: 18-Year Follow-Up in a Single University Unit

Obes Surg. 2017;27:630-40.

K. Arapis[1] · P. Tammaro[1] · L. Ribeiro Parenti[1] · A.L. Pelletier[2] · D. Chosidow[1] · M. Kousouri[1] · C. Magnan[3] · B. Hansel[4] · J.P. Marmuse[1]

Table 3 Complications in 18 years

Complication	Perigastric technique $n = 376$	Pars flaccida technique $n = 521$	p	Total
	Follow-up (mean) 162 months	Follow-up (mean) 119 months	<0.01	
Band-related complications				
1. Gastric pouch/esophageal dilatation	81 (21.5 %)	94 (18 %)	<0.05	175 (19.5 %)
2. Slippage	51 (13.5 %)	48 (9.2 %)	<0.05	99 (11 %)
3. GERD	18 (4.7 %)	13 (2.5 %)	<0.05	31 (3.5 %)
4. Band erosion	11 (2.9 %)	13 (2.5 %)	NS	24 (3 %)
5. Band infection	4 (1 %)	4 (0.7 %)	NS	8 (1 %)
Port-related complication				
1. Tubing disconnection or breakage	68 (18 %)	49 (9.4 %)	<0.01	117 (13.6 %)
Number of patients	73	58		131
Number of complications				
2. Port rotation	28 (7.4 %)	19 (3.6 %)	<0.01	47 (5.4 %)
Number of patients	42	25		67
Number of complications				
3. Port infection	2	1		3
Total number of patients (%)	263 (69.9 %)	241 (46.2 %)	<0.01	504 (56.1 %)
Total number of complications	282	256		538

Low vs high BMI outcomes with LAGB

Long-term results of adjustable gastric banding in a cohort of 186 super-obese patients with a BMI ≥ 50 kg/m²

Journal of Visceral Surgery (2012) 149, e143—e152

K. Arapis[a,*,b], D. Chosidow[a], M. Lehmann[a], A. Bado[a,b], M. Polanco[a], S. Kamoun-Zana[a], A.L. Pelletier[a,b], M. Kousouri[a], J.-P. Marmuse[a,b]

[a] Service de chirurgie générale, CHU Bichat—Claude-Bernard, 46, rue Henri-Huchard, 75018 Paris, France

Results: Thirty-five men (18.8%) and 151 women (81.2%), with a mean age of 38.9 years (range: 16—65) underwent AGB between September 1995 and December 2007. The mean BMI was 55.06 kg/m² (range: 50—74.4). Mean follow-up was 112.5 months with a minimum of 28 months and a maximum of 172 months. The follow-up rate was maintained at 89% at ten years. The

JAMA Surgery | Original Investigation

JAMA Surgery Published online May 17, 2017

Reoperation and Medicare Expenditures After Laparoscopic Gastric Band Surgery

Andrew M. Ibrahim, MD, MSc; Jyothi R. Thumma, MPH; Justin B. Dimick, MD, MPH

Table 2. Laparoscopic Gastric Band-Associated Reoperations[a]

Lap Band Specific Reoperation	Cumulative %
Any reoperation	100.00
Band removal	41.8
Band and port replacement	28.6
Conversion to Roux-en-Y gastric bypass (laparoscopic)	13.1
Band revision	10.7
Port replacement	5.4
Conversion to sleeve gastrectomy (laparoscopic)	5.3
Port revision	5.2
Port removal	2.9
Conversion to Roux-en-Y gastric bypass (open)	0.7
Mean No. of reoperations per patient	3.78

[a] Data source: Medicare claims, 2006 to 2013.

Figure 1. Variation in Reoperation Rates Across Hospital Referral Regions in the United States

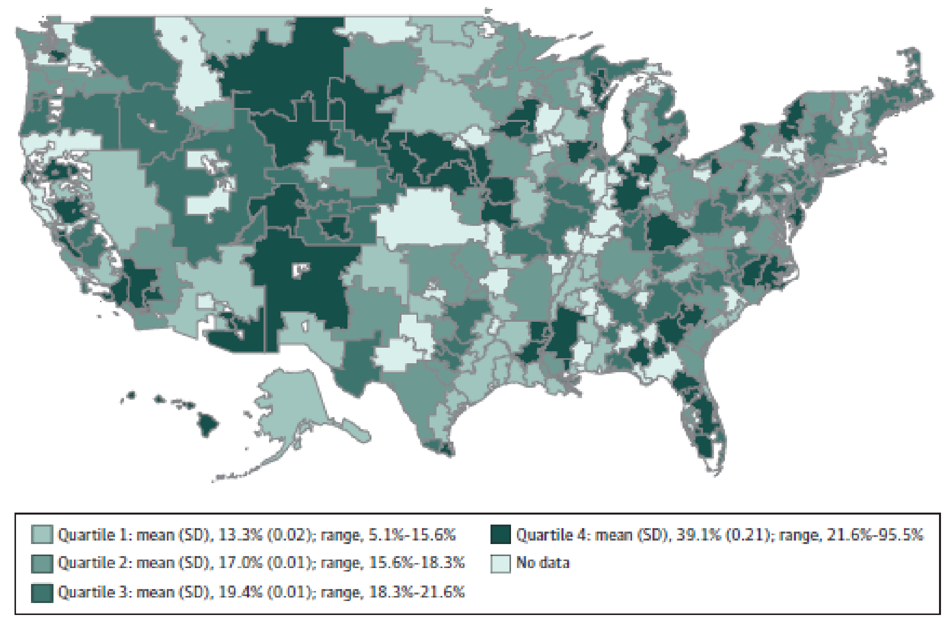
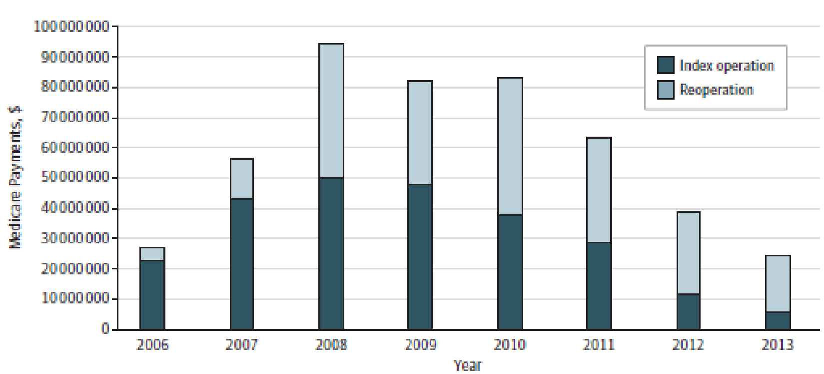


Figure 2. Annual Medicare Spending on Gastric Band Procedures



	2006	2007	2008	2009	2010	2011	2012	2013
Reoperation	4424990	13466180	44567582	34669983	45463800	35027950	27534175	18998759
Index operation	22573077	43128201	49882214	47712709	37812492	28385757	11433436	5571338
All	26998067	56594381	94449796	82382693	83276292	63413707	38967611	24570097

Conclusions

Among Medicare beneficiaries undergoing laparoscopic adjustable gastric band surgery, reoperation was common, costly, and varied widely across hospital referral regions. These findings suggest that payers should reconsider their coverage of the gastric band device.

Duodenal switch

- 14 studies ≥ 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

Author (publication year)	Country	F/u yrs	Number of eligible pts	Weight loss at 1-2 year	Weight loss (at end of f/u)	Diabetes resolution	Criteria used
Anthone (2003)	USA	5	50 (20 MO, 30 SO)	69% (76% MO, 64% SO)	66% (71% MO, 63% SO)	_	%EWL
Michaud (2016)	Canada	7.1± 4.1	105(Age<55) 105(Age>60)	_	73% 68%	91.7% 83.3%	%EWL
Skroubis (2014)	Greece	8	38	83.06±11.6	71.55±14.97%	_	% EWL
Strain (2017)	USA	9	68	70.7%	76.8%	100% at 9y	%EWL
Topart (2017)	France	10	64	_	73.4±26.7%	_	%EWL
Ballestros-Pomar (2016)	Spain	10	34	64.7%	63.7%	_	%EWL
Hess (2005)	USA	10	167	_	75%	100% at 6m	%EWL
Bolckmans (2016)	Belgium	10	113	_	93.7±24.4%	87.5% at 10y	%EWL
Aasprang (2016)	Norway	10	38	_	66.2%	_	%EBMIL
Larrad (2007)	Spain	10	29 MO 36 SO	81.6± 16.1% MO 70.2± 16.7% SO	77.8±11.2% MO 63.2±11.8% SO	98% at 2 y	%EWL
Pata (2013)	Italy	>10	328	68%	74%	67% at 1 y	%EWL
Sethi (2016)	USA	10-15	56	65.1%	67.9%	58%	%EWL
Marceau (2015)	Canada	5-20	2577	_	70.9±20	93.4%	%EWL
Marinari (2004)	Italy	14	60	67±18%	69±15%	100%	%EWL

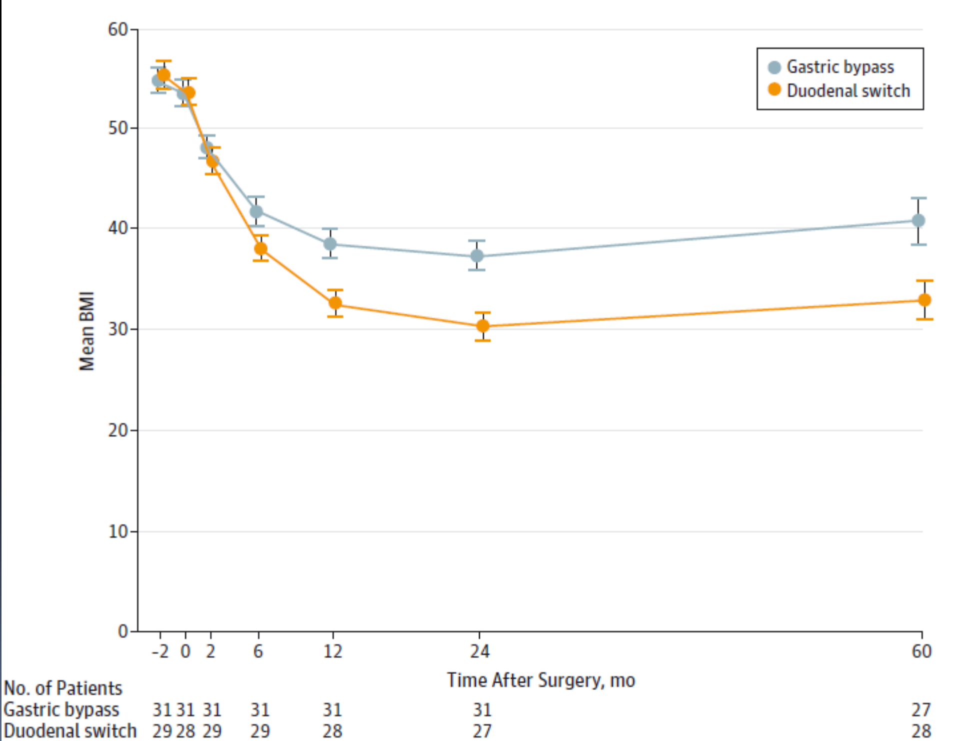
JAMA Surg. 2015;150(4):352-361. doi:10.1001/jamasurg.2014.3579

Five-Year Outcomes After Laparoscopic Gastric Bypass and Laparoscopic Duodenal Switch in Patients With Body Mass Index of 50 to 60

A Randomized Clinical Trial

Hilde Risstad, MD; Torgeir T. Søvik, MD, PhD; My Engström, RN, PhD; Erlend T. Aasheim, MD, PhD; Morten W. Fagerland, MSc, PhD; Monika Fagevik Olsén, RPT, PhD; Jon A. Kristinsson, MD, PhD; Carel W. le Roux, MD, PhD; Thomas Bøhmer, MD, PhD; Kåre I. Birkeland, MD, PhD; Tom Mala, MD, PhD; Torsten Olbers, MD, PhD

Figure 2. Observed Mean Body Mass Index (95% CI) at Each Time

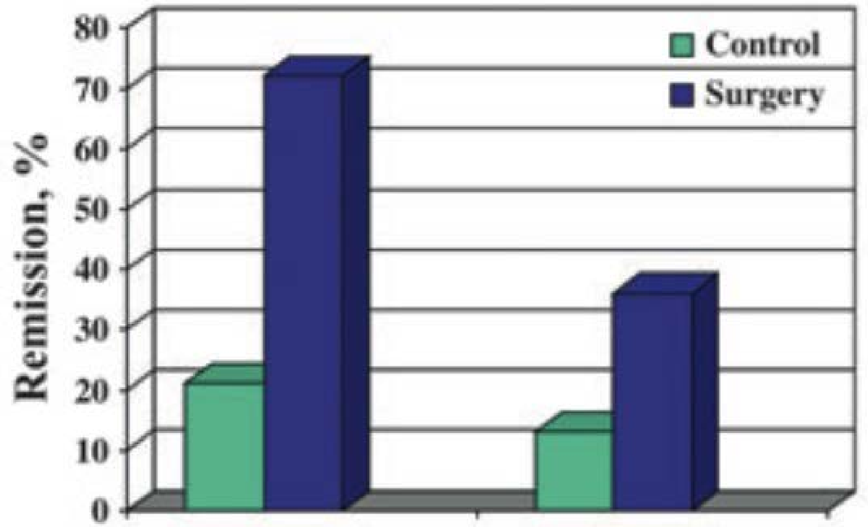


Adverse Event	Gastric Bypass (n = 31)	Duodenal Switch (n = 29)
Other		
Inguinal hernia	0	1
Umbilical hernia	1	1
Impingement syndrome shoulder	0	1
Knee pain requiring arthroscopy	1	1
Acute renal failure	1	0
Lymphodema	1	0
Chronic venous disease	1	1
Total adverse events, No.	41	65
Patients with adverse events, No. (%)[k]	21 (67.7)	23 (79.3)
Adverse events per patient, mean (SD), No.[l]	1.7 (2.4)	2.7 (2.7)
Surgeries related to the initial procedure, No.	4	14
Patients with surgeries related to the initial procedure, No. (%)[m]	3 (9.7)	13 (44.8)
Total hospital admissions, No.[n]	16	40
Patients with hospital admissions, No. (%)[o]	9 (29.0)	17 (58.6)

Type 2 Diabetes

Sjostrom L. **Review of the key results from the Swedish Obese Subjects (SOS) trial - a prospective controlled intervention study of bariatric surgery.** J Intern Med 2013;273:219–34.

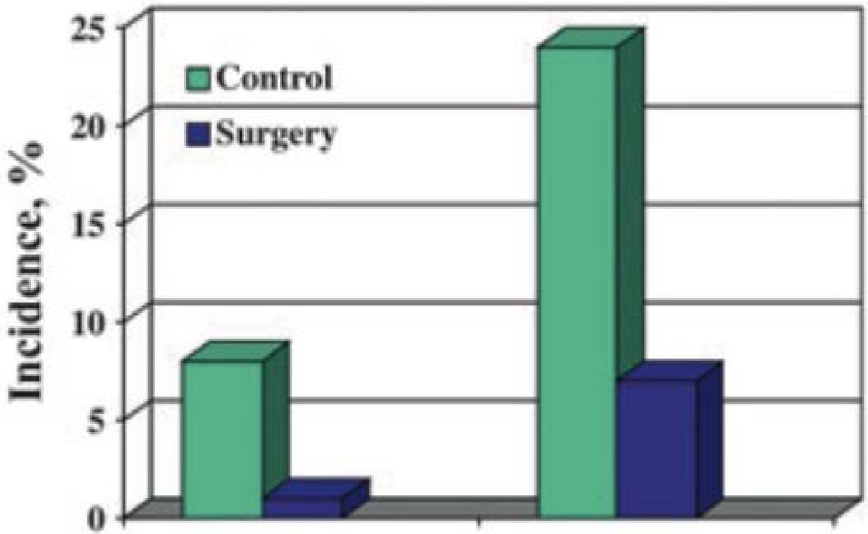
Remission DM II



	2 year	10 year
Number of subjects:		
Control	248	84
Surgery	342	118
Adjusted Odds ratio	8.42	3.45
95% CI	5.68 - 12.5	1.64 - 7.28
P value	<0.001	<0.001

Sjostrom L. **Review of the key results from the Swedish Obese Subjects (SOS) trial - a prospective controlled intervention study of bariatric surgery.** J Intern Med 2013;273:219–34.

Prevention DM II

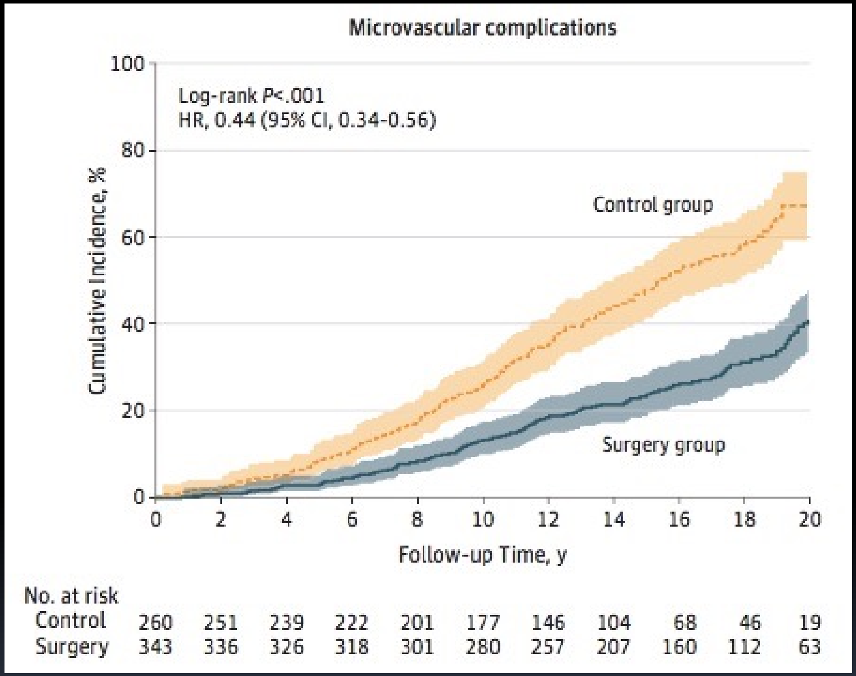


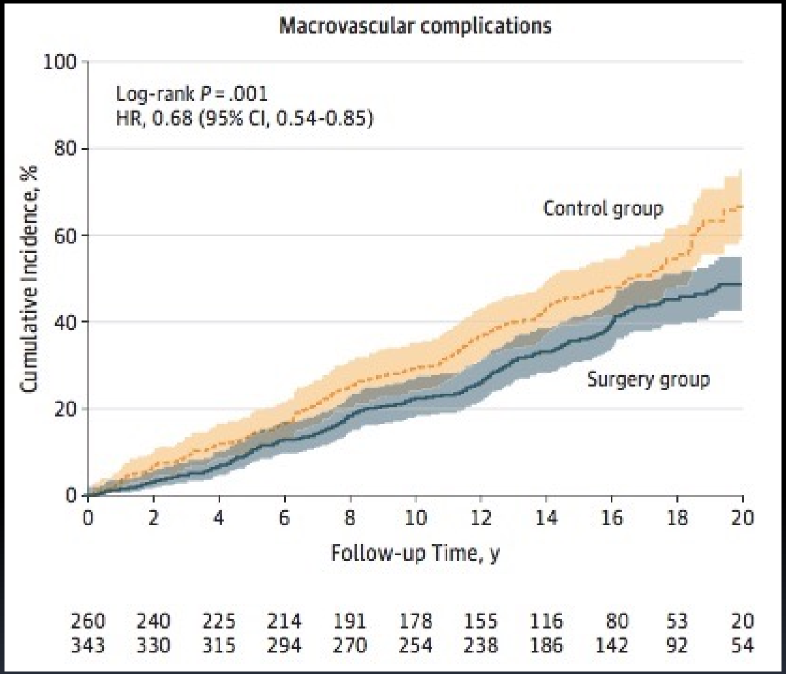
Number of subjects:	2 year	10 year
Control	1402	539
Surgery	1489	517
Adjusted Odds ratio	0.14	0.25
95% CI	0.08 - 0.24	0.17 - 0.38
P value	<0.001	<0.001

Sjöström L, Peltonen M, Jacobson P, Ahlin S, Andersson-Assarsson J, Anveden Å, Bouchard C, Carlsson B, Karason K, Lönroth H, Näslund I, Sjöström E, Taube M, Wedel H, Svensson PA, Sjöholm K, Carlsson LM.

Association of bariatric surgery with long-term remission of type 2 diabetes and with microvascular and macrovascular complications.

