BARIATRIC AND METABOLIC SURGERY EVIDENCE

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BARIATRIC SURGERY IN THE MEDICARE POPULATION

- Analyses of Medicare data for patients receiving bariatric surgery shows:
  - 65-70% of Medicare beneficiaries undergoing bariatric surgery are <65 years
  - Average age of Medicare beneficiaries undergoing surgery is ~46 years
  - Average age in commercial insurance population is ~43 years

- Of the 70 studies that met eligibility criteria of AHRQ review regarding safety and efficacy of bariatric surgery, majority (57 studies) were on patient populations with a mean and/or median age of 55 years or above

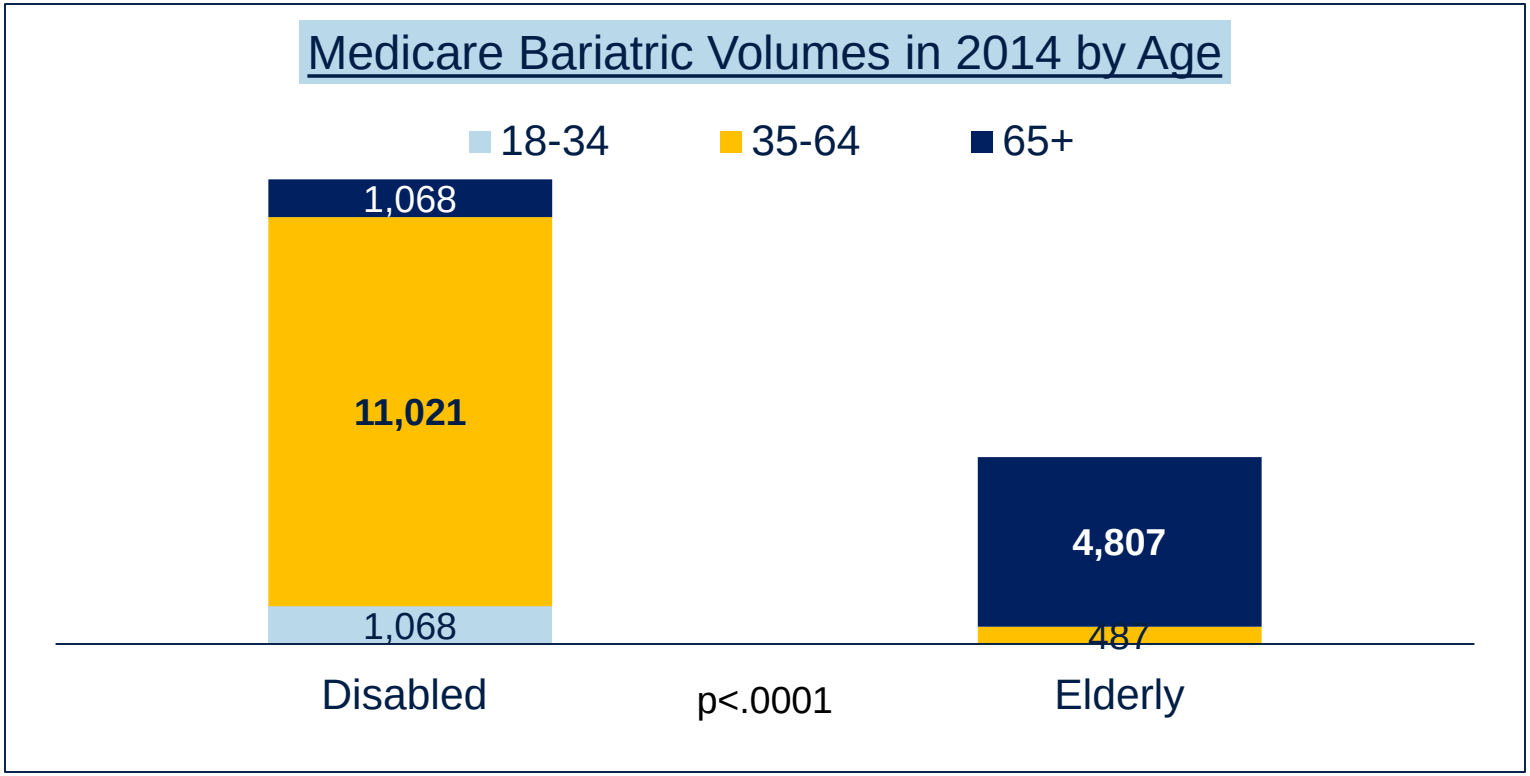
- Conclusion of AHRQ review that the strength of evidence is low to moderate does not include 25+ RCT's, technology assessments by CTAF and the State of Washington HCA, and numerous prospective and retrospective trials that are directly relatable to the majority of Medicare beneficiaries who undergo bariatric surgery

- Published body of evidence that supports safety and efficacy of bariatric surgery for treatment of obesity and related co-morbidities, notably Type 2 Diabetes, is substantial, continues to grow, and should be applied in the evaluation of its benefits for the Medicare population

Young et al. A Decade Analysis of Trends and Outcomes of Bariatric Surgery in Medicare Beneficiaries. J Am Coll Surg 2014;219:480e488.