JAMA.2014





11 RCT's Surgical v Medical Rx of T2DM (n=794)

Study	BMI >35 <35	Design	# pts randomized n=	Follow-up (Mo)	Remission Criteria	Outcome = Remission or change in A1c
Dixon 2008	<35 22%	AGB v. control	60	24	A1c < 6.2%	73% v 13% p<0.001
Schauer 2012, 14	< 35 36%	RYGB v. SG v. control	150	36	A1c < 6.0%	38% v. 24% v. 5% p=0.01
Mingrone 2012, 15	> 35	RYGB v. BPD v. control	60	60	A1c < 6.5%	37% v. 63% v. 0 P=0.007
Ikramuddin 2013, 15	<35 59%	RYGB v. control	120	24	A1c <6%	44% v 9% p<0.001
Liang 2013	<35 100%	RYGB v. control	101	12	A1c < 6.5% *	90% v 0 v 0 p<0.0001
Halperin 2014	< 35 34%	RYGB v. control	38	12	A1c < 6.5%	58% v. 16% p=0.03
Courcoulas 2014, 15	<35 43%	RYGB v. AGB v. control	69	36	A1c < 6.5%	50% v. 27% v. 0 p<0.001
Wentworth 2014	≤ 30 100%	AGB v. control	51	24	FBS < 7.0 mmol/L	52% v. 8% p=0.001
Parikh 2014	<35 100%	BS (RYGB, AGB, SG) v. control	57	6	A1c < 6.5%	65% v. 0 p=0.0001
Ding 2015	<35 34%	AGB v. control	45	12	A1c<6.5%	33% v. 23% p=0.46
Cummings 2015	<35 25%	RYGB v. control	43	12	A1c < 6.0%	60% v. 5.9% p=0.002

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 3-Year Outcomes

Philip R. Schauer, M.D., Deepak L. Bhatt, M.D., M.P.H., John P. Kirwan, Ph.D., Kathy Wolski, M.P.H., Stacy A. Brethauer, M.D., Sankar D. Navaneethan, M.D., M.P.H., Ali Aminian, M.D., Claire E. Pothier, M.P.H., Esther S.H. Kim, M.D., M.P.H., Steven E. Nissen, M.D., and Sangeeta R. Kashyap, M.D., for the STAMPEDE Investigators*

3 Year results March 31, 2014

5 year results - Presented at ACC 2016 (under review)

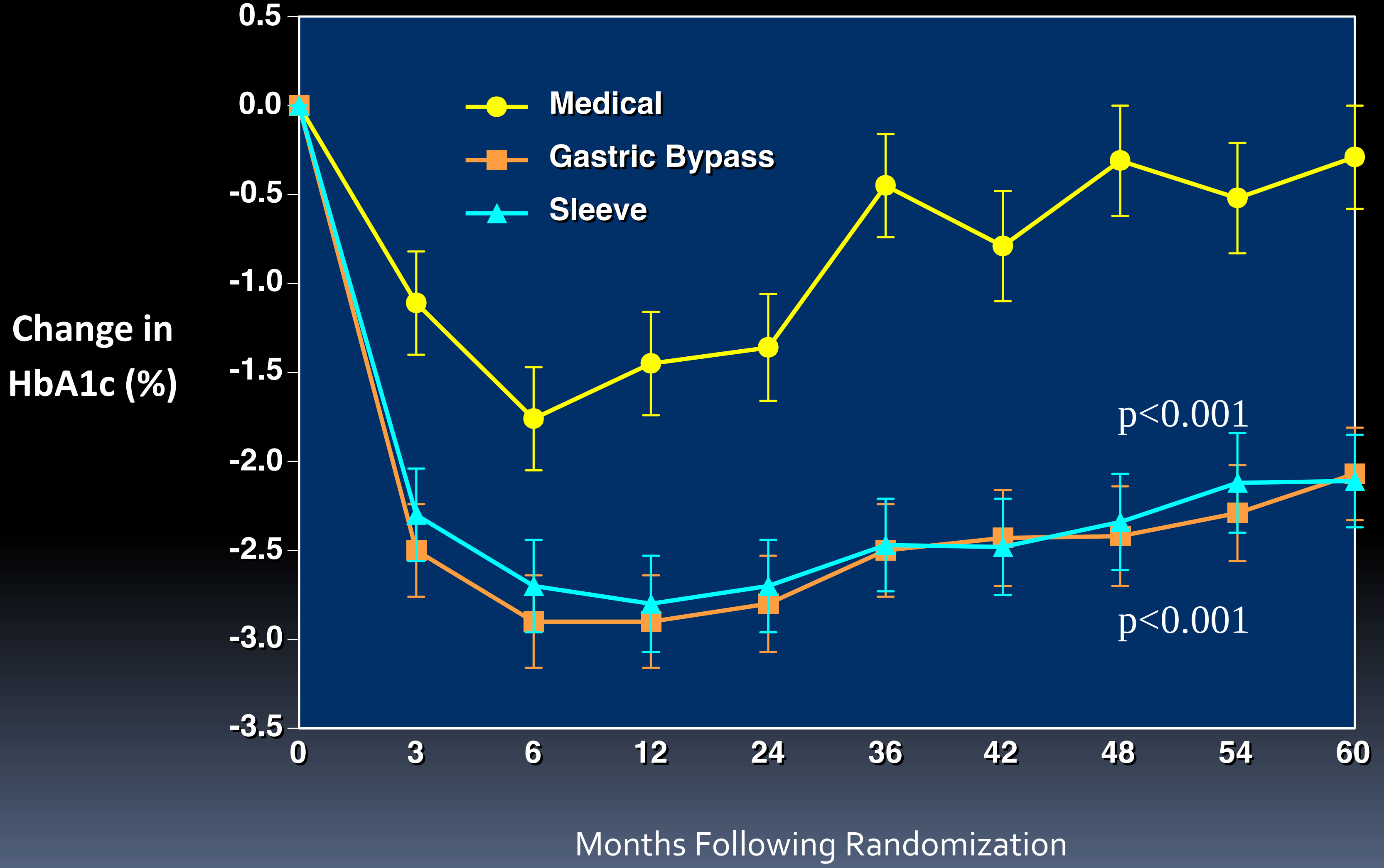
Funded by Ethicon/Lifescan/NIH/Cleveland Clinic

Primary and Secondary Endpoints at 5 Years

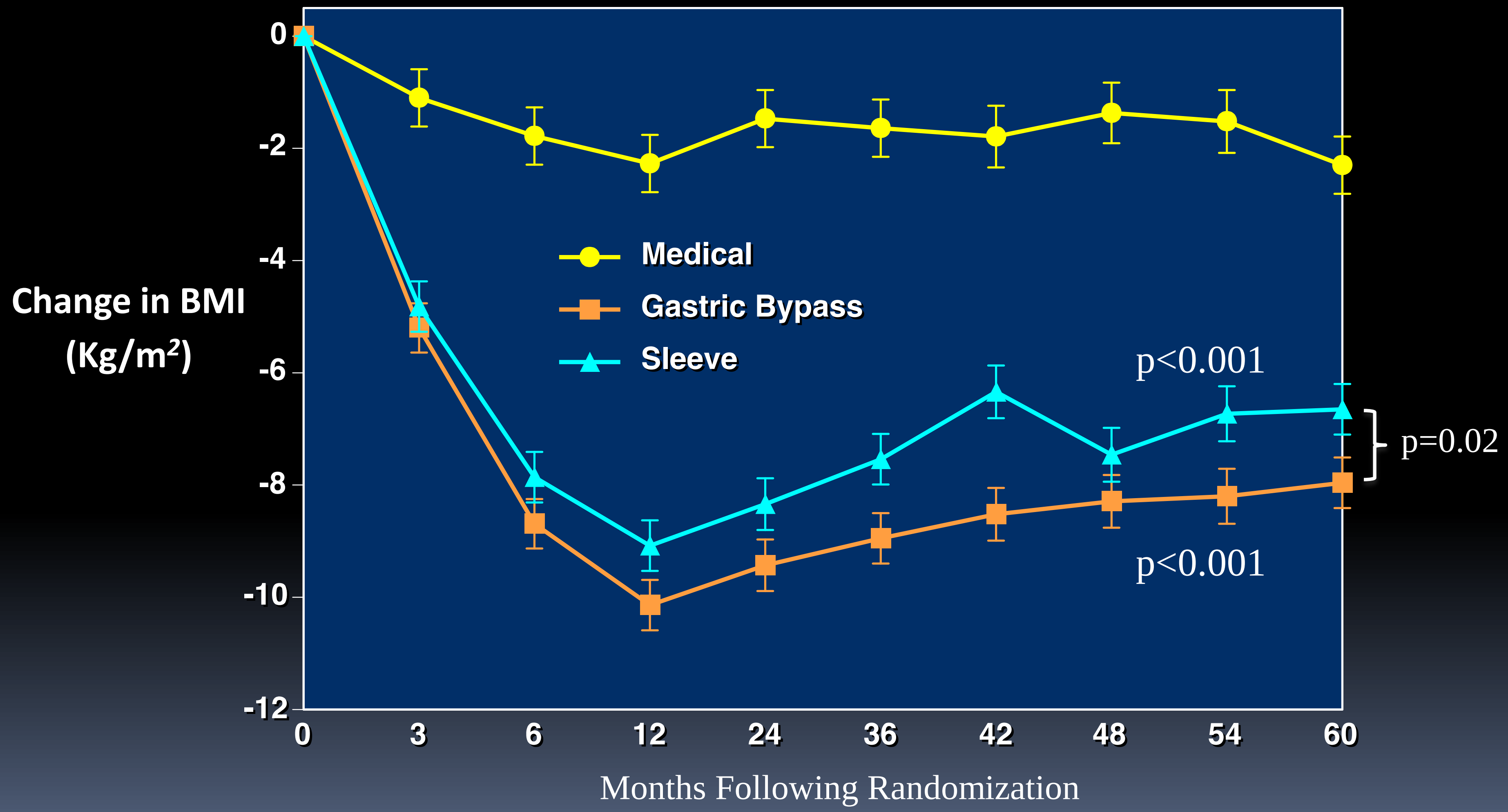
Parameter	Medical Therapy (n=38)	Bypass (n=49)	Sleeve (n=47)	P Value[1]	P Value[2]
HbA1c ≤ 6%	**5%**	**29%**	**23%**	**0.005**	**0.02**
HbA1c ≤ 6% (without DM meds)	0%	22%	15%	0.002	0.02
Median change in FPG (mg/dL)	-14	-72	-49	<0.001	0.01
Relapse of glycemic control	80%	40%	50%	0.16	0.34
Weight Loss	-5%	-22%	-19%	<0.001	<0.001
Medication use	No change	Decrease	Decrease	<0.05	<0.05
% change in HDL	+7%	+32%	+30%	0.003	0.008
Median % change in TG	-8%	-40%	-29%	0.01	0.02
Quality of Life	Decrease	Increase	Increase	<0.05	<0.05

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

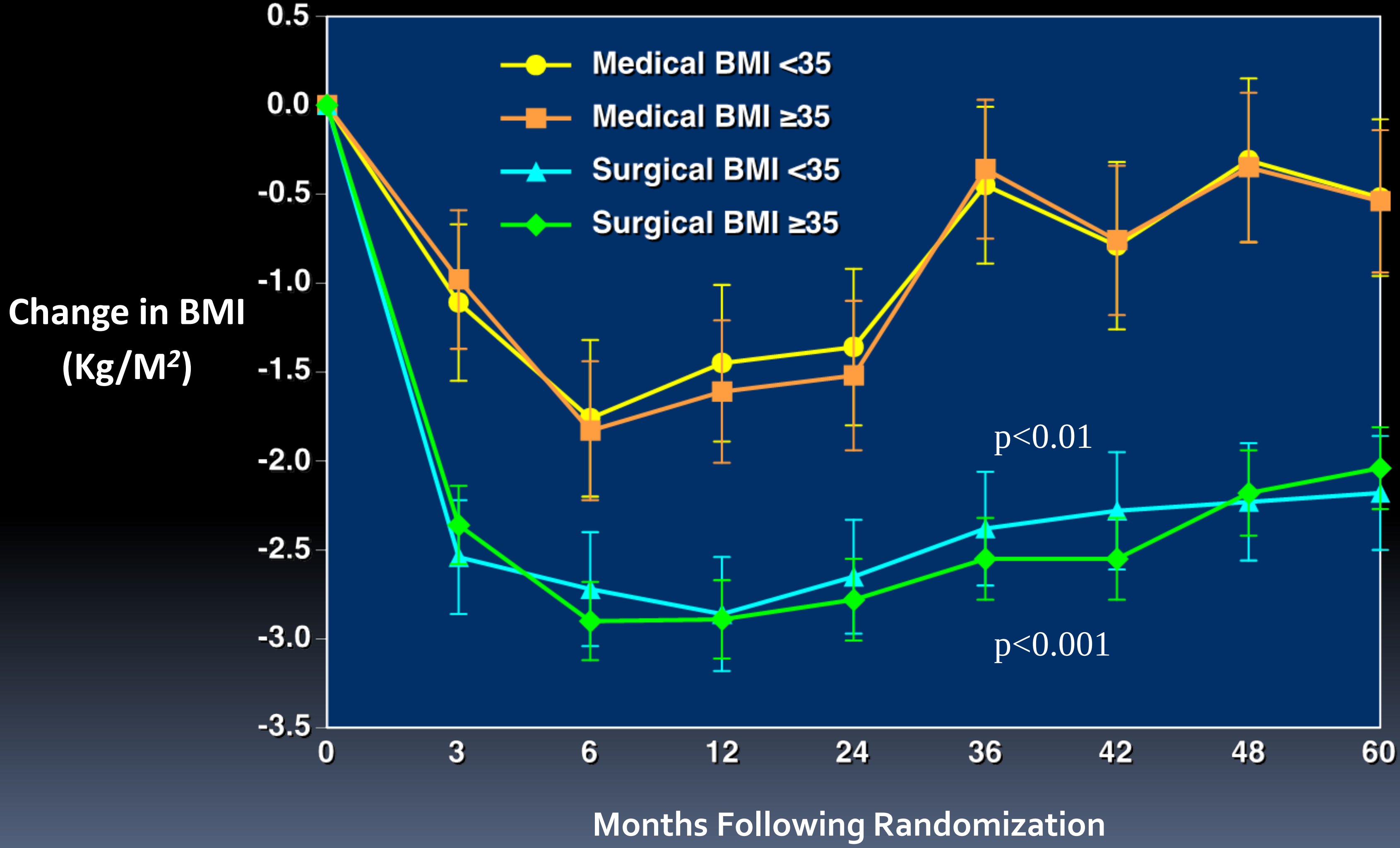
Change in HbA1c Over 5 Years



Change in Body Mass Index Over 5 years



Change in HbA1c for BMI < 35 vs. ≥ 35 Over 5 Years



Adverse Events Over 5 Years

Parameter	Medical Therapy (n=43)	Bypass (n=50)	Sleeve (n=49)
Fatal myocardial infarction	1 (2%)	0	0
Stroke	0	0	1 (2%)
Nephropathy	6 (14%)	11 (22%)	9 (18%)
Bowel obstruction	1 (2%)	1 (2%)	1 (2%)
Stricture	0	1 (2%)	1 (2%)
Gastric Fistula	0	0	1 (2%)
Ulcer	1(2)	4 (8%)	1(2%)
Severe hypoglycemia	0	2 (4)	0
Anemia (mild)	7 (16%)	14 (28%)	24 (49%)*
Weight gain >5%	8 (19%)	0 *	0 *
Re-operation	NA	3 (6%)	4(8%)

* $p<0.05$ compared to medical therapy group

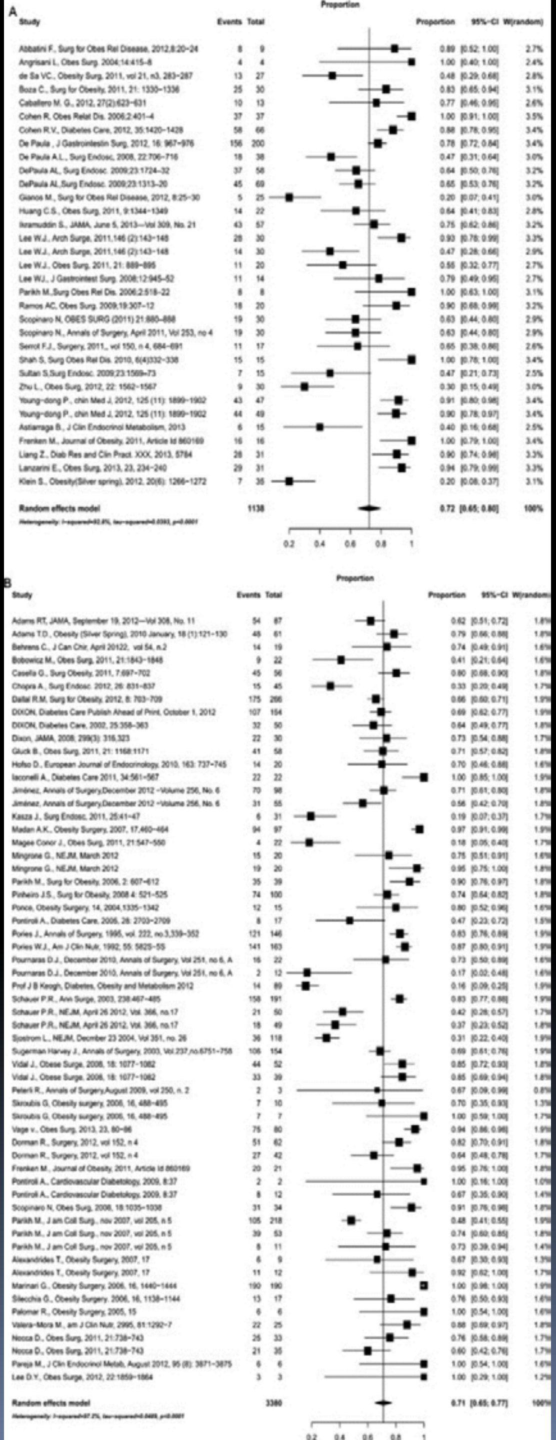
- 1300 T2DM patients with BMI<35 kg/m2
- All major complications ≤0.5% except for postoperative bleeding (1.7%)
- Smoking =modifiable risk factor for early complications
- 30 day postoperative complications for entire cohort (note RYGB not sig different vs. LSG)
  - composite morbidity 4.2%
  - serious morbidity 0.7%
  - mortality 0.15% (1 per 666 ops)
  - Reoperation within 30 days 1.6%

Surgery for Obesity and Related Diseases 12 (2016) 1163–1170

T2DM Remission Rates in Meta-Analysis of *All* Studies of *Metabolic Surgery*

94 studies

94,579 surgical patients



Studies of BMI <35

DM Remission: 72%

Studies of BMI ≥35

DM Remission: 71%

Panuzi S…..Mingrone G. *Ann Surg* 261:459 (2015)

AHRQ Systematic Review

- Comparative effectiveness of surgical *vs*. non-surgical approaches to metabolic conditions such as diabetes with baseline BMI 30–35
- >100-page detailed report
- Surgery caused greater reductions of BMI, HbA1c, hypertension, LDL, & triglycerides
- "Adverse events of surgery were relatively low."
- Surgical mortality: 0.0–0.3%
- "Most surgical complications were minor and tended not to require major intervention."

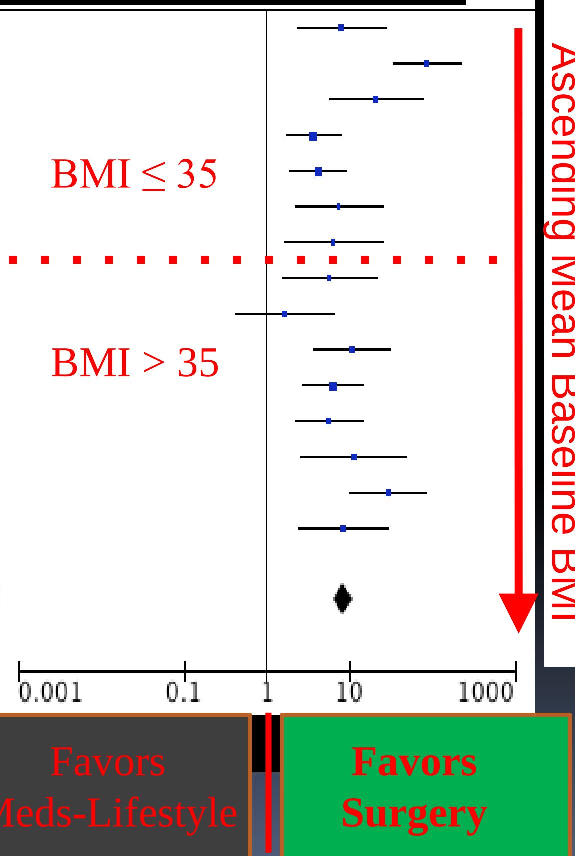
AHRQ: Maglione MA et al (online)

Odds of Diabetes Remission or Glycemic Control in All 11 RCTs of Surgery *vs.* Meds/Lifestyle Care for T2DM

Study (Operation) [Follow	Surgery Glyc. Endp.	Surgery N	Medical/ Lifestyle Glyc. Endp.	Medical/ Lifestyle N	Weight	Peto, Fixed, 95% CI
Wentworth 2014 (LAGB) [24 mo; ≤7.0%]	12	23	2	25	4.9%	8.11 [2.37, 27.84]
Liang 2013 (RYGB) [12 mo; ≤7.0% off meds]	28	31	0	70	8.4%	86.76 [33.89, 222.08]
Parikh 2014 (RYGB/LAGB/SG) [6 mo; ≤6.5% off meds]	13	20	0	24	4.5%	21.15 [5.85, 76.51]
Ikramuddin 2013 (R					5%	3.72 [1.72, 8.04]
Ikramuddin 2015 (R					3%	4.25 [1.92, 9.38]
Courcoulas 2014 (RY					1%	7.51 [2.24, 25.21]
Courcoulas 2015 (RY					0%	6.44 [1.65, 25.21]
Halperin 2014 (RYGI					3%	5.82 [1.59, 21.39]
Ding 2015 (LAGB) [1					0%	1.68 [0.42, 6.66]
Dixon 2008 (LAGB) [					7%	10.83 [3.79, 30.96]
Schauer 2012 (RYGB					3%	6.39 [2.74, 14.88]
Schauer 2014 (RYGB					7%	5.73 [2.28, 14.42]
Cummings 2015 (RY					3%	11.48 [2.63, 50.13]
Mingrone 2012 (RYGB/BPD) [24 mo; ≤6.5% off meds]	34	40	0	20	6.4%	30.08 [10.28, 88.06]
Mingrone 2015 (RYGB/BPD) [60 mo; ≤6.5% off meds]	19	38	0	15	4.9%	8.44 [2.46, 29.01]
Total (95% CI) / Fixed Effect Model		624		466	100.0%	8.45 [6.44, 11.10]
Total events	301		34			

Heterogeneity: Chi^2 = 45.43, df = 14 (P < 0.0001); I^2 = 69%

Test for overall effect: Z = 15.36 (P < 0.00001)



Level 1A Evidence:

Surgical Superiority is Similar in BMI ≤35 and >35

Rubino F…..Cummings DE
Diabetes Care (June 2016)

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

Diabetes Care 2016;39:861–877 | DOI: 10.2337/dc16-0236

*Francesco Rubino,[1] David M. Nathan,[2] Robert H. Eckel,[3] Philip R. Schauer,[4] K. George M.M. Alberti,[5] Paul Z. Zimmet,[6] Stefano Del Prato,[7] Linong Ji,[8] Shaukat M. Sadikot,[9] William H. Herman,[10] Stephanie A. Amiel,[1] Lee M. Kaplan,[2] Gaspar Taroncher-Oldenburg,[11] and David E. Cummings,[12] on behalf of the Delegates of the 2nd Diabetes Surgery Summit**

Endorsed by The American Diabetes Association

- ADA Delegates: William Cefalu MD, Robert Eckel MD, Richard Grant MD, William Herman MD, David Nathan MD, Robert Ratner MD

- **Endorsed by 45+ Diabetes, Medical, Surgical Organizations** including: ADA, IDF, Chinese Diabetes Society, Diabetes India, Diabetes UK

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Metabolic Surgery for patients with T2DM should be

- **Recommended** for BMI ≥ 40 regardless of glycemic control
- **Recommended** for BMI ≥ 35 with inadequately controlled hyperglycemia
- **Considered** for BMI 30-34.9 with inadequately controlled hyperglycemia
- **Considered** for Asians with BMI as low as 27.5 with inadequately controlled hyperglycemia

DSS-2: Surgery in the T2DM Treatment Algorithm

Patients with Type 2 Diabetes

Obese
BMI ≥ 30 kg/m²
or ≥ 27.5 for Asians

Non-Obese
BMI < 30 kg/m²
or < 27.5 for Asians

Class III
BMI ≥ 40
or ≥ 37.5

Expedited
for Metab

Metabolic surgery may be considered to treat T2DM in patients with a BMI ≥30 kg/m², or down to 27.5 for Asians

Metabolic Surgery

Metabolic Surgery

Treatment

Rubino F…..Cummings DE
Diabetes Care (June 2016)

CONCLUSION

- The evidence for Metabolic Surgery as a relatively safe and effective treatment for T2DM is very good and supported by multiple RCT's.
- Widely Endorsed International Guidelines for T2DM NOW include evidence based recommendations for surgery to treat T2DM and it co-morbidities.

Technology Evaluation Center

Bariatric Surgery in Patients with Diabetes and Body Mass Index Less than 35 kg/m²

Tec

Therefore, gastric bypass for the treatment of type 2 diabetes in patients with a body mass index less than 35 kg/m² meets the TEC criteria.

Executive Summary

CTAF

CALIFORNIA TECHNOLOGY ASSESSMENT FORUM℠

Surgical procedures and devices

1. For adult patients with a BMI of 30.0-34.9 and Type 2 diabetes, is the evidence adequate to demonstrate that the net health benefit of bariatric surgery is greater than that of conventional weight-loss management?

   CTAF Panel Vote: 11 Yes (100%) 0 No (0%)

Cardiovascular disease

Obesity and Cardiovascular Disease

Surgical weight loss impacts cardiovascular disease by inducing improvement of known cardiac risk factors, including

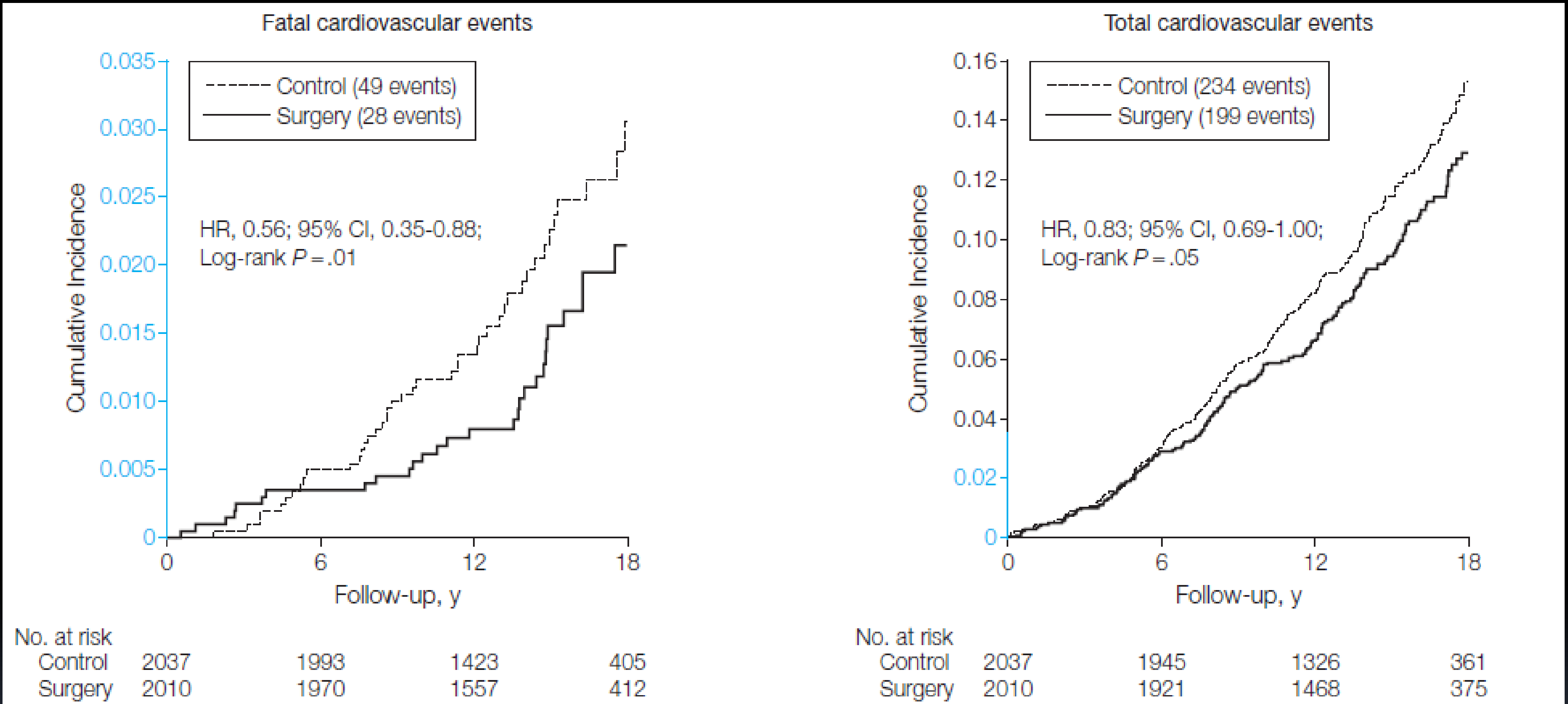
- hypertension
- hypercholesterolemia
- hypertriglyceridemia
- diabetes

Kwok, C.S., Pradhan, A., Khan, M.A. et al. Bariatric surgery and its impact on cardiovascular disease and mortality: a systematic review and meta-analysis. Int J Cardiol. 2014; 173: 20–28

- 14 studies included 29,208 patients who underwent bariatric surgery and 166,200 nonsurgical controls
  - mean age 48 years, 30% male, follow up period from 2 years to 14.7 years
- Compared to nonsurgical controls >50% reduction in mortality in patients who had bariatric surgery
  - OR 0.48 95% CI 0.35–0.64, I^2 = 86%, 14 studies
- In pooled analysis of four studies with adjusted data, bariatric surgery was associated with a significantly reduced risk of composite CV adverse events
  OR 0.54 95% CI 0.41–0.70, I^2 = 58%
- Bariatric surgery was also associated with significant reduction in specific endpoints of
  - myocardial infarction (OR 0.46 95% CI 0.30–0.69, I^2 = 79%, 4 studies)
  - stroke (OR 0.49 95% CI 0.32–0.75, I^2 = 59%, 4 studies).

Data from observational studies indicates that patients undergoing bariatric surgery have a reduced risk of myocardial infarction, stroke, cardiovascular events and mortality compared to non-surgical controls.

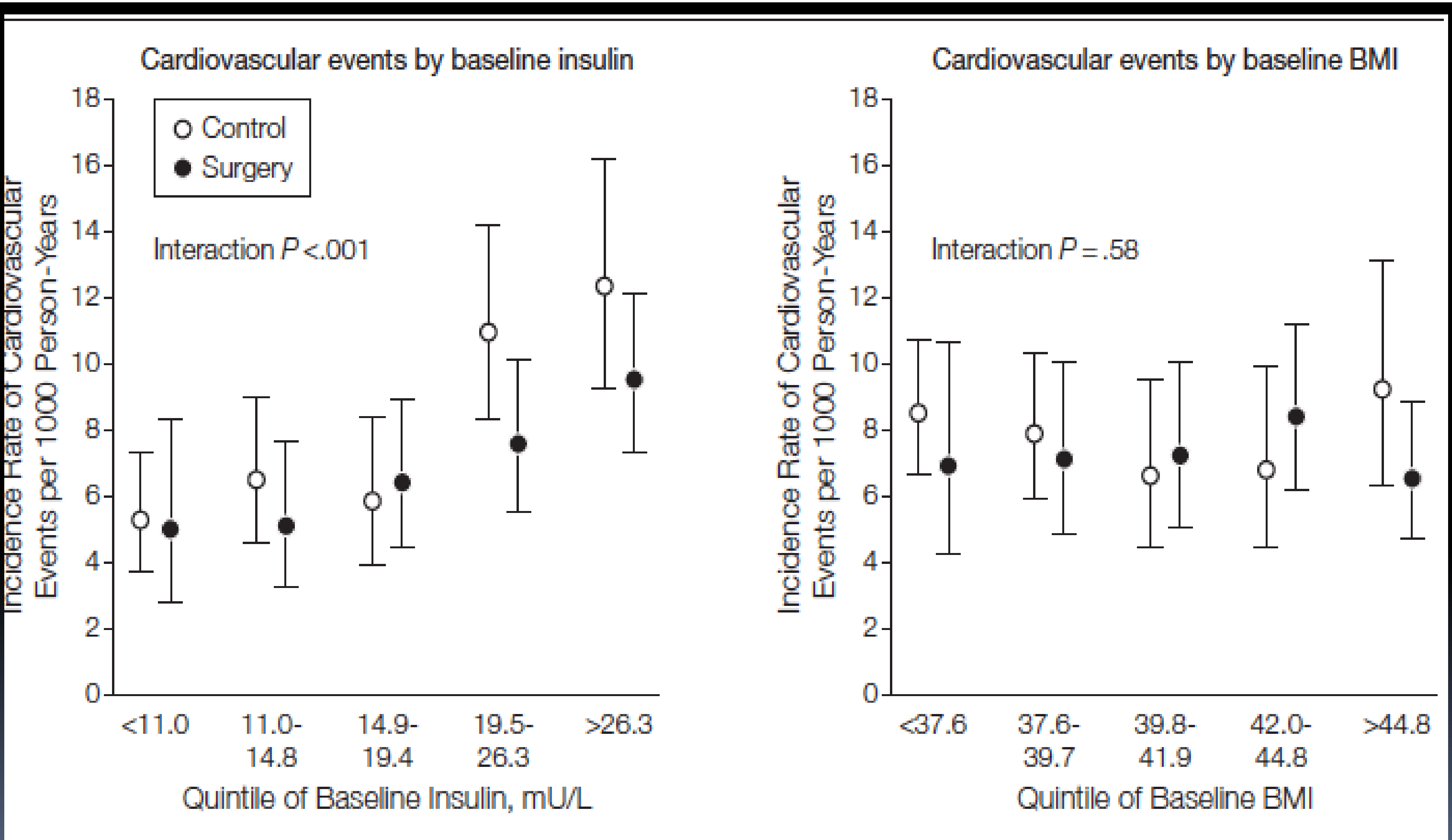
Bariatric Surgery and Long-term Cardiovascular Events



The combined end point of myocardial infarction and stroke, whichever came first, with fatal cardiovascular events and total (fatal and nonfatal) cardiovascular events are shown. The incidence data are based on observations until December 31, 2009. Follow-up time is truncated at 18 years, because number of persons at risk beyond this point was low. All persons are included in the calculation of hazard ratios (HRs). The incidence rates per 1000 person-years for fatal cardiovascular events were 0.9 (95% CI, 0.6-1.3) in the surgery group and 1.7 (95% CI, 1.3-2.2) in the control group; and for total cardiovascular events, 6.9 (95% CI, 6.0-8.0) and 8.3 (95% CI, 7.3-9.4), respectively. Y-axis regions shown in blue indicate range from 0 to 0.035.

JAMA, January 4, 2012—Vol 307, No. 1 Sjostrom, L et al

Bariatric Surgery and Long-term Cardiovascular Events



JAMA, January 4, 2012—Vol 307, No. 1

Table 1. Multivariable Cox Proportional Hazards Regression Models for Fatal and Total Cardiovascular End Points in the Swedish Obese Subjects Study[a]

	Cardiovascular Events[b]		MI		Stroke	
	Hazard Ratio (95% CI)	*P* Value	Hazard Ratio (95% CI)	*P* Value	Hazard Ratio (95% CI)	*P* Value
Fatal Cardiovascular End Points						
Surgery, yes vs no	0.47 (0.29-0.76)	.002	0.52 (0.31-0.89)	.02	0.34 (0.12-1.00)	.05
Male sex, yes vs no	3.23 (1.93-5.41)	<.001	3.28 (1.80-5.98)	<.001	3.12 (1.10-8.81)	.03
Age, per 6.1 y	1.48 (1.14-1.91)	.003	1.56 (1.18-2.08)	.002	1.24 (0.68-2.26)	.49
MI or stroke before baseline, yes vs no	3.11 (1.52-6.35)	.002	3.24 (1.47-7.13)	.003	2.09 (0.32-13.8)	.44
Diabetes at baseline, yes vs no[c]	1.44 (1.21-1.73)	<.001	1.38 (1.13-1.68)	.002	1.68 (1.16-2.42)	.006
Smoking at baseline, yes vs no	1.47 (1.19-1.81)	<.001	1.40 (1.11-1.78)	.005	1.76 (1.17-2.65)	.007
Systolic BP, per 18.7 mm Hg	1.18 (0.92-1.51)	.19	1.11 (0.84-1.47)	.47	1.44 (0.88-2.36)	.14
Total cholesterol, per 42.4 mg/dL	1.32 (1.05-1.66)	.02	1.47 (1.15-1.88)	.002	0.90 (0.56-1.45)	.66
HDL cholesterol, per 12.3 mg/dL	1.07 (0.83-1.38)	.60	0.88 (0.64-1.20)	.41	1.81 (1.20-2.72)	.005
Total Cardiovascular End Points						
Surgery, yes vs no	0.67 (0.54-0.83)	<.001	0.71 (0.54-0.94)	.02	0.66 (0.49-0.90)	.008
Male sex, yes vs no	1.78 (1.38-2.29)	<.001	1.91 (1.36-2.67)	<.001	1.49 (1.05-2.12)	.03
Age, per 6.1 y	1.45 (1.30-1.61)	<.001	1.46 (1.27-1.68)	<.001	1.43 (1.21-1.68)	<.001
MI or stroke before baseline, yes vs no	2.83 (1.93-4.16)	<.001	3.64 (2.35-5.63)	<.001	1.51 (0.76-3.03)	.24
Diabetes at baseline, yes vs no[b]	1.71 (1.35-2.18)	<.001	1.73 (1.27-2.36)	.001	1.68 (1.20-2.37)	.003
Insulin, per 12.7 mU/L	1.12 (1.05-1.20)	.001	1.12 (1.04-1.21)	.005	1.04 (0.93-1.17)	.48
Smoking at baseline, yes vs no	1.92 (1.55-2.38)	<.001	2.05 (1.57-2.69)	<.001	1.81 (1.31-2.50)	<.001
BMI, per 4.7 units	1.06 (0.87-1.28)	.57	1.05 (0.81-1.36)	.71	1.02 (0.78-1.33)	.90
Waist circumference, per 11.5 cm	1.11 (0.92-1.35)	.28	1.12 (0.87-1.43)	.39	1.25 (0.95-1.66)	.11
Hip circumference, per 10.2 cm	0.82 (0.69-0.98)	.03	0.84 (0.67-1.04)	.11	0.81 (0.63-1.03)	.09
Systolic BP, per 18.7 mm Hg	1.36 (1.23-1.50)	<.001	1.31 (1.15-1.50)	<.001	1.46 (1.27-1.68)	<.001
Total cholesterol, per 42.4 mg/dL	1.30 (1.17-1.43)	<.001	1.49 (1.32-1.69)	<.001	1.03 (0.89-1.18)	.69
HDL cholesterol, per 12.3 mg/dL	0.94 (0.84-1.06)	.31	0.85 (0.73-0.98)	.03	1.03 (0.87-1.21)	.76
Triglycerides, per 131.2 mg/dL	0.97 (0.88-1.06)	.47	0.95 (0.84-1.06)	.34	0.96 (0.84-1.11)	.60
Lipid-lowering medication, yes vs no	1.52 (0.92-2.53)	.10	2.11 (1.22-3.64)	.008	0.68 (0.22-2.04)	.49
Antihypertensive medication, yes vs no	1.18 (0.95-1.46)	.13	1.03 (0.77-1.36)	.86	1.41 (1.05-1.89)	.02

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; HDL, high-density lipoprotein; MI, myocardial infarction.
SI conversions: To convert total and HDL cholesterol to mmol/L, multiply by 0.0259; triglycerides to mmol/L, multiply by 0.0113; and insulin to pmol/L, multiply by 6.945.
[a] Hazard ratios for continuous variables are expressed per 1-SD difference at baseline in the study population with men and women combined. For fatal cardiovascular end points, the number of events for surgery and control groups were 28 and 49, respectively, for cardiovascular events; 22 and 37, respectively, for MI; and 6 and 12, respectively, for stroke. For total cardiovascular end points, the number of events for surgery and control groups were 199 and 234, respectively, for cardiovascular events; 122 and 136, respectively, for MI; and 93 and 111, respectively, for stroke.
[b] Cardiovascular events included MI and stroke combined, whichever came first.
[c] Self-reported diabetes medication and/or fasting blood glucose of at least 109.9 mg/dL (corresponding to fasting plasma glucose of ≥126.1 mg/dL).

JAMA, January 4, 2012—Vol 307, No. 1

Table 2. Distribution of Deaths and Death Rates per 10,000 Person-Years, According to Study Group.*

End Point	All Subjects				Matched Subjects			
	Surgery Group (N=9949)		Control Group (N=9628)		Surgery Group (N=7925)		Control Group (N=7925)	
	no.	*no./10,000 person-yr*	*no.*	*no./10,000 person-yr*	*no.*	*no./10,000 person-yr*	*no.*	*no./10,000 person-yr*
All causes of death	288	37.2	425	61.1	213	37.6	321	57.1
All deaths caused by disease	198	25.6	380	54.7	150	26.5	285	50.7
Cardiovascular disease	66	8.5	134	19.3	55	9.7	104	18.5
Coronary artery disease	17	2.2	46	6.6	15	2.6	33	5.9
Heart failure	2	0.3	7	1.0	2	0.4	6	1.1
Stroke	9	1.2	14	2.0	7	1.2	11	2.0
Other cardiovascular disease	38	4.9	67	9.6	31	5.5	54	9.6
Diabetes	2	0.3	24	3.5	2	0.4	19	3.4
Cancer	42	5.4	102	15.0	31	5.5	73	13.3
Other diseases	88	11.4	120	17.0	62	11.0	89	15.5
All nondisease causes	90	11.6	45	6.5	63	11.1	36	6.4
Accident unrelated to drugs	29	3.7	19	2.7	21	3.7	17	3.0
Poisoning of undetermined intent	15	1.9	4	0.6	9	1.6	4	0.7
Suicide	21	2.7	8	1.2	15	2.6	5	0.9
Other nondisease cause	25	3.2	14	2.0	18	3.2	10	1.8

* Deaths that were caused by disease include all deaths minus those caused by accidents unrelated to drugs, poisonings of undetermined intent, suicides, and other nondisease deaths.

Adams, et al. N Engl J Med 2007;357:753-61

Heart Failure–Associated Hospitalizations in the United States

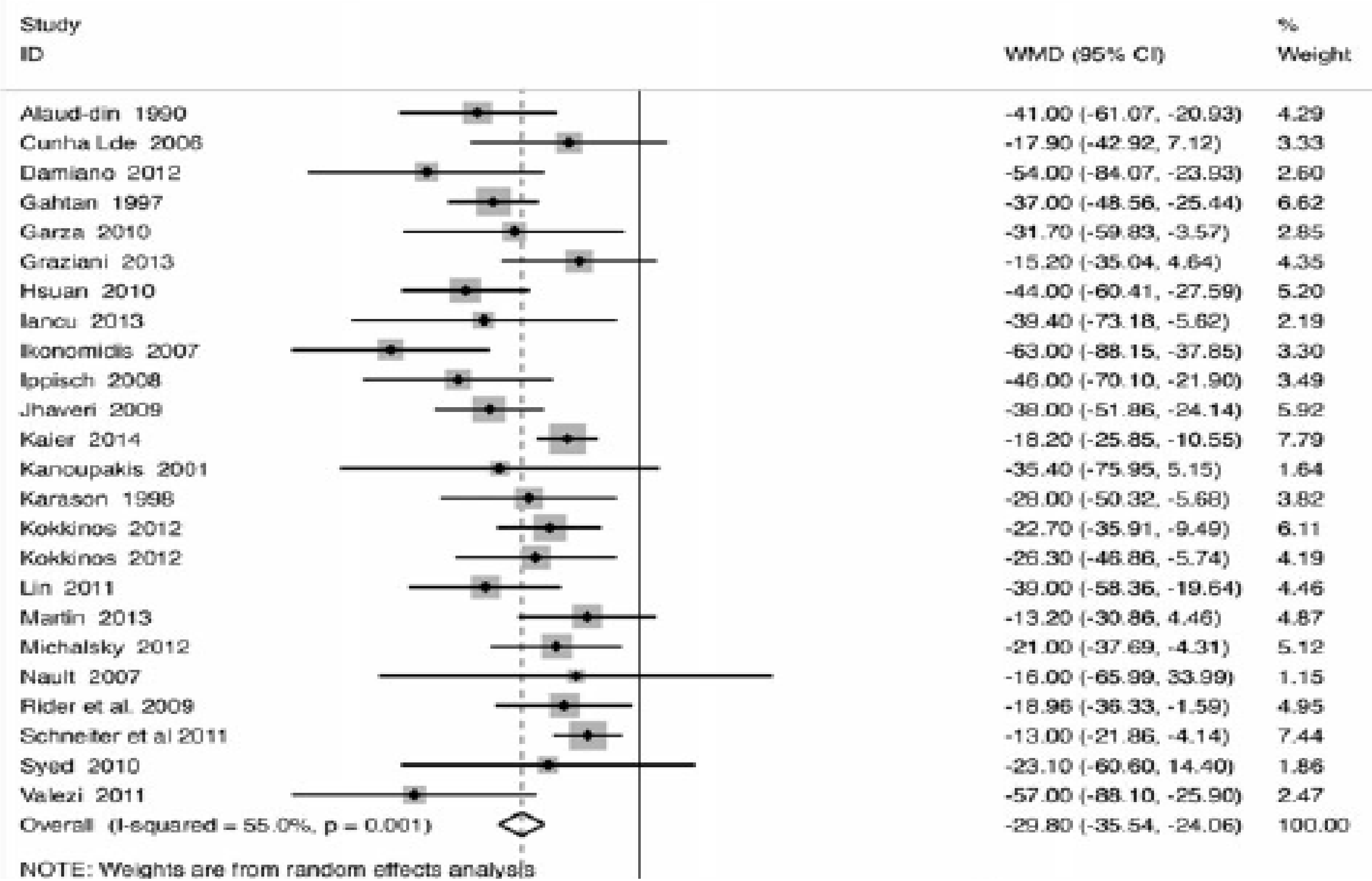
Table 1 Characteristics of Hospitalizations With a Primary or Secondary Diagnosis of Heart Failure