MOST MEDICARE BARIATRIC CASES ARE IN THE DISABLED AVERAGE AGE OF MEDICARE BARIATRIC PATIENTS IS 46

- 71% of Medicare beneficiaries undergoing bariatric surgery were disabled
- 66% of Medicare beneficiaries undergoing bariatric surgery <65 years old
- 46 years: average age of Medicare beneficiaries undergoing bariatric surgery



Medtronic analysis of Medicare 2014 data

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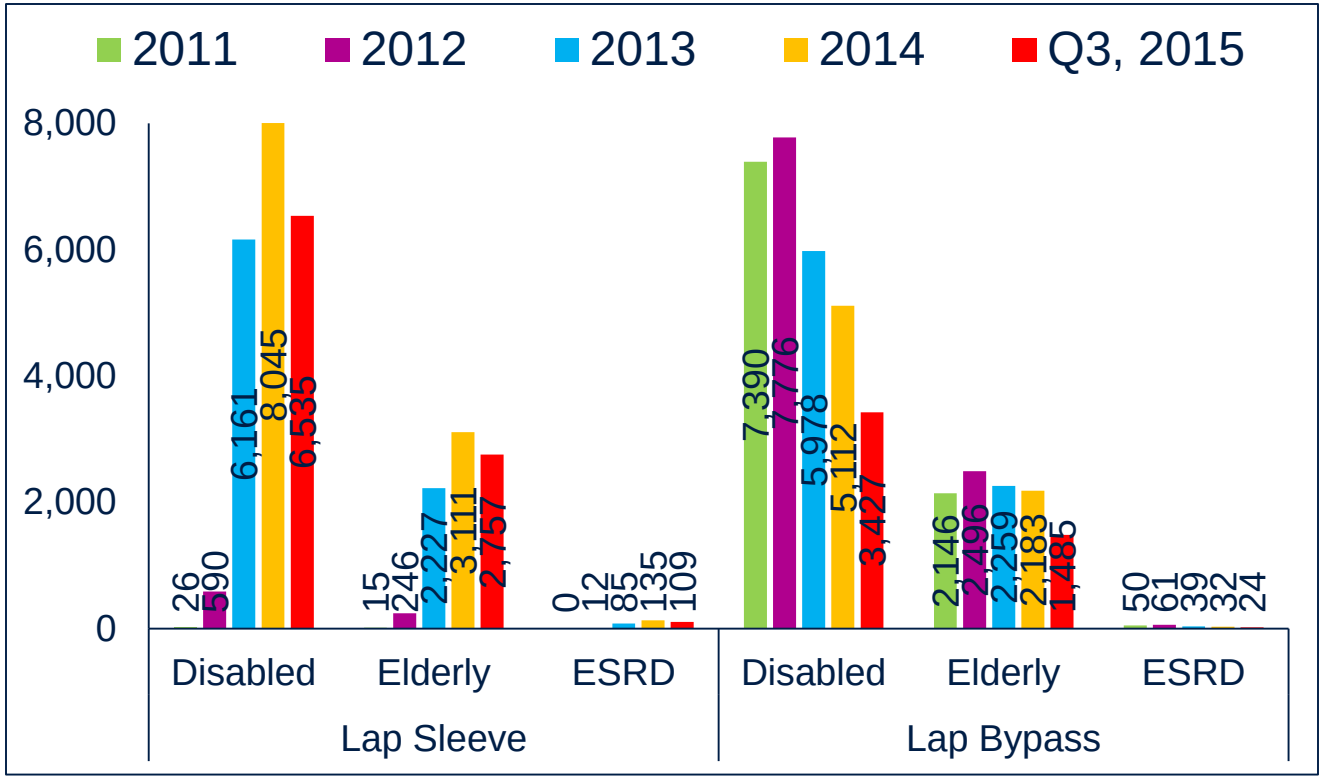
DISABLED POPULATION HAS CONSISTENTLY REPRESENTED THE MAJORITY OF BARIATRIC MEDICARE BENEFICIARIES

PROCEDURES DATA 2011-Q3,2015 (LAP SLEEVE & LAP BYPASS)

Procedural Volumes				
2011	2012	2013	2014	Q1-Q3, 2015
9,627	11,181	16,749	18,618	14,337