Characteristics	2001	2002	2003	2004	2005	2006	2007	2008	2009
Heart failure hospitalizations	3,891,737	3,979,482	4,146,308	4,230,905	4,302,805	4,388,414	4,209,367	4,169,995	4,244,865

Over 4 million hospitalizations for heart failure with a 20-50% readmission rate

JACC Vol. 61, No. 12, 2013

(a) Left Ventricular Mass(g) change following Bariatric Surgery



Weight Loss and Heart Failure

A Nationwide Study of Gastric Bypass Surgery Versus Intensive Lifestyle Treatment

Johan Sundström, MD, PhD
Gustaf Bruze, PhD

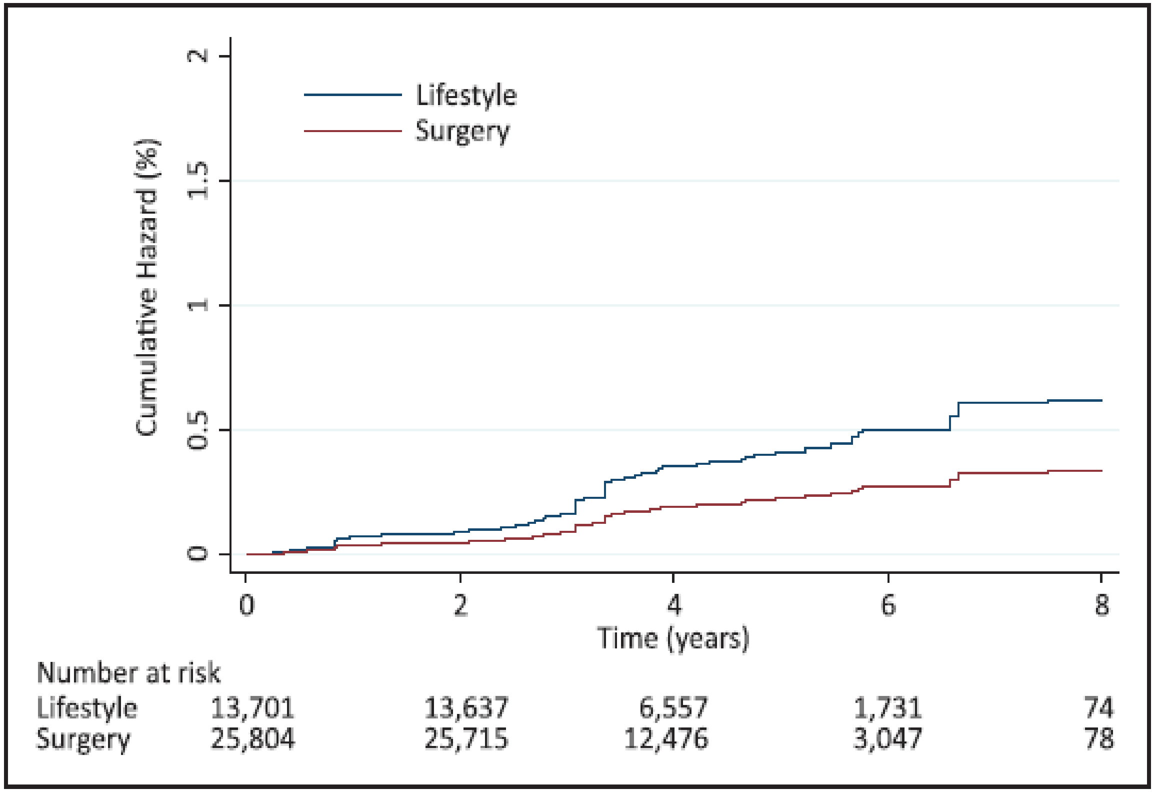


Figure 2. Cumulative hazard of heart failure in individuals treated with lifestyle or gastric bypass surgery.
Data are from an inverse probability-weighted sample.

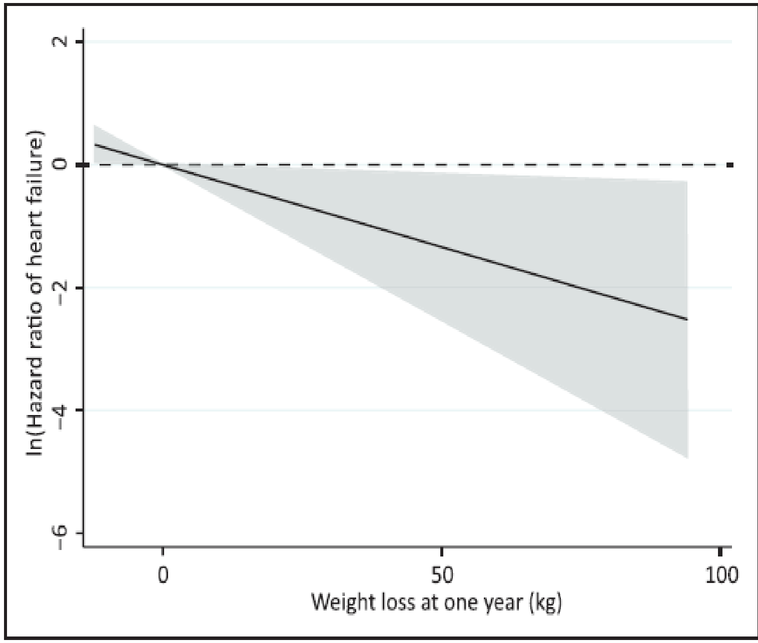
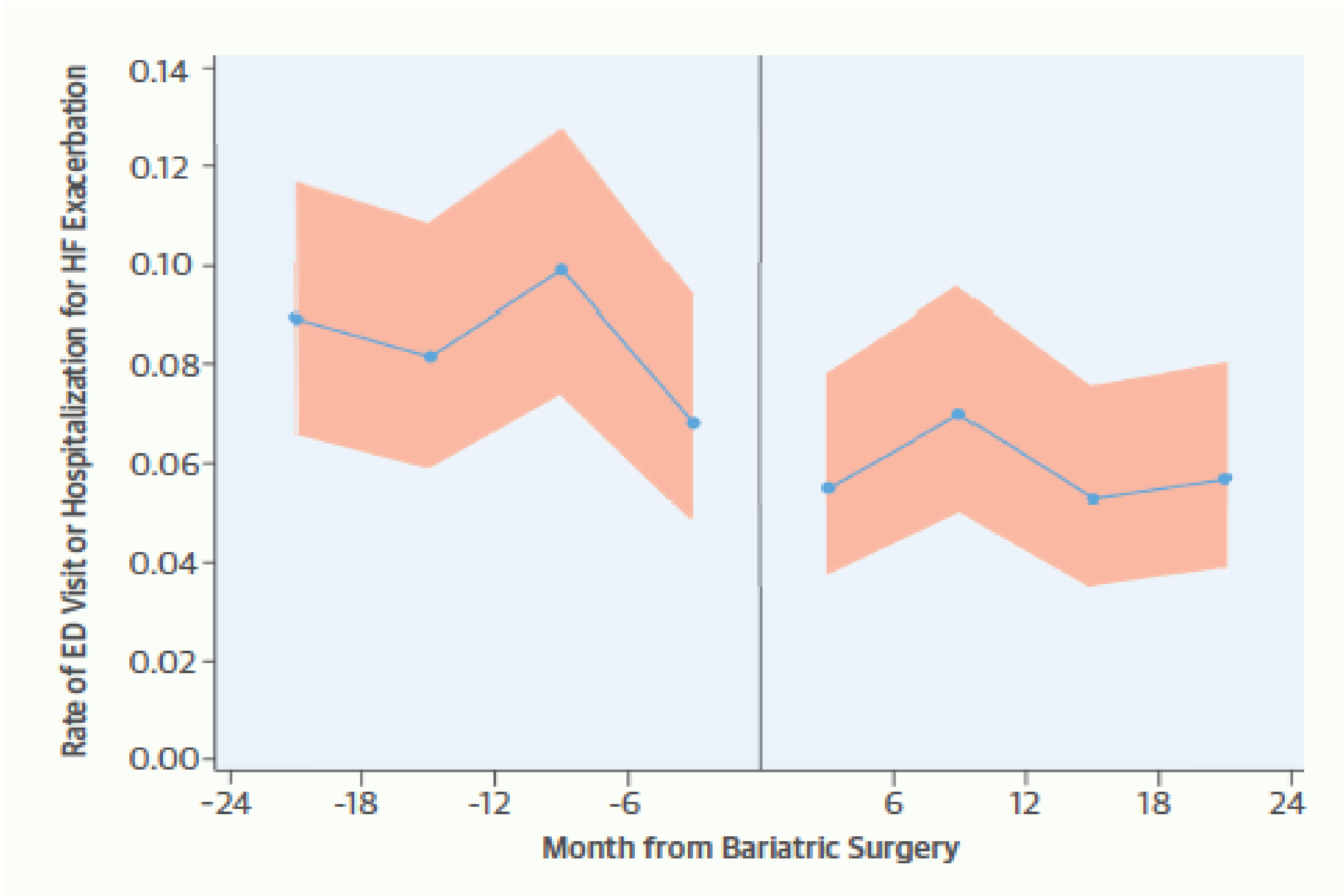


Figure 3. Hazard ratio of heart failure in relation to achieved weight loss at 1 year.
Data are from an inverse probability-weighted sample of both lifestyle and gastric bypass surgery patients combined. The model included the 3 variables of baseline weight, treatment group, and achieved weight loss at 1 year. Shaded area is 95% confidence interval.

Bariatric Surgery and Emergency Department Visits and Hospitalizations for Heart Failure Exacerbation

Article

CENTRAL ILLUSTRATION Bariatric Surgery and HF Exacerbation: Rate of HF Exacerbation Before and After Bariatric Surgery in a 6-Month Interval



Shimada, Y.J. et al. J Am Coll Cardiol. 2016; 67(8):895-903.

Cancer

Obesity and Cancer risk

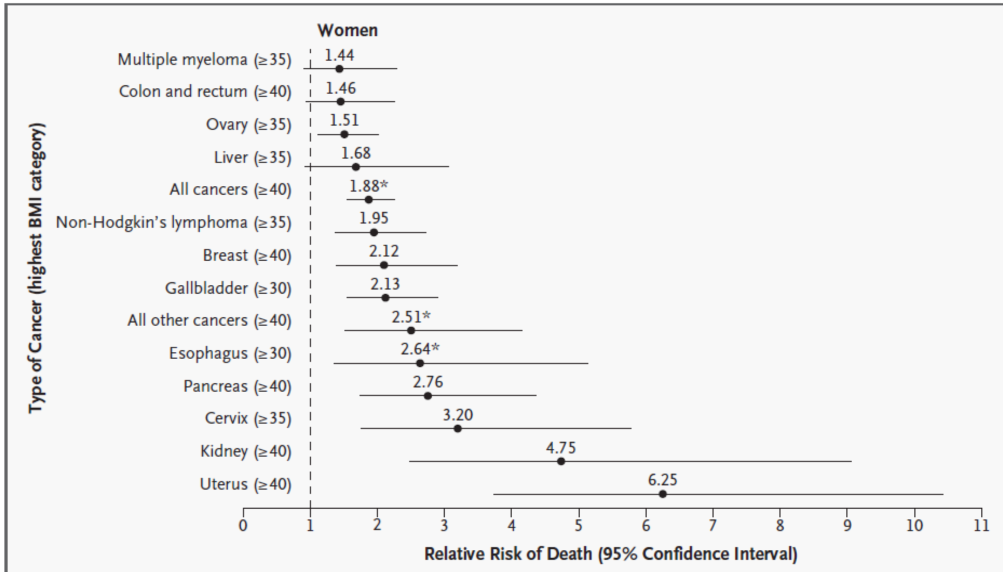


Figure 2. Summary of Mortality from Cancer According to Body-Mass Index for U.S. Women in the Cancer Prevention Study II, 1982 through 1998.

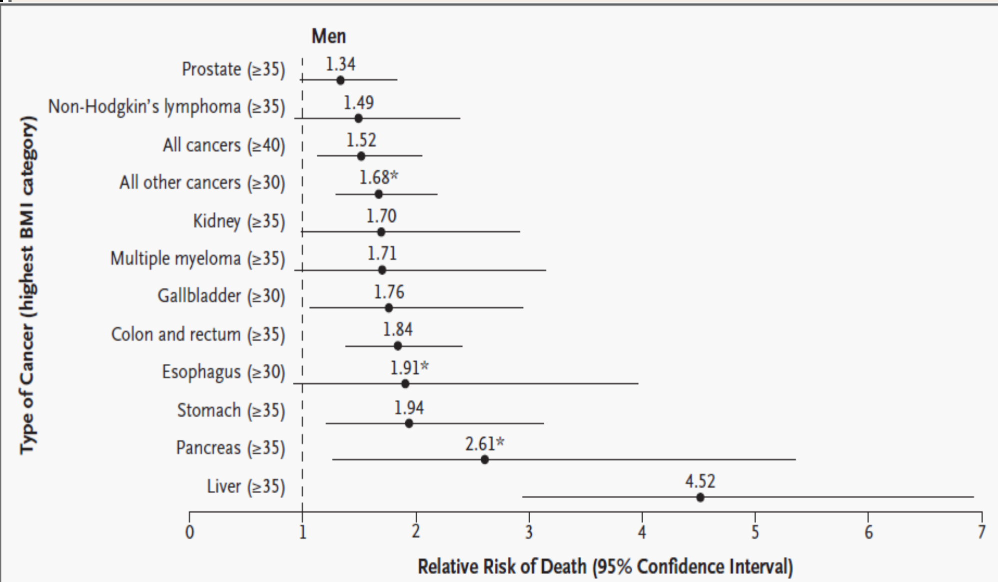


Figure 1. Summary of Mortality from Cancer According to Body-Mass Index for U.S. Men in the Cancer Prevention Study II, 1982 through 1998.

For each relative risk, the comparison was between men in the highest body-mass-index (BMI) category (indicated in parentheses) and men in the reference category (body-mass index, 18.5 to 24.9). Asterisks indicate relative risks for men who never smoked. Results of the linear test for trend were significant (P≤0.05) for all cancer sites.

Table 2 Obesity and gastrointestinal related cancers- relative risks (RR) and population attributable fraction (PAF) (adapted from Calle and Kaaks[4] with permission)

	RR		PAF (%)
	BMI 25–30 kg/m²	BMI > 30 kg/m²	
Colorectal cancer (men)	1.5	2.0	35.4
Colorectal cancer (women)	1.2	1.5	20.8
Esophageal adenocarcinoma	2.0	3.0	52.4
Gastric cardia adenocarcinoma	1.5	2.0	35.5
Pancreatic cancer	1.3	1.7	26.9
Gallbladder cancer	1.5	2.0	25.5

BMI, body mass index.

Goh & Goh J Gastroenter and Hepatol 2013;28 (Suppl.4):54-58

Diabetes, Obesity and Metabolism 13: 1063–1072, 2011.

Does intentional weight loss reduce cancer risk?

T. Byers & R. L. Sedjo

Colorado School of Public Health, Aurora, CO, USA

Table 2. The relationship between intentional weight loss and cancer incidence, coming from observational cohort studies, trials of bariatric surgery, and from dietary randomized controlled trials (RCTs) that examined weight loss as a secondary outcome.

Type of study/Author (ref)	Cancer site	Population studied	Body weight loss	Cancer risk reduction (%)
Cohort studies				
Parker [4]	All sites	Post-menopausal Iowa women	≥16.4%*	11
Eliassen [5]	Breast	US nurses	≥14.5%†, ‡	57
Harvie [6]	Breast	Post-menopausal Iowa women	≥5%	64§
Bariatric surgery studies				
Sjöström [7]	All sites	Women	31.9%	42
		Men	19.3%	3
Adams [8]	All sites	Women	31.1%	24
		Men		2
Christou [9]	All sites	Men and women	31.9%¶	78
Dietary RCTs				
Pierce [10]	Breast‖	Women	0.5% group difference	4
Prentice [11]	Breast	Women	1.0% group difference	9
Chlebowski [12]	Breast‖	Women	3.7% group difference	24

*Percent body weight loss was calculated using mean weight of 122 lbs (55.5 kgs) at age 18 years [6] along with ≥20.0 lbs (9.1 kgs) mean weight loss [4].
†Among women who never used post-menopausal hormones; weight loss since menopause.
‡Percent body weight loss was calculated using mean weight of 151 lbs (68.8 kgs) from 1423 post-menopausal women in the Nurses' Health Study [13] along with 22 lbs (10.0 kgs) mean weight loss [5].
§Among women who maintained or lost weight ≥5% BW from age 18 to 30 years followed by weight loss ≥5% BW from age 30 years to menopause [8].
¶Weight loss data for men and women combined, estimated from a subset of patients [14].
‖Endpoint was recurrence of breast cancer.

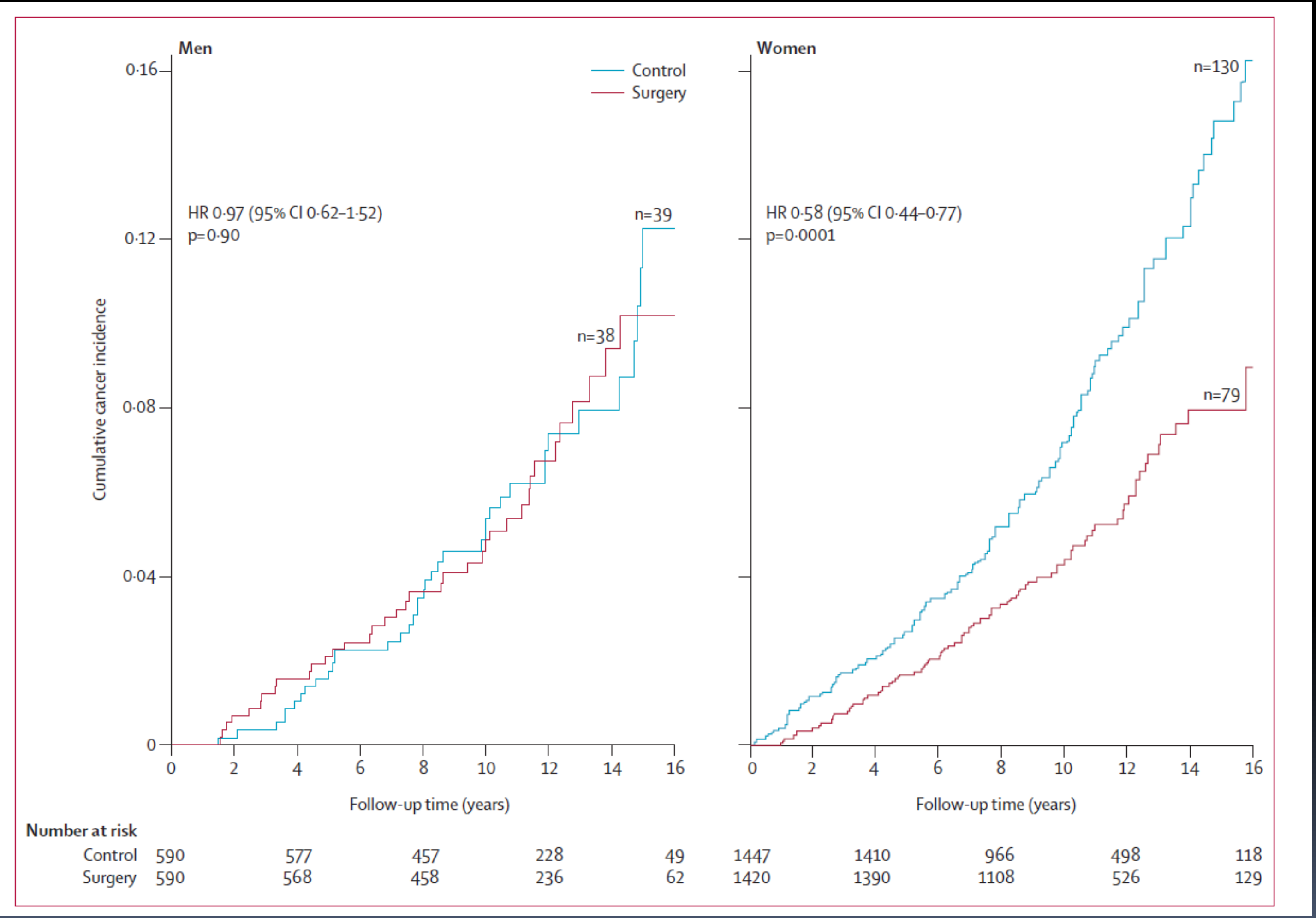
Does intentional weight loss reduce cancer risk?

T. Byers & R. L. Sedjo

Colorado School of Public Health, Aurora, CO, USA

Obesity is clearly associated with increased risk for many of the common types of cancer, and limited information from observational studies suggests that intentional weight loss can reduce this risk. Both bariatric surgery trials and dietary intervention trials also support the hypothesis that intentional weight loss can reduce cancer risk, even with latencies as short as a few years.

Overall Cancer Effect of Bariatric Surgery: Swedish Obese Subjects Study



- *Sjostrom L et al. Lancet Oncol 2009;10:653-62*

JAMA Surg. 2016 July 1; 151(7): 631–637. doi:10.1001/jamasurg.2015.5501.

Association of Patient Age at Gastric Bypass Surgery with Long-term All-cause and Cause-specific Mortality

Lance E. Davidson, PhD,
Department of Exercise Science, Brigham Young University, Provo, UT and Division of Cardiovascular Genetics, University of Utah, SLC, UT

Ted D. Adams, PhD, MPH,

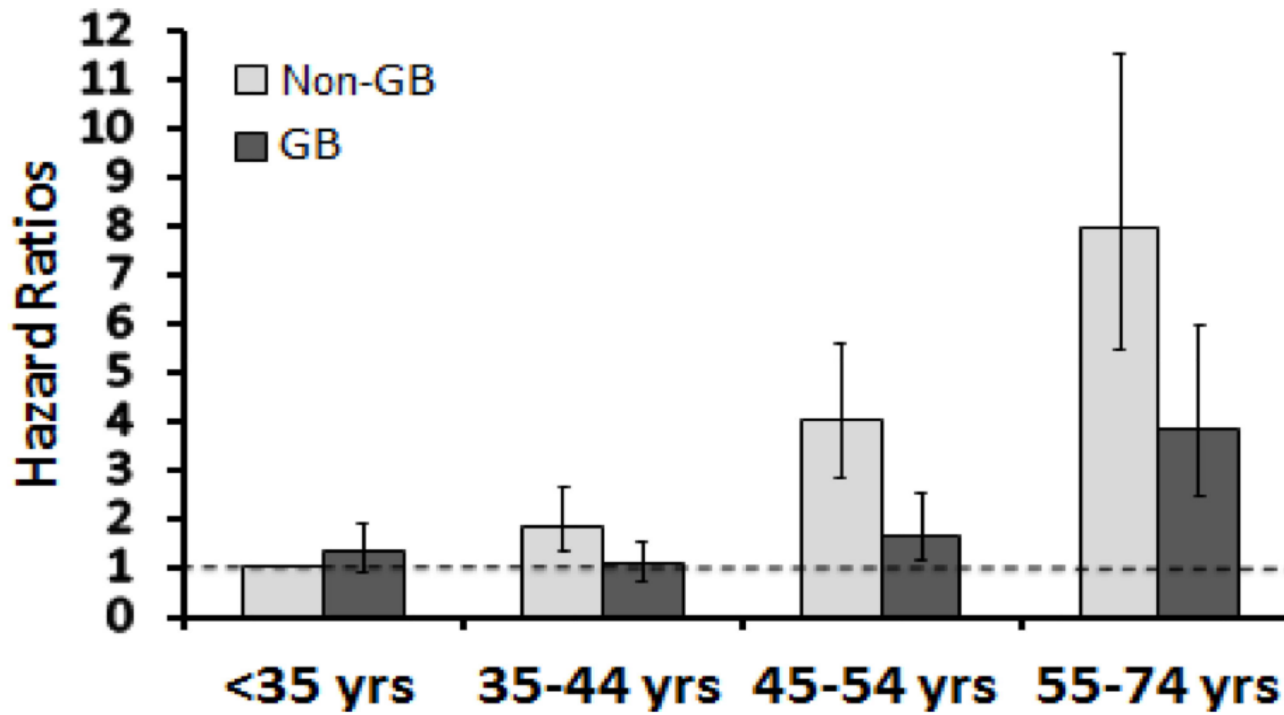


Figure 1. All-Cause Mortality Hazard Ratios by Age and Surgery Group
All-cause mortality hazard ratios of each study group and age-at-surgery group relative to the referent group of non-operated, severely obese subjects younger than 35. GB: gastric bypass surgery. Non-GB: non-operated, severely obese subjects. Error bars represent 95% confidence intervals.

	Males		Females	
Age Group	HR, 95% CI*	N, P*	HR, 95% CI*	N, P*
All ages	0.44 (0.31–0.63)	2,602, p<0.0001	0.68 (0.54–0.85)	13,248, p=0.0007
<35 years	0.79 (0.35–1.76)	700, p=0.56	1.42 (0.90–2.26)	4,760, p=0.13
35–44 years	0.41 (0.22–0.76)	894, p=0.005	0.63 (0.40–0.97)	4,630, p=0.04
45–54 years	0.39 (0.19–0.80)	720, p=0.010	0.43 (0.28–0.67)	2,936, p=0.0001
55–74 years	0.23 (0.07–0.74)	288, p=0.014	0.61 (0.36–1.03)	922, p=0.07

Davidson, et al. JAMA Surg 2016 July 1; 151(7): 631–637.

Utah Obesity Study

Table 2. Death in Patients Undergoing Gastric Bypass Surgery Compared With Individuals Not Undergoing Surgery by Age Group

	Adjusted HR (95% CI)[a]									
			Age Group, y							
End Point	All	P Value	<35	P Value	35-44	P Value	45-54	P Value	55-74	P Value
All deaths	0.60 (0.50-0.73)	<.001	1.22 (0.82-1.81)	.34	0.54 (0.38-0.77)	<.001	0.43 (0.30-0.62)	<.001	0.50 (0.31-0.79)	.003
All externally caused deaths[b]	1.58 (1.02-2.45)	.04	2.53 (1.27-5.07)	.009	0.86 (0.40-1.87)	.70	1.32 (0.44-3.97)	.63	1.30 (0.25-6.86)	.76
All deaths other than externally caused deaths	0.48 (0.39-0.60)	<.001	0.79 (0.47-1.32)	.37	0.48 (0.32-0.72)	<.001	0.37 (0.25-0.55)	<.001	0.46 (0.28-0.75)	.002
Cardiovascular disease-related deaths[c]	0.51 (0.36-0.73)	<.001	0.64 (0.29-1.41)	.27	0.56 (0.29-1.08)	.08	0.34 (0.16-0.69)	.003	0.57 (0.28-1.15)	.12
Cancer-related deaths	0.40 (0.25-0.64)	.001	NA[d]		0.53 (0.22-1.28)	.16	0.40 (0.19-0.85)	.02	0.54 (0.21-1.35)	.19

Abbreviations: BMI, body mass index (calculated as the weight in kilograms divided by height in meters squared); HR, hazard ratio; NA, not applicable.

[a] All HRs were adjusted for sex, age at surgery, and a cubic polynomial of the baseline BMI.

[b] Unintentional injury unrelated to drugs, poisoning of undetermined intent, suicide, and other externally caused deaths.

[c] Coronary artery disease, heart failure, stroke, and other cardiovascular disease.

[d] There were no cancer deaths in the patients younger than 35 years undergoing gastric bypass surgery compared with 8 cancer-related deaths in individuals not undergoing surgery.

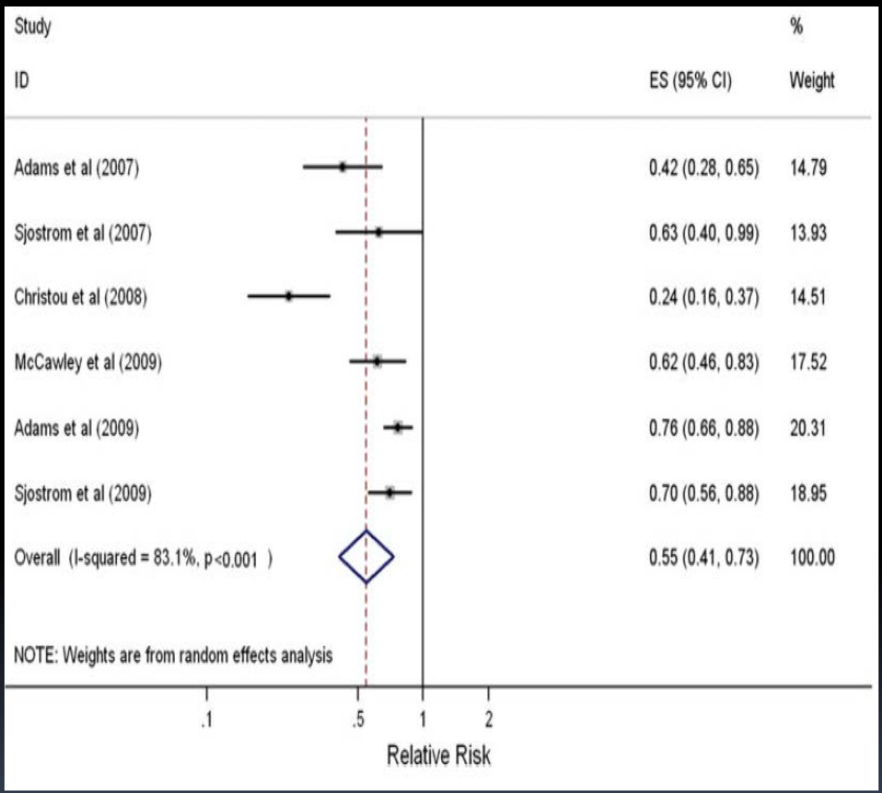
Overall Cancer
Effect of Bariatric Surgery

- Metanalysis
- All human studies with oncologic outcomes after bariatric surgery
- Six observational studies (n=51,740) comparing RR of cancer in BS patients vs. control.
- RR after BS = 0.55 (women= 0.68 vs men=0.99).

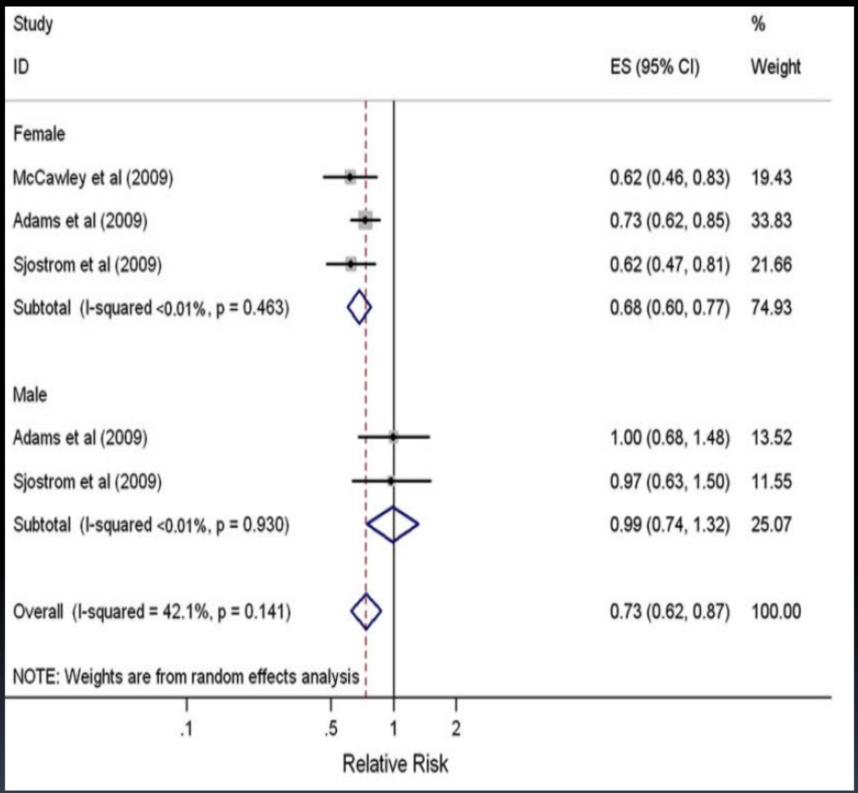
Tee MC et al. Surg Endosc 2013;27:4449-4456.

Metanalysis: Effect of Bariatric Surgery
All human studies with oncologic outcomes
6 observational studies, n= 51,740

Effect of BS on cancer incidence and mortality



Gender-specific effect of BS on cancer incidence



RR after BS = 0.55 (women= 0.68 vs men=0.99)

Tee MC et al. Surg Endosc 2013;27:4449-4456

Overall Cancer
Effect of Bariatric Surgery

First author (country)	Study setting	Mean follow-up (years)	Surgery cases (cohort)	Control cases (cohort)	Risk ratio (95% CI)	Adjustments
Women						
Sjöström,[4] 2009 (Sweden)	Prospective intervention trial	10·9*	79 (1410)	130 (1447)	0·58 (0·44–0·77)	Age, smoking, weight change, energy intake, and matching†
Adams,[5] 2009 (Utah, USA)	Retrospective registry	12·5	215 (5654)	412 (7872)	0·73 (0·62–0·86)	Age and BMI
McCawley,[6] 2009 (Virginia, USA)	Retrospective clinical data repository	9·9	53 (1482)	203 (3495)	0·62 (0·46–0·83)‡	None
Men						
Sjöström,[4] 2009 (Sweden)	Prospective intervention trial	10·9*	38 (590)	39 (590)	0·97 (0·62–1·52)	Age, smoking, weight change, energy intake, and matching
Adams,[5] 2009 (Utah, USA)	Retrospective registry	12·5	39 (942)	65 (1570)	1·02 (0·69–1·51)	Age and BMI
Men and women combined						
Christou,[7] 2008 (Canada)	Retrospective hospital-based	5·0§	21 (1035)	487 (5746)	0·22 (0·14–0·34)	Age, sex, and BMI

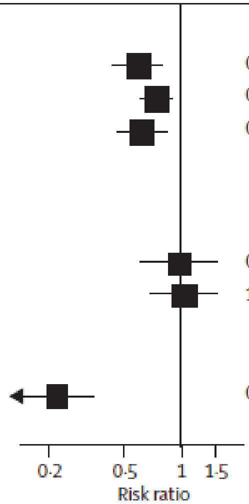
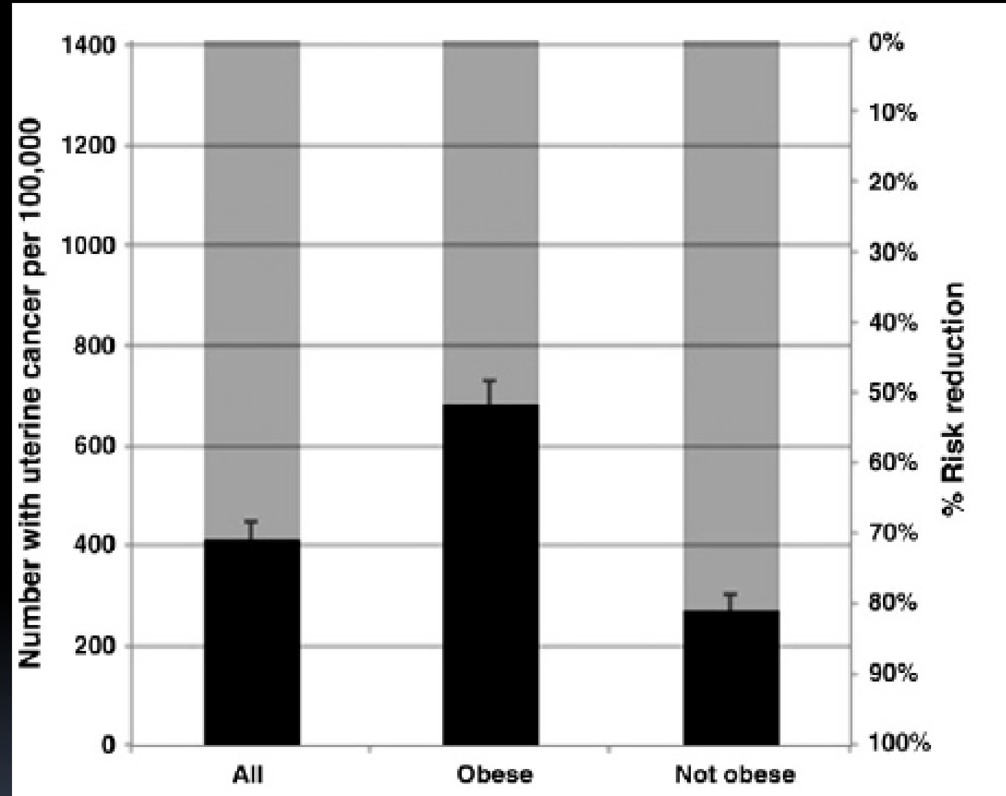


Figure: Study characteristics and summary findings from bariatric surgery studies and cancer occurrence

Renehan AG. Lancet Oncology 2009;10:640-641

Endometrial Cancer
Effect of Bariatric Surgery

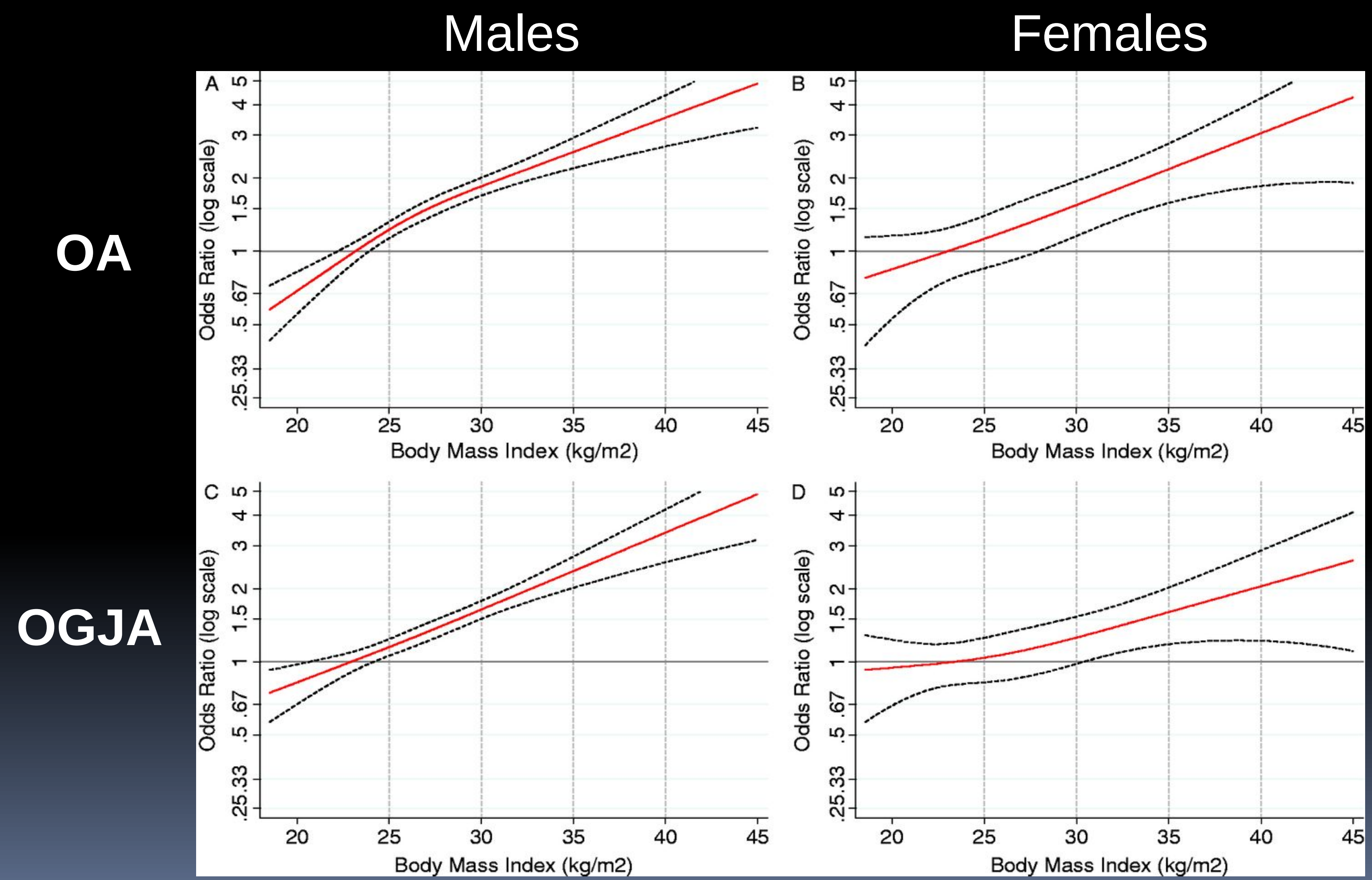
- Bariatric surgery is associated with a 71% risk reduction for uterine cancer and an 81% reduced risk if normal weight is maintained after surgery.



1. Potential endometrial cancer risk reduction after bariatric surgery. Among all

Ward KK et al. Gynec Oncology 2014;133:63-66

Relationship between body mass index and adenocarcinomas of the oesophagus (OA) and oesophagogastric junction (OGJA)



Hoyo C et al. Int. J. Epidemiol. 2012;ije.dys176

Bariatric Surgery and Colorectal Cancer Risk

- Systematic review 4 observational studies met inclusion criteria
- Meta-analysis
  - bariatric surgery was associated with a significantly lower CRC incidence vs.obese non-operated individuals
  - RR = 0.73, 95 % confidence interval, 0.58 - 0.90, p=0.004
  - bariatric surgery associated with a 27 % lower CRC risk.

Afshar S, et al. The effects of bariatric surgery on colorectal cancer risk: systematic review and meta-analysis. Obes Surg. 2014 Oct;24(10):1793-9.

Liver Cancer

- Administrative data from UHC
- Prevalence of liver cancer among admissions with and without a history of bariatric surgery within a 3-year period.

- History of bariatric surgery had a 61 % lower prevalence of liver cancer compared to those without a history of bariatric surgery
- prevalence ratio 0.39, 95 % confidence interval 0.35-0.44
  - Inverse associations persisted despite sex, race, and ethnicity.

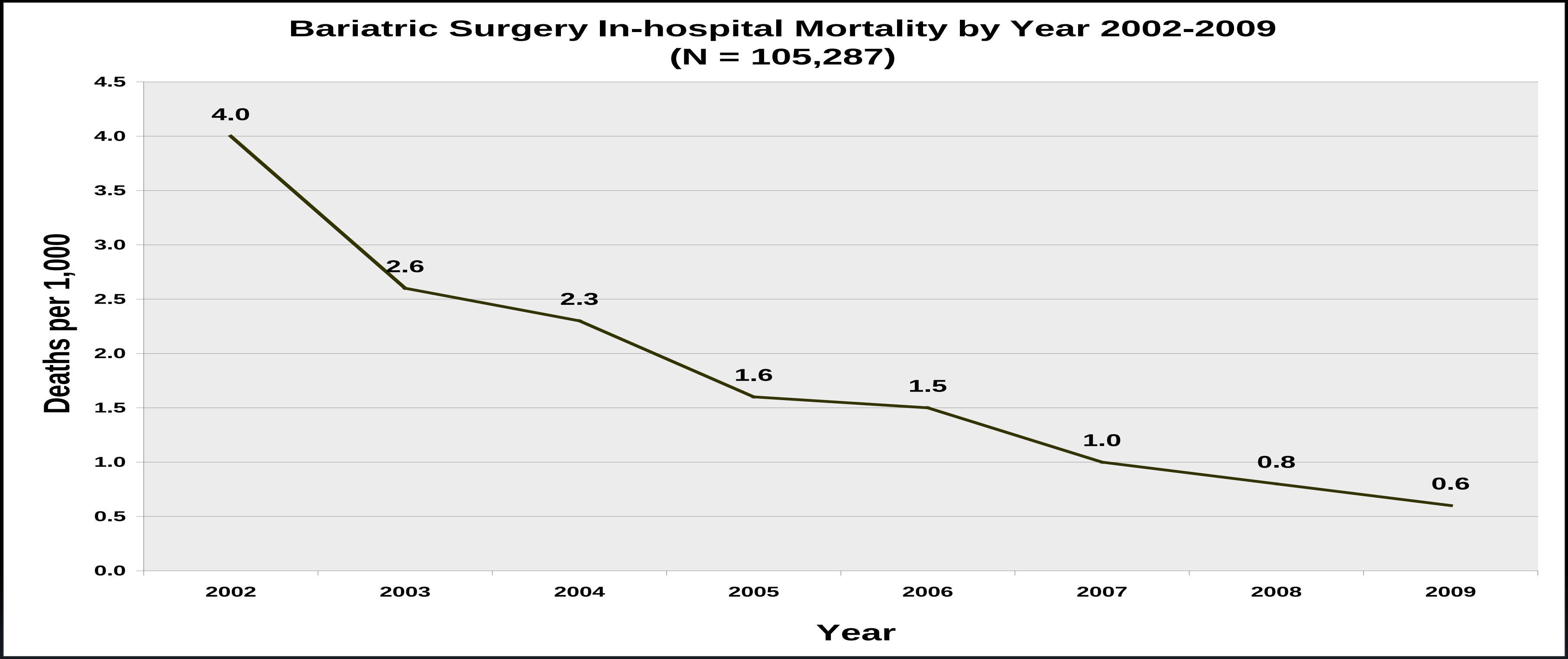
Yang B(1), et al. Bariatric Surgery and Liver Cancer in a Consortium of Academic Medical Centers. Obes Surg. 2016 Mar;26(3):696-700.

Quality and patient safety

Outcome improvements and surgical morbidity reductions over past decade

National QI projects and results

BARIATRIC SURGERY: AMERICAN SURGICAL SUCCESS STORY



Nguyen et al. SOARD 2012

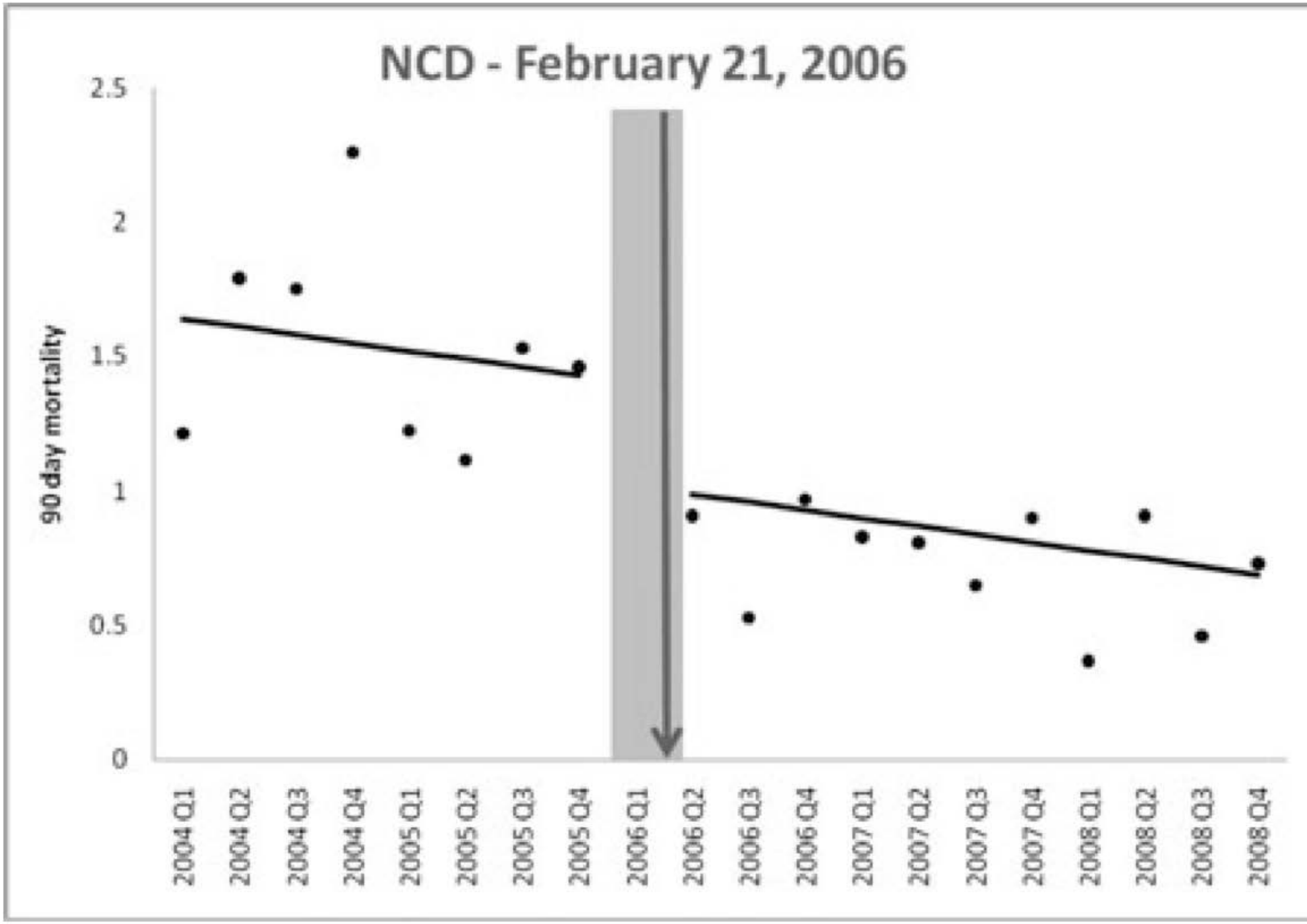
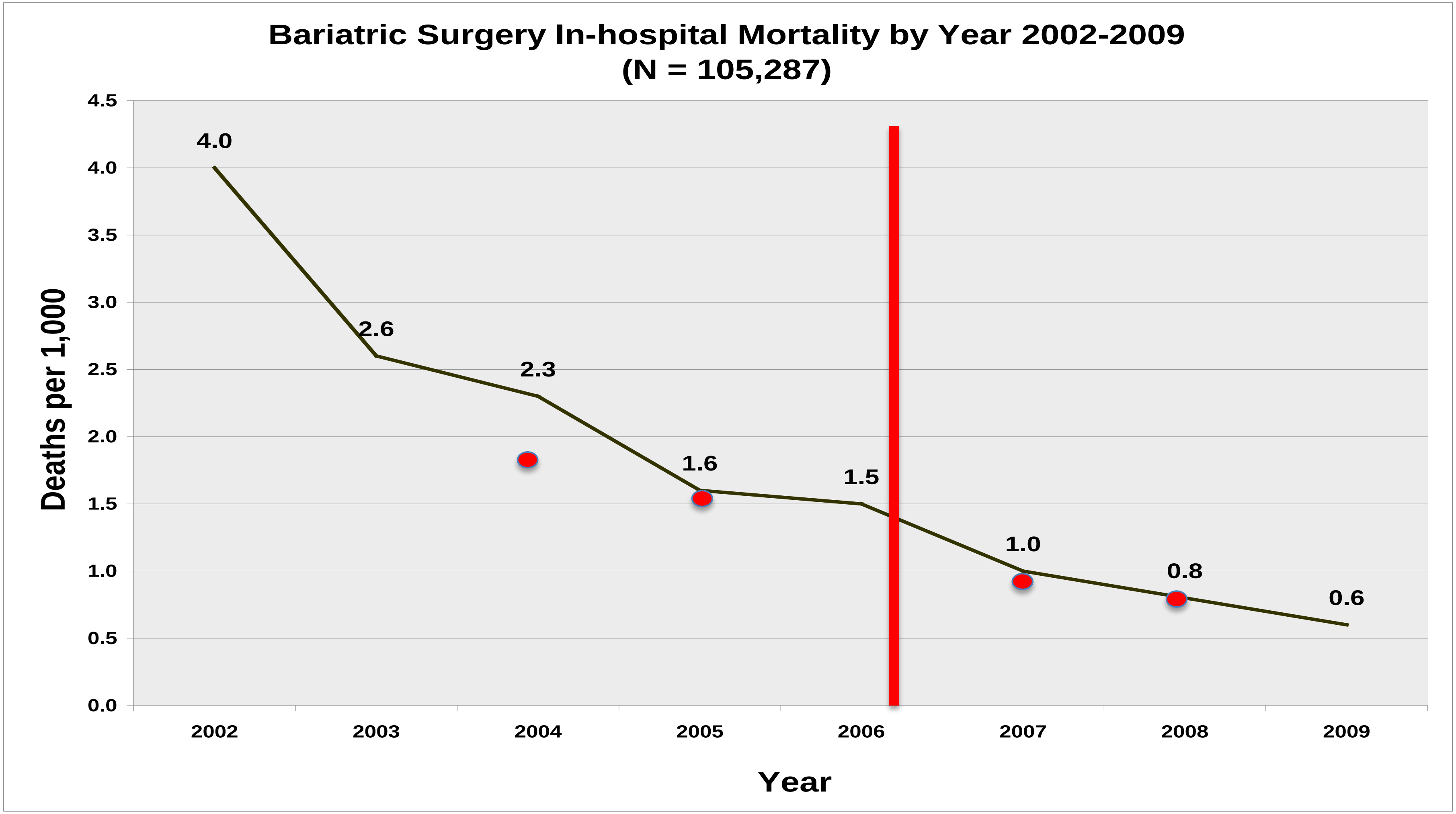


FIGURE 3.

Time series of 90-day mortality rates for the CMS beneficiaries undergoing bariatric surgery. Q denotes quarter, and the fitted trend lines show predicted values for segmented time-series regressions for pre-NCD and post-NCD periods (adjusted only for temporal trends). The shaded bar represent transitional quarter between policy period, not included in this analysis.

BARIATRIC SURGERY: AMERICAN SURGICAL SUCCESS STORY



Superimposed data from Flum et al 2011- CMS patients

Nguyen et al. SOARD 2012

CMS: Inpatient Discharge Data (2010)

Morbidity & mortality rates of gastric bypass are similar to other common procedures

Procedure		Complications	Mortality
Bariatric surgeries	Gastric bypass	0.4%	0.2%
	Gastric banding	*	*
Other common procedures	Colectomy	2.4%	0.8%
	Hysterectomy	0.4%	*
	Cholecystectomy	0.9%	0.9%
	Hip replacement	1.0%	0.2%

*≤10 cases reported.

Center for Medicare and Medicaid Services, FY 2010 MedPAR, Medicare Fee for Service Inpatient Discharges with Selected Procedures

Surgery for Obesity and Related Diseases 11 (2015) 393–398

Original article

Bariatric surgery in the elderly: 2009–2013

Alana Gebhart, B.A., Monica T. Young, M.D., Ninh T. Nguyen,
Department of Surgery, University of California Irvine Medical Center, Orange, California

Received March 1, 2014; accepted April 17, 2014

Table 1
Demographic characteristics and co-morbidities of nonelderly versus elderly patients who underwent bariatric surgery, 2009–2013

Variables	Nonelderly (18–60 yr)	Elderly (>60 yr)
Total no. of cases	54,604	6,105
No. of academic centers	136	122
Female gender (%)	79.12	68.65*
Caucasian (%)	67.00	84.22*
Hypertension (%)	54.43	83.90*
Chronic pulmonary disease (%)	20.12	22.34*
Liver disease (%)	13.79	15.18*
Congestive heart failure (%)	1.79	4.86*
Diabetes mellitus (%)	28.41	49.53*
Diabetes with complications (%)	2.46	6.88*
Renal failure (%)	1.77	6.31*

*$P < .05$ compared to nonelderly group, χ^2 tests.

Table 2
Outcomes of bariatric surgery in the nonelderly versus elderly patients, 2009–2013

Variables	Nonelderly (18–60 yr)	Elderly (>60 yr)
Mean length of stay (d)	2.32 ± 3.14	2.60 ± 3.20*
Serious morbidity (%)	.73	1.33†
In-hospital mortality (%)	.05	.11 ($P = .05$)
Observed-to-expected mortality ratio	.69	.86

*$P < .05$ compared to nonelderly group, unpaired t test.
†$P < .05$ compared to nonelderly group, $\chi 2$ tests.

Drivers of Improved Outcomes in Bariatric Surgery

- Dedicated multi-disciplinary teams
- Comprehensive, holistic approach
- Improved patient selection.
- Improved patient evaluation.
- Improved patient optimization.
- Standardized operations.
- Accreditation

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

SAR Summary Data for Cases in CY2016

30-day Mortality Snapshot – All Cases

Number of Sites	Total Cases	Death Cases	Mortality Rate (%)	Mean Site Mortality Rate (%)
783	185883	207	0.1114	0.1176

National Outcomes: MBSAQIP Overall vs. Age >65

	Band		Bypass		Sleeve		Balloon Insertion	
	Overall	Age >= 65	Overall	Age >= 65	Overall	Age >= 65	Overall	Age >= 65
N	2846	158	40142	2180	107041	5597	1003	57
Mean # comorbidities	1.6	3.2	2.3	3.7	1.8	3.4	1.1	2.2
Outcome (%)								
Mortality	0.0	0.0	0.1	0.3	0.1	0.2	0.0	0.0
Morbidity	0.9	1.9	3.8	4.6	1.6	2.7	0.2	0.0
All Occurrences Morbidity	2.5	5.7	9.2	9.0	4.1	5.4	4.3	3.5
Leak	0.0	0.0	0.3	0.5	0.2	0.2	0.0	0.0
Bleeding	0.1	0.6	1.7	2.0	0.6	0.9	0.3	0.0
SSI	0.4	0.6	1.4	1.0	0.4	0.5	0.0	0.0
All Cause Reoperation	0.7	3.2	2.2	2.2	0.8	1.0	0.9	1.8
Related Reoperation	0.6	3.2	1.8	1.7	0.6	0.6	0.9	1.8
All Cause Intervention	0.6	1.9	2.5	2.1	0.9	1.0	4.2	7.0
Related Intervention	0.5	1.9	2.1	1.7	0.6	0.6	3.6	1.8
All Cause Readmission	1.9	5.7	5.9	6.3	3.1	3.6	2.2	1.8
Related Readmission	1.6	5.1	4.7	4.4	2.1	2.2	2.0	1.8

Impact of ACS-ASMBS Accreditation on BS Outcomes

- 2010 Nationwide Inpatient Sample (NIS) dataset
- 72,615 bariatric patient discharges
- 145 hospitals, of which 79 (54%) were accredited.
- Unaccredited centers had a higher LOS (2.25 vs. 1.99 days).
- Unaccredited centers had higher total charges ($51,189 vs. $42,212)

Morton JM et al. Ann Surg 2014;260(3):504-8

Impact of ACS-ASMBS Accreditation on BS Outcomes

- Unaccredited centers had <u>*higher complication rates*</u> (12.3% vs. 11.3%, *p<0.0001*)
- Unaccredited centers had <u>*higher mortality rates*</u> (0.13% vs. 0.07%, *p=0.019*)
- Multivariable logistic regression analysis identified <u>*unaccredited status as a positive predictor of incidence of complications*</u>.

Morton JM et al. Ann Surg 2014;260(3):504-8

Bariatric Surgery Outcomes in US Accredited vs Non-Accredited Centers: A Systematic Review

Dan Azagury, MD, John M Morton, MD, MPH, FACS, FASMBS

RESULTS: Thirteen studies were published in a very short time frame and covered >1.5 million patients. Ten of the 13 studies identified a substantial benefit of Center of Excellence accreditation for risk-adjusted outcomes. Six of the 8 studies reported a considerable reduction in mortality in patients operated on in Centers of Excellence, with odds ratios ranging from 2.26 to 3.57 for non-accredited centers; 2 studies showed no significant difference. Similarly, morbidity was reduced in 8 of 11 studies, although more discreetly, with odds ratios ranging from 1.09 to 1.39.

http://dx.doi.org/10.1016/j.jamcollsurg.2016.06.014
ISSN 1072-7515/16

MBSAQIP Accreditation Required

- **Blue Cross Centers of Distinction**
- **Aetna Institutes of Quality**
- **United/Optum Centers of Excellence**
- **Cigna Bariatric Centers of Excellence**

BlueCross BlueShield

Bariatric Centers of Excellence Network

UnitedHealthcare

aetna

CIGNA JPMC Bariatric Centers of Excellence

CIGNA

AMERICAN COLLEGE of SURGEONS

ACS QUALITY and SAFETY CONFERENCE

Decreasing Readmissions through Opportunities Provided (*DROP)*: The First National Quality Improvement Collaborative from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (*MBSAQIP*)

John Morton MD, MPH; Stacy Brethauer MD;
Teresa Fraker RN, Jennifer Bradford MFA,
Kristopher Huffman MS, Elizabeth Berger MD,
Anthony Petrick MD, Cliff Ko MD

Study Aim

To demonstrate the impact of a readmission bundle to decrease 30-day all-cause readmissions in a nationally representative bariatric surgery population

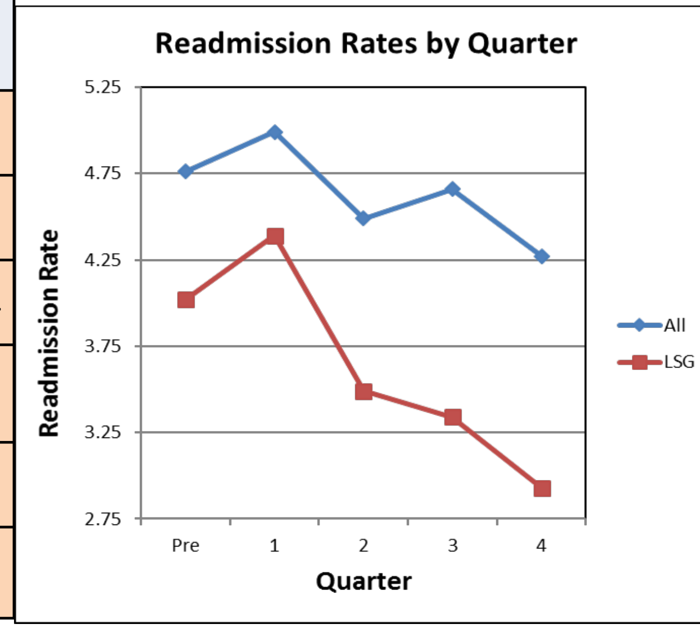
Methods

- Setting: 128 Representative Hospitals
- Piloted in 5 centers
- Time Period: April 2015-March 2016

Interventions:

- 14 Webinars
- In Person Meetings @ Obesity Week 2015 & Obesity WE 2016
- MBSAQIP QI Cmte Mentor Assigned to Each Center for Monthly Phone Calls
- Site Specific Reports for Benchmarking
- Readmission Bundle

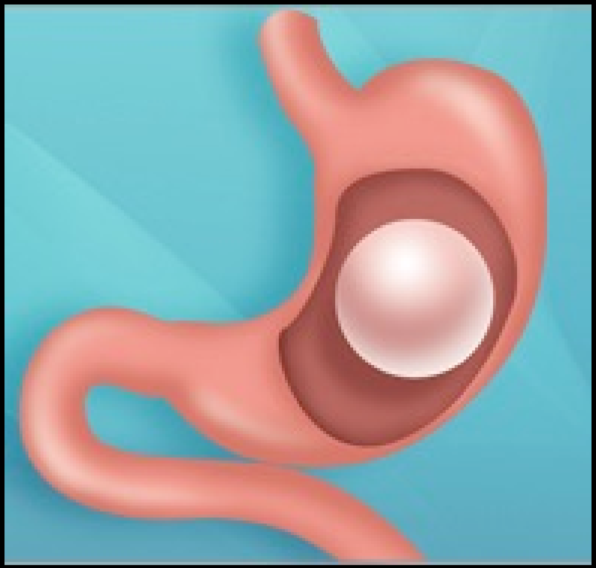
	All 128 Sites							
Procedure	**LAGB**		**LRYGB**		**LSG**		**All**	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
Cases	1592	1028	10255	10638	18230	22358	30077	34024
Readmission Rate	1.88	1.95	6.53	7.13	4.02	3.54	4.76	4.61
Percent Change		3.24		9.06		-12.01		-3.21
Chi-square P-value		0.91		0.09		0.01		0.36

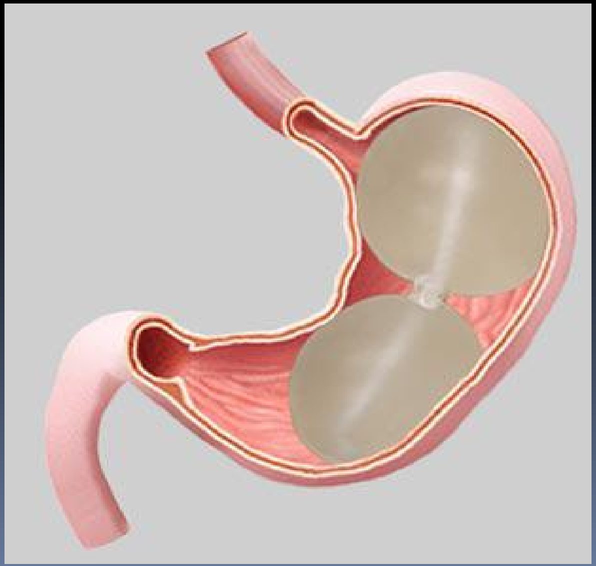


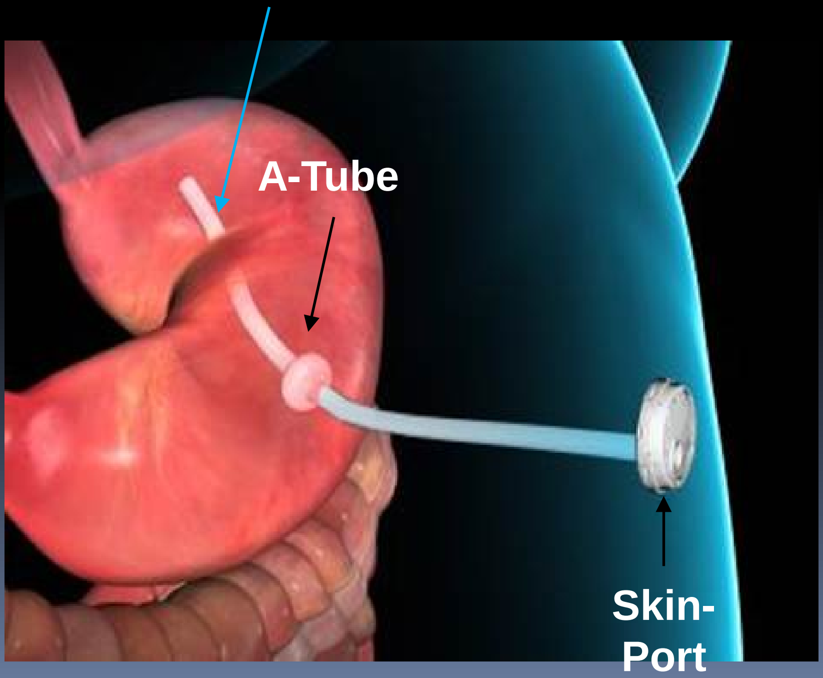
- **Significant Sleeve Gastrectomy 30 Day Readmission Decline of -12.01 % with Accelerating Decline over Time (Last Qtr -27%)**
- **Significant Decline in LOS for Band/Sleeve/All**
- **NS change in Morbidity Band/Sleeve/All**
- **Hospitals with a Pre-Intervention Readmission Rate of >4.84% Benefitted Most**
- **Bundle Elements of Discharge Phone Call and Postop Visit with Surgeon and Nutritionist < 30 days Mattered Most**

Newer FDA approved devices

Newer FDA approved interventions







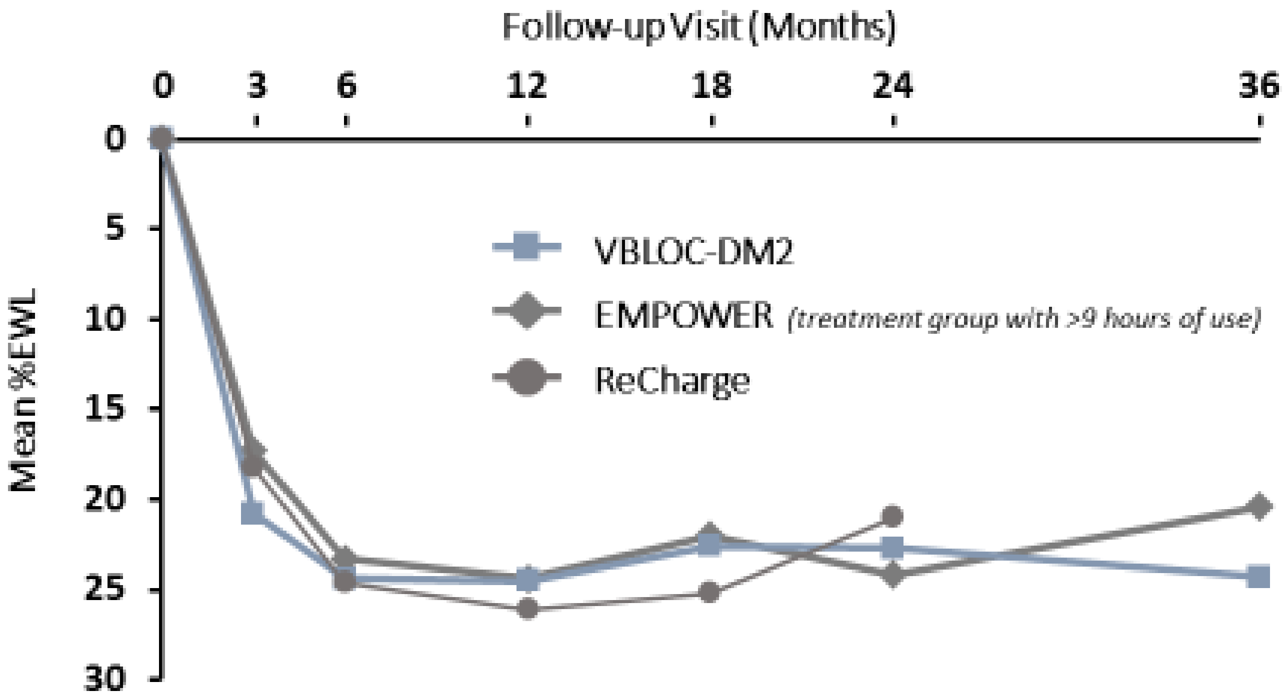
VBLOC

- Vagal nerve blocking device
- Neuroregulator interrupts signaling between
  the vagus nerve and the brain non-continuously for 5 minutes out of every 10 minutes, 12 hours a day
  Delivery of therapy in mAmp can be adjusted depending on patient's response to therapy
  Delivery of daily therapy duration can be adjusted according to patient's lifestyle and schedule
- Induces delayed gastric emptying and reduces gastric accommodation
- Overall effect is that patients eat smaller portions and feel fuller longer
- FDA approved in 2015 for BMI 35-45; best results seen in BMI 35-40

CLINICAL EVIDENCE SUMMARY

	Patients	Design	Key Outcomes
vBloc – RF1 (Proof of Concept)[1]	31	Prospective, observational 6 month study, BMI 31.5-55 kg/m[2]	▪ 14% EWL ▪ No device-related SAEs ▪ Calorie intake ↓ 30% with ↑ fullness and ↓ hunger ▪ Pancreatic polypeptide reduced (indirect measure of vagal blocking)
vBloc – RF2 (Safety and Efficacy)[2]	27	Prospective, observational 6 month study, 2nd generation RF device, BMI 31.5-55 kg/m2	▪ 23% EWL ▪ 1 device-related SAE ▪ Greater weight loss than 1st generation device due to 2 minute ON times (intermittent algorithm)
vBloc DM2 (Safety and Efficacy)[3,4]	28	Prospective, observational 1 and 2 year studies with a rechargeable device, BMI 30-40 kg/m^2 and T2DM	▪ 1 & 2 year results: ▪ 25% & 22% EWL ▪ 1 & 0.6 percentage point reduction in HbA1c ▪ In hypertensive subjects, 8 & 7 mmHg reduction in mean arterial pressure ▪ 1 and 2 device-related SAE
vBloc EMPOWER[5] (level I study)	294	Prospective, randomized, double-blind, 2:1 allocation, sham control, external power source, 1 year study	▪ Greater weight loss with ↑ hours of therapy (30% EWL with ≥12 hrs/day) ▪ Unanticipated therapeutic effect in control arm from safety checks ▪ Safety endpoint met
vBloc RECHARGE (level I study)[6,7]	239	Prospective, randomized, double-blind, 2:1 allocation, sham control, rechargeable device, 12 and 18 month study	▪ 24.4% EWL ITT group ▪ Unprecedented super-superiority endpoint not met, but superiority shown over sham (sham effect) ▪ Safety endpoint met (3.7% related SAEs) ▪ Durable WL in vBloc and not sham at 18 mo

Overall Efficacy: vBloc® Therapy EWL Results



VBLOC-DM2	28	26	25	26	24	22	18
EMPOWER	79	77	78	79	67	60	45
ReCharge	162	151	149	147	117	103	

Clinically significant weight loss, 28% EWL at 12 months*

Sustainable weight loss across all trials up to 36 months

Over 50% of VBLOC patients achieved +20% EWL

Nearly 20% lost half of their excess weight

*when used as directed

vBloc Clinical Evidence: Reduction in Comorbidities

vBloc Therapy patients experienced a **reduction in comorbidities** and improvements in overall cardiovascular health at **1 and 2 years**

CLINICAL STUDY PATIENTS AT 1 YEAR

- ↓ Waist circumference reduced by 7" (~18 cm)
- ↓ Drop in "bad" cholesterol
- ↓ HbA1c (%) reduction of 1.0 point

CLINICAL STUDY PATIENTS AT 2 YEARS

- ↓ 50% remittance of pre-diabetes
- ↓ 50% remittance of metabolic syndrome

the health care system

15. Shikora, Scott, et al. "Vagal Blocking Improves Glycemic Control and Elevated Blood Pressure in Obese Subjects with Type 2 Diabetes Mellitus." *Journal of Obesity*, (2013) Article ID 245683. DOI: 10.1155/2013/245683.

Slide courtesy of EnteroMedics

Intra-Gastric Balloons for Weight Loss

“Reshape Dual®”

ReShape Medical

Two attached 450mL fluid filled silicone balloons

FDA approved in 2015 for BMI 30-40 with co-morbidity

Endoscopically inserted and removed

“Orbera®”

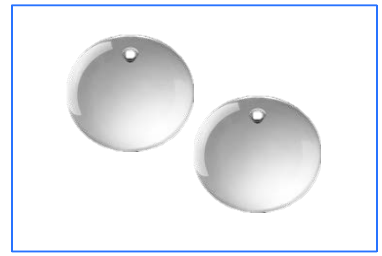
apollo endosurgery

Single 550mL fluid filled silicone balloon

FDA approved in 2015 for BMI 30-40

Endoscopically inserted and removed

“Obalon™ ”



OBALON

Up to three 250mL gas-filled balloons

FDA approved in 2016 for BMI 30-40

Swallowed and endoscopically removed

“Elipse®”

allurion

Single 550ml, fluid filled balloon

Pending FDA approval in 2018 for BMI 30-40

Swallowed and Spontaneously Passes through GI Tract

ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies

Prepared by: ASGE BARIATRIC ENDOSCOPY TASK FORCE AND ASGE TECHNOLOGY COMMITTEE

Barham K. Abu Dayyeh, MD, MPH, Nitin Kumar, MD, Steven A. Edmundowicz, MD, FASGE, Co-Chair, Bariatric Endoscopy Task Force, Sreenivasa Jonnalagadda, MD, FASGE, Michael Larsen, MD, Shelby Sullivan, MD, Christopher C. Thompson, MD, MSc, FASGE, Co-Chair, Bariatric Endoscopy Task Force, Subhas Banerjee, MD, FASGE, Chair, Technology Committee

This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

- 82 publications included re ORBERA IGB
- 6,845 pts
- TBWL at 6 months:
  - 13.16%
- TBWL at 12 months:
  - 11.1% (25.4%EWL)

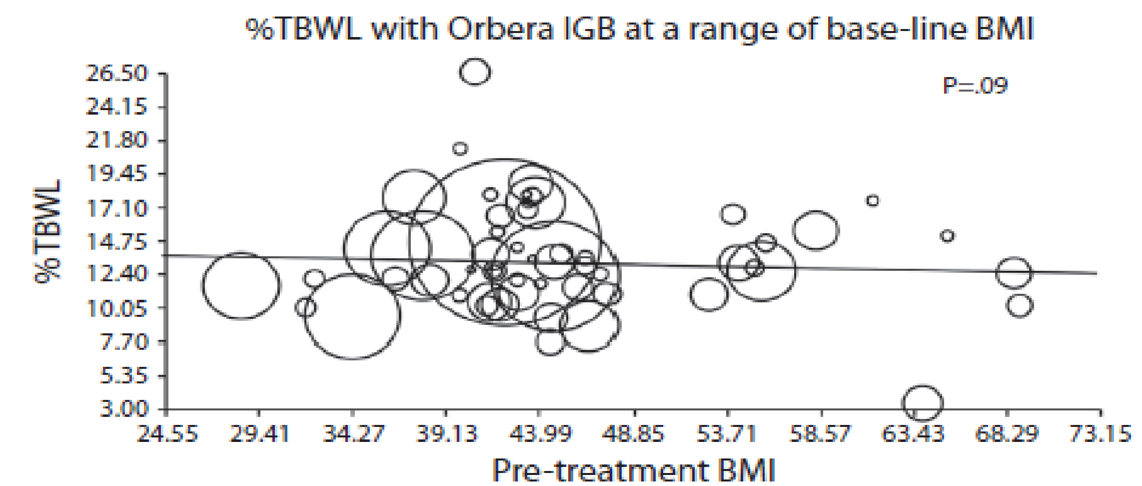
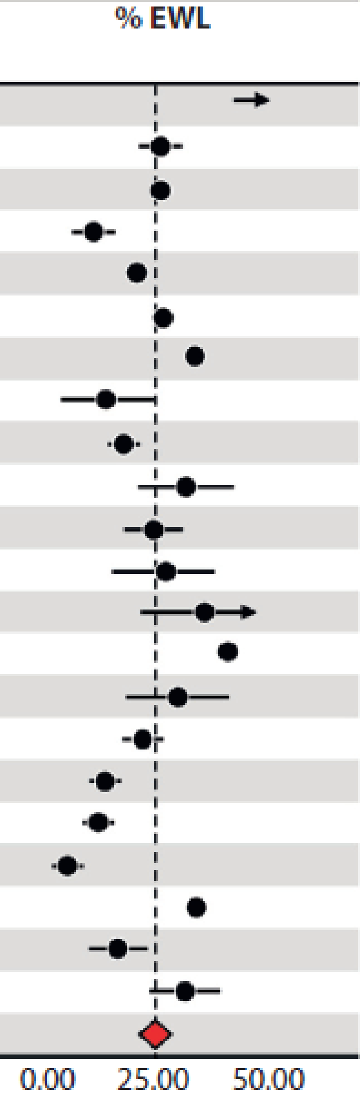


Figure 10. Meta-regression linear plot depicting the best-fit regression line of the association between baseline body mass indexes (BMIs) and percentage of excess weight loss (%EWL) at 6 months after Orbera intragastric balloon (IGB) implantation. The sample size of individual studies is proportional to the diameter of the circle by which it is represented on the graph.

ASGE meta-analysis

% EWL at 12 months with Orbera IGB

Study name	Subgroup within study	Statistics for each study			
		Mean	Lower limit	Upper limit	Total
Sallet 2004	Orbera	50.900	44.777	57.023	85
Herve 2005	Orbera	27.000	21.747	32.253	100
Angrisani 2006	Orbera	27.100	25.001	29.199	82
Ganesh 2006	Orbera	10.900	5.559	16.241	16
Genco 2007	Orbera	21.300	17.900	24.700	129
Crea 2008	Orbera	27.400	26.616	28.184	138
Genco 2009	Orbera	35.100	33.961	36.239	80
Ohta 2009	Orbera	14.000	2.913	25.087	8
Al Kahtan 2009	Orbera	18.000	13.680	22.320	137
Mui 2010	Orbera	32.900	21.325	44.475	68
Genco 2010	Orbera	25.100	17.838	32.362	50
Nikolic 2011_1	Orbera	27.800	15.300	40.300	19
Nickolic 2011_2	Orbera	37.400	22.437	52.363	24
Kotzampassi 2012	Orbera	43.000	41.127	44.873	384
Bozkurt_1_2012	Orbera	30.900	18.248	43.552	15
Bozkurt_2	Orbera	22.500	17.509	27.491	68
Bozkurt_3	Orbera	13.500	9.917	17.083	57
Boskurt_4	Orbera	12.300	8.741	15.859	62
Boskurt_5	Orbera	4.700	0.667	8.733	18
Farina 2012	Orbera	34.900	31.495	38.305	14
Dogan 2013	Orbera	16.700	9.743	23.657	50
Fuller 2013	Orbera	32.700	23.900	41.500	31
	Random	25.441	21.457	29.426	



ASGE meta-analysis complications

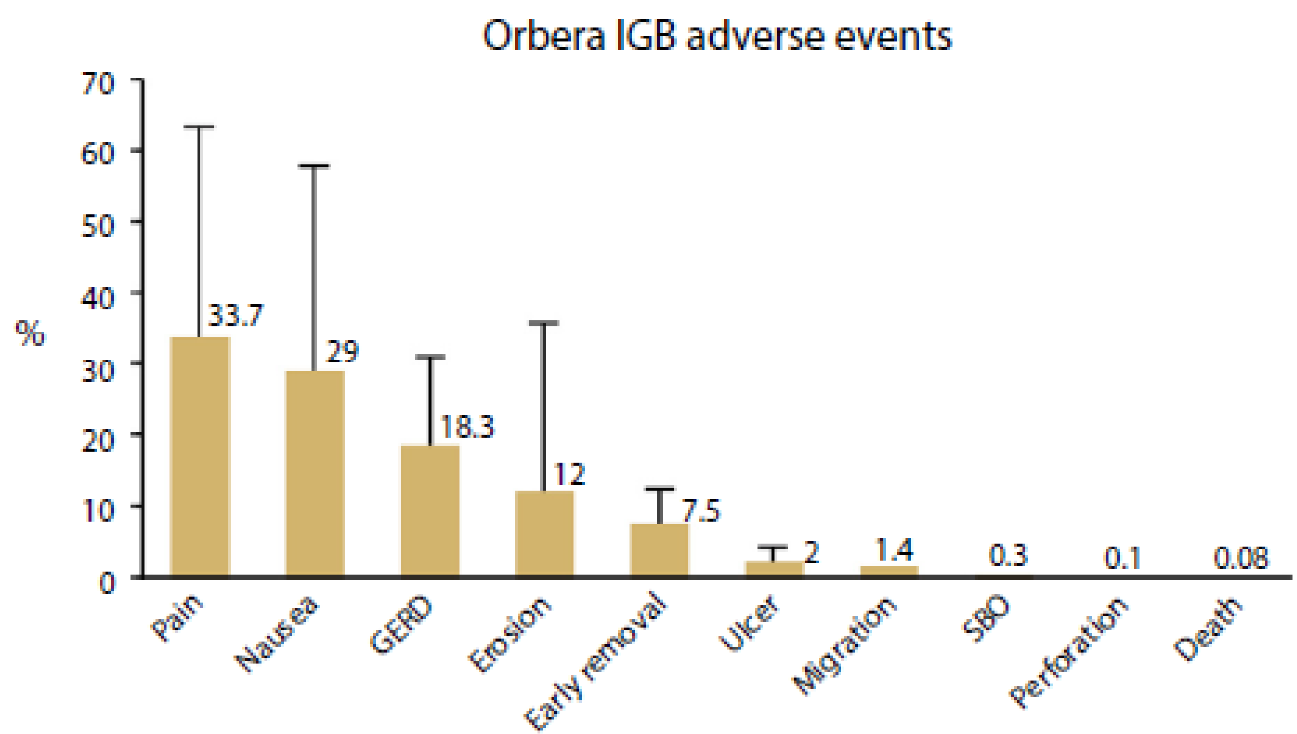


Figure 11. Pooled rates of adverse events observed with the Orbera intragastric balloon (IGB). *SBO*, small bowel obstruction.

The Impact of Intragastric Balloons on Obesity-Related Co-Morbidities: A Systematic Review and Meta-Analysis

Violeta B. Popov, MD, PhD[1], Amy Ou, MD[1], Allison R. Schulman, MD[2] and Christopher C. Thompson, MD, MHES[2]

Am J Gastroenterol advance online publication, 24 January 2017; doi:10.1038/ajg.2016.530

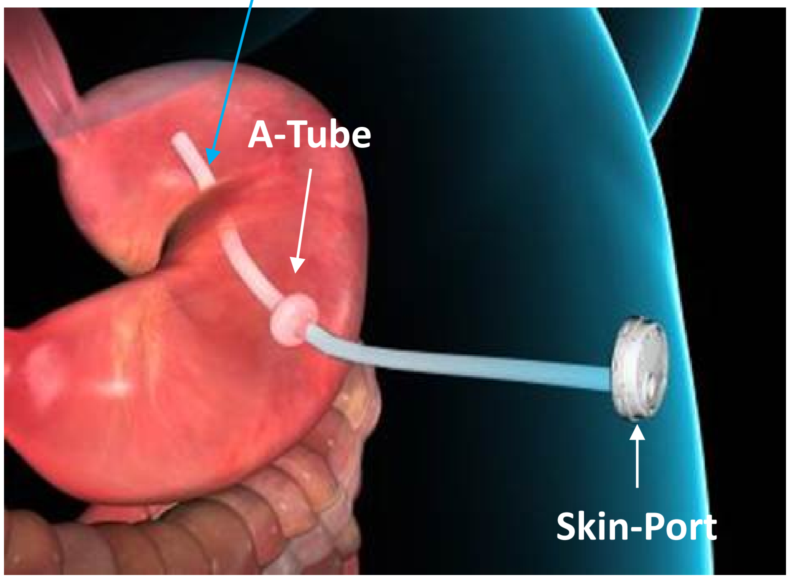
- 10 RCT and 30 observational studies including 5,668 subjects
- moderate-quality evidence for improvement in most metabolic parameters in subjects assigned to IGB therapy as compared to conventional non-surgical therapy in RCTs: mean difference (MD) in
  - fasting glucose change: -12.7 mg/dl (95% confidence interval (CI) -21.5, -4);
  - triglycerides: -19 mg/dl (95% CI -42, 3.5);
  - waist circumference: -4.1 cm (95% CI -6.9, -1.4);
  - diastolic blood pressure: -2.9 mm Hg (95% CI -4.1, -1.8).

  The odds ratio for diabetes resolution after IGB therapy was 1.4 (95% CI 1.3, 1.6). The rate of serious adverse events was 1.3%.

  IGBs are more effective than diet in improving obesity-related metabolic risk factors with a low rate of adverse effects, however the strength of the evidence is limited given the small number of participants and lack of long-term follow-up.

AspireAssist® System

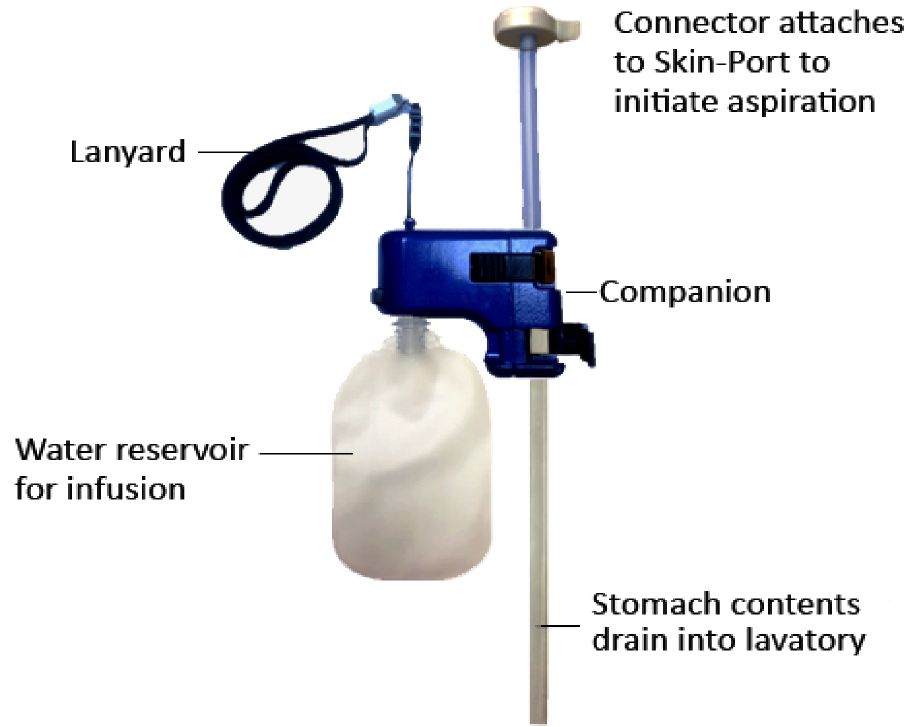
A-Tube, modified PEG tube, identical placement to PEG, placed endoscopically, using conscious sedation, on an out-patient basis

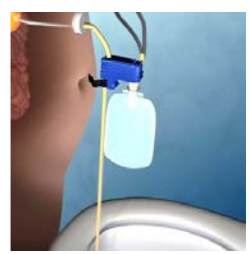


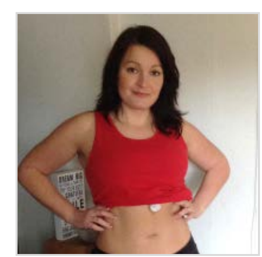
PEG tubes

- Used for feeding in patients unable to eat
- Used for removal of gastric fluid in patients with intestinal obstruction
- Have been in widespread use for 30+ years
- Best practice to avoid complications widely practiced

Two modes: Drain & Lavage

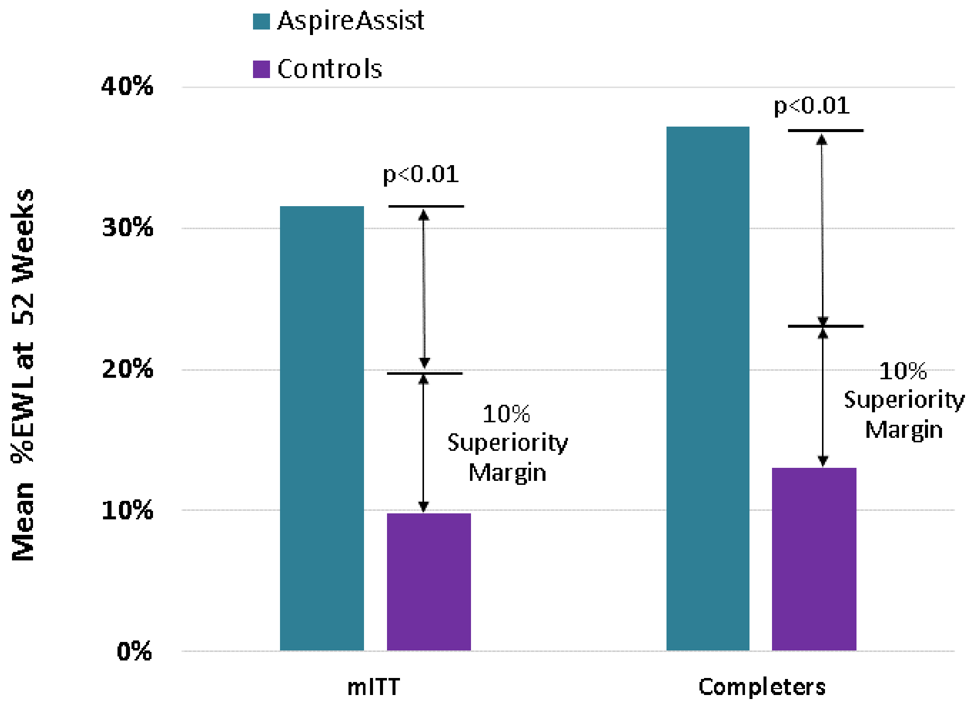



Device in Use

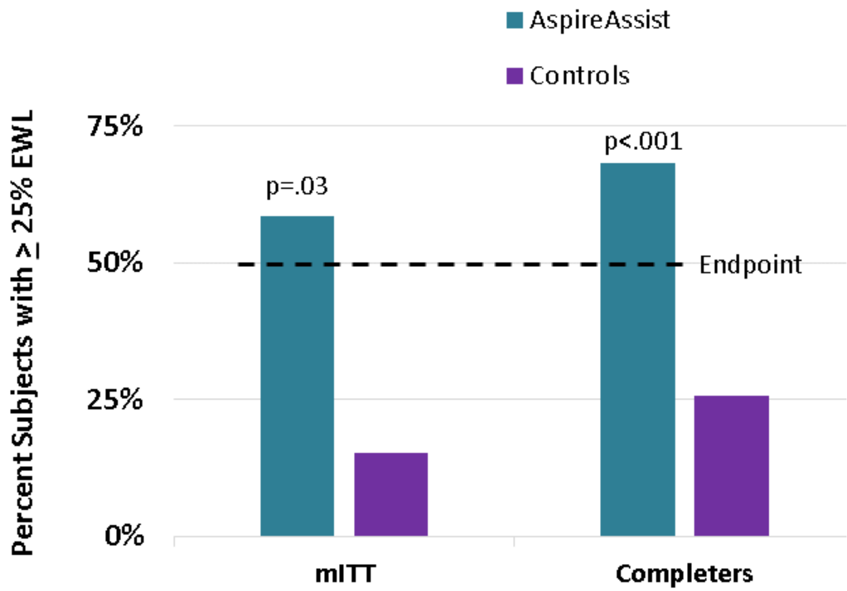

Device Not in Use

US Pivotal Study*: Two Co-Primary Endpoints Met

Co-Primary Endpoint #1
Mean %EWL at 52 Weeks of AT Group at least 10% greater than Control Group



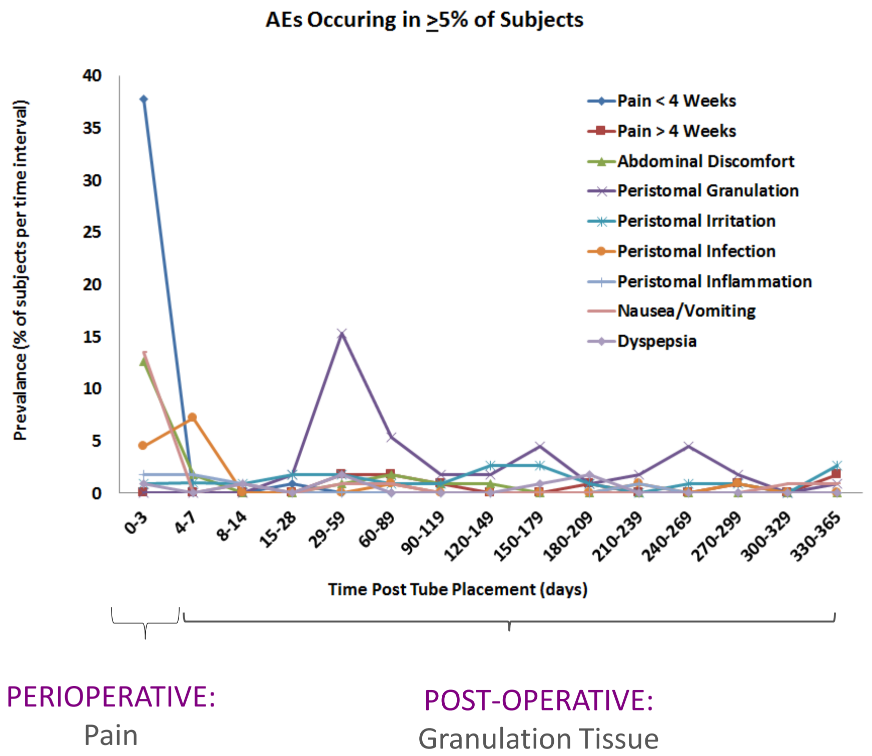
Co-Primary Endpoint #2
At least 50% of AT group achieves 25 %EWL or more at 52 Weeks



*Baseline BMI range: 35-55 kg/m^2; mean BMI=42.4 kg/m^2
Population 28% black/ African-American, 10% Hispanic, 4% other, 57% white/ non-Hispanic
171 Subject, 2:1 randomization

Excellent Safety from US Clinical Study

Few and relatively minor adverse events



Low Rate of Serious Adverse Events

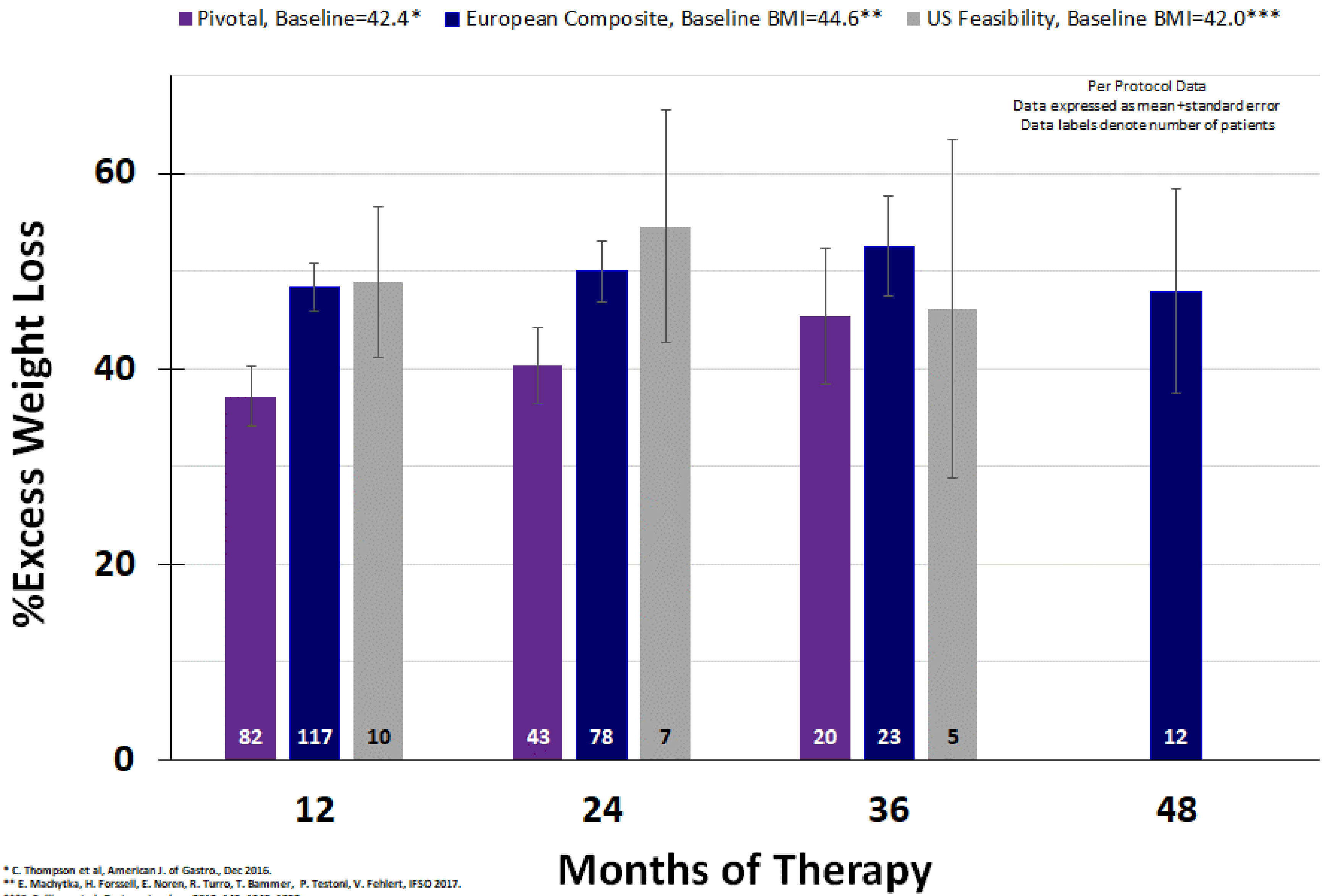
Only 5 SAEs in 4 subjects, all easily resolved (3.6% SAE rate)

1. Perioperative pain, 1 night stay Resolved with pain medication
2. Perioperative mild peritonitis, 2 night stay. Resolved w/ IV antibiotics
3. Post-operative: Mild ulceration. Resolved w/ A-Tube removal
4. Postoperative: A-Tube fungal growth, resolved w/ A-Tube replacement

No Metabolic / Electrolytic Abnormalities

Consistent Durable Weight Loss: 3 Different Studies

AspireAssist used in over 1,000 patients worldwide



* C. Thompson et al, American J. of Gastro., Dec 2016.
** E. Machytka, H. Forssell, E. Noren, R. Turro, T. Bammer, P. Testoni, V. Fehlert, IFSO 2017.
***S. Sullivan et al, Gastroenterology 2013; 145: 1245–1252

Barriers to care

1. National estimates of eligibility vs. procedure numbers
2. Obesity in American national poll results
3. Physician behavior

ASMBS Guidelines/Statements

American Society for Metabolic and Bariatric Surgery estimation of bariatric surgery procedures in 2015 and surgeon workforce in the United States

Jaime Ponce, M.D.[a,*], Eric J. DeMaria, M.D.[b], Ninh T. Nguyen, M.D.[c], Matthew Hutter, M.D.[d], Ranjan Sudan, M.D.[e], John M. Morton, M.D.[f]

Table 1
Total number of bariatric procedures, 2011–2015

Year	2011	2012	2013	2014	2015
Total	158,000	173,000	179,000	193,000	196,000
RYGB	36.7%	37.5%	34.2%	26.8%	23.1%
LAGB	35.4%	20.2%	14%	9.5%	5.7%
SG	17.8%	33%	42.1%	51.7%	53.8%
BPD/DS	.9%	1%	1%	.4%	.6%
Revisions	6%	6%	6%	11.5%	13.6%
Other	3.2%	2.3%	2.7%	.1%	3.2%

ASMBS Guidelines/Statements

American Society for Metabolic and Bariatric Surgery estimation of bariatric surgery procedures in 2015 and surgeon workforce in the United States

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According to the 2015 projections from the U.S. Census [2] the total population of the United States was 321,418,820, of whom 247,773,209 were adults aged 18 years or older. Using the obesity prevalence data (body mass index ≥40; 6.4% of adults) [3] 15,857,485 estimated individuals qualified for bariatric surgery. Thus, the rate of bariatric surgery in the qualified population based solely on body mass index criteria in 2015 is estimated at 1.24%. When analyzing only the numbers of primary procedures compared with the number of "eligible" candidates, the penetration rate of surgery in the candidate population in 2011 was .976% and increased to 1.068% in 2015. Over the 5-year period between 2011 and 2015, these data suggest that the penetration rate of surgery in the "eligible" population increased by an annual average of only 1.9% (number of primary procedures per eligible candidate).

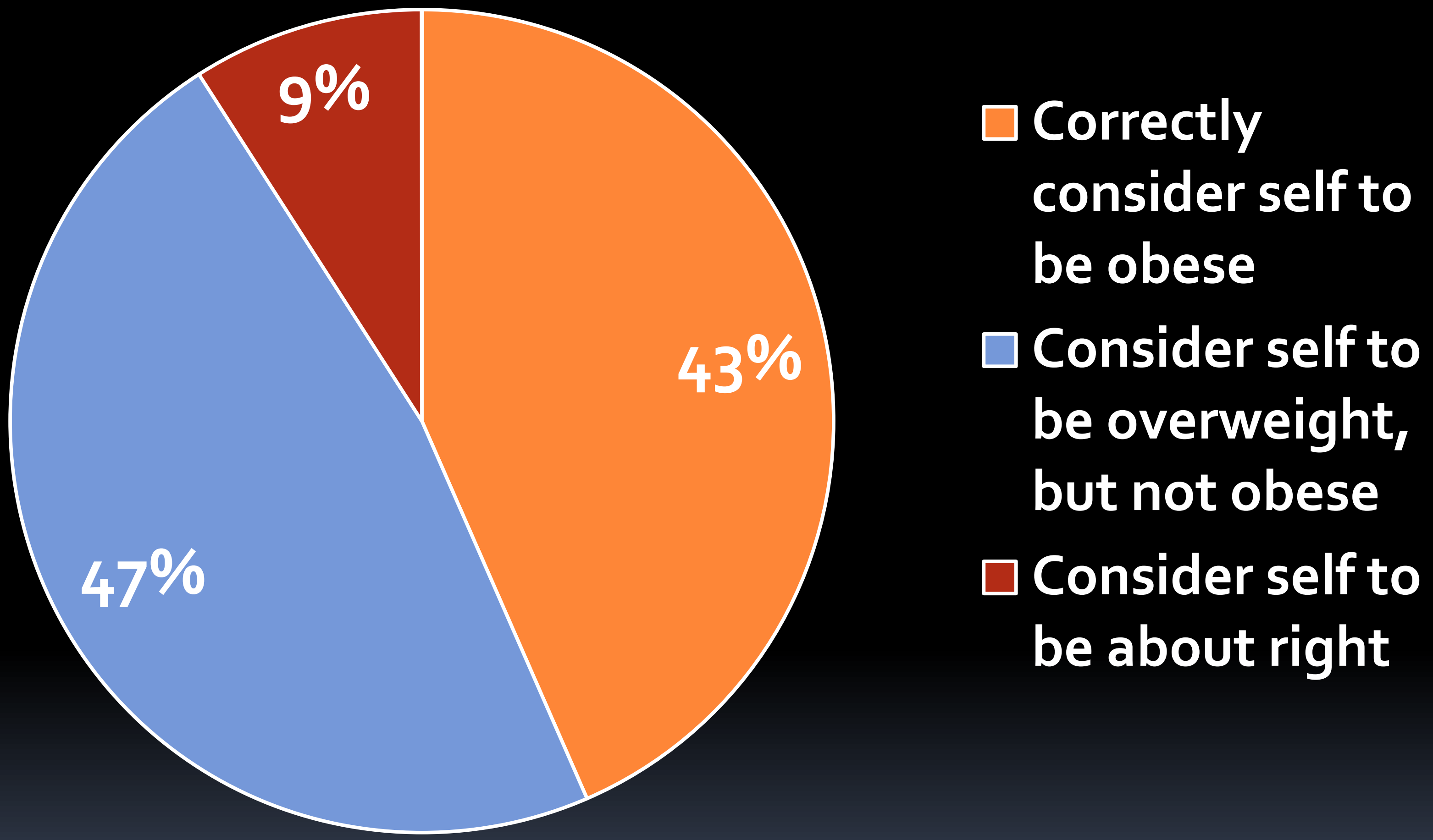
Bariatric surgery procedure numbers are increasing primarily due to the overall growth of the US population.

Annual increase in application of surgical treatment in the eligible population (based on BMI) was only 1.9%

Obesity in America Survey

- Obesity and cancer tied top 2 most often cited serious health problem
- 86% obesity is very high risk to a person's overall health
- 93% agree obesity increases a person's risk of dying young
- Only 37% believe obesity itself is a disease
- 40% with BMI criteria for obesity have not talked with a doctor / health professional about their weight

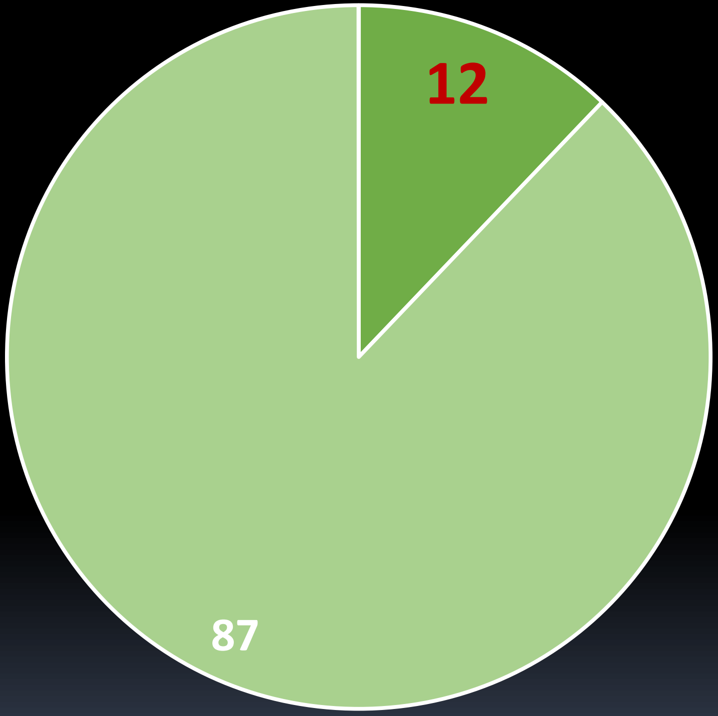
Among those whose BMI places them as obese…



Obesity in America Survey What are the most effective treatments?

- Losing weight on one's own through diet and exercise is considered the most effective weight loss method (78%)
- Formal exercise programs (72%)
- losing weight with the help of a doctor (68%)
- one-on-one dietary counseling (61%)
- weight loss surgery (59%)……in 5th place
- formal weight loss programs (53%)

Percent of Americans Who Are Surgically Eligible Whose Doctor Suggested Surgery = 12%



Doctor said person is candidate for weight loss surgery

Doctor hasn't suggested surgery

Which treatments are viewed as SAFE?

- Weight Loss Surgery
  - 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
- Prescription medications and dietary supplements
  - Only 17% rate these methods as very safe or safe

Physicians / Providers

knowledge
awareness
behavior
priorities

NATIONAL OBESITY COLLABORATIVE CARE

SUMMIT '16

eat right. Academy of Nutrition and Dietetics

American Association of Clinical Endocrinologists
AACE
The Voice of Clinical Endocrinology

American Society of Anesthesiologists

OAC
Obesity Action Coalition

ADA

AAOS
American Academy of Orthopaedic Surgeons

American College of Occupational and Environmental Medicine
ACOEM
·1916·

ASCO
American Society of Clinical Oncology

ENDOCRINE SOCIETY

American Sleep Apnea Association

American Academy of Physician Assistants
Connecting PAs, Transforming Care

American Diabetes Association

American Society of Plastic Surgeons

STOP
Strategies to Overcome & Prevent Obesity Alliance

American College of Sports Medicine
Leading the Way
Founded 1954

AMA
American Medical Association

ASMBS

International Society for the Perioperative Care of the Obese Patient
ISPCOP

BlueCross BlueShield

AANP
American Association of Nurse Practitioners

PROVIDER
American Association for the Study of Liver Diseases
AASLD

American College of Surgeons
Inspiring Quality: Highest Standards, Better Outcomes
100+years

Obesity Society

nla
National Lipid Association

OPTUM

PBGH
Pacific Business Group on Health

American Academy of Sleep Medicine
Wake
Sleep

The American College of Obstetricians and Gynecologists
Women's Health Care Physicians
1951

American Society of Bariatric Physicians
Established 1950

American Society for Reproductive Medicine
1944

American Society for Gastrointestinal Endoscopy
ASGE

Towers Watson

Conclusions

- Bariatric surgery is SAFE
- Bariatric surgery is EFFECTIVE
  - Improves SURVIVAL
  - Improves HEALTH
  - Improves QUALITY OF LIFE

- Only 1% of eligible people are treated / year

The only successful longterm treatment for the disease of obesity is not currently being optimally utilized in treatment

Next steps for CMS

- Approve coverage for DIABETES SURGERY in patients with BMI <35
- Require MBSAQIP Accreditation
  - Tracking outcomes with clinically rich data
- Approve less invasive treatments to fill the gap in the continuum of obesity care
  - Intragastric balloons, aspireassist, VBLOC

Critical to mount awareness campaigns for both the Public and Physicians