Bariatric surgery in the Medicare population

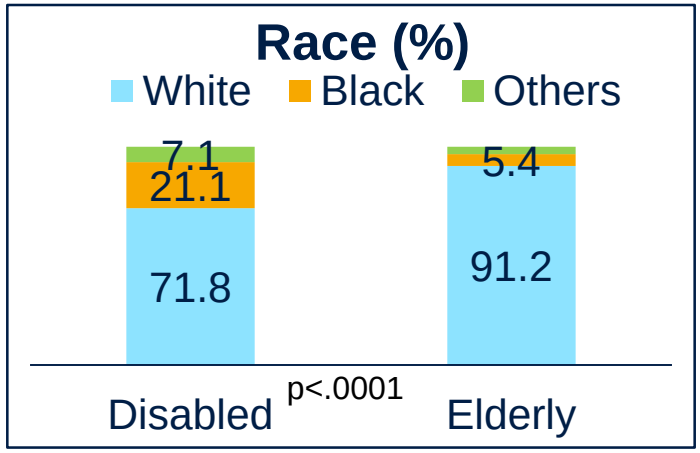
Time	% Disabled+ ESRD
2011	77%
2012	75%
2013	73%
2014	72%
Q1-Q3, 2015	71%

Medtronic analysis of Medicare data

Medtronic

DISABLED BARIATRIC SURGERY COMPRISES A HIGHER PROPORTION OF WOMEN AND MINORITIES
MEDICARE DATA 2014 (LAP SLEEVE & LAP BYPASS)

	Disabled	Elderly	p-value
# cases	13,157	5,294	
Lap Sleeve	61.1%	58.8%	0.0028
Lap Bypass	38.9%	41.2%	
Female	75.8%	67.0%	<0.0001
Midwest	24.7%	21.8%	<0.0001
Northeast	20.4%	17.3%	
South	40.4%	44.1%	
West	14.4%	16.8%	



Percent of Medicare bariatric surgeries in the non-white population	
Disabled	28%
Elderly	9%

Medtronic analysis of Medicare data

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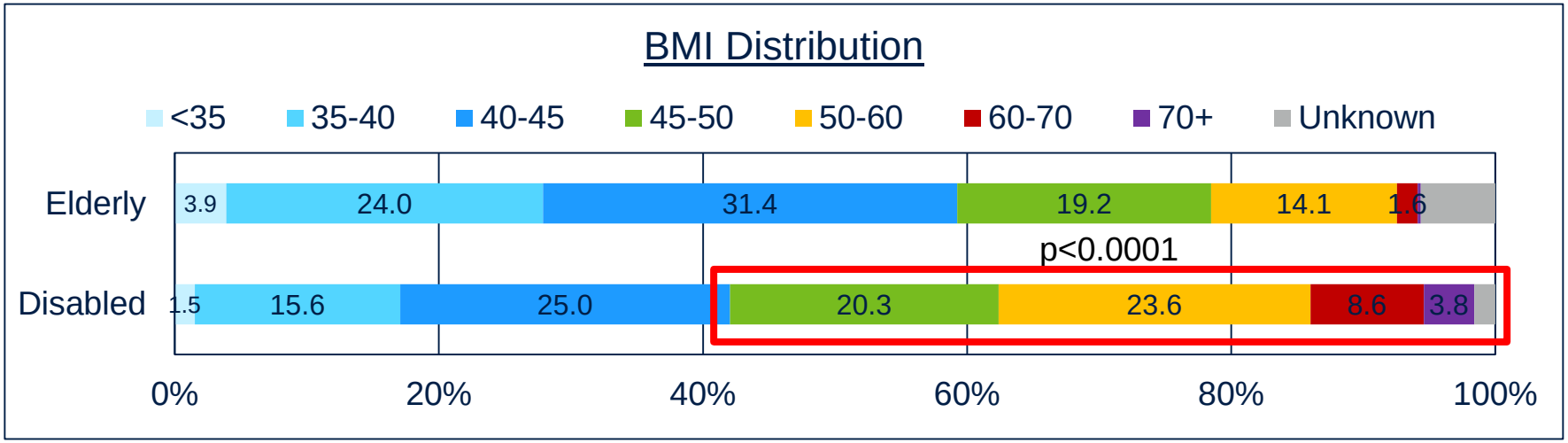
DISABLED POPULATION HAVE SIGNIFICANTLY HIGHER BMI THAN ELDERLY

MEDICARE DATA 2014



Comorbidity	Disabled	Elderly	p-value
Hyperlipidemia	64.5%	74.3%	<0.0001
Hypertension	80.3%	87.0%	<0.0001
CAD	15.5%	22.9%	<0.0001
Type 2 Diabetes	55.7%	57.4%	0.0404
Sleep apnea	67.4%	60.0%	<0.0001
Osteoarthritis	24.7%	24.1%	0.3436
GERD	66.0%	60.0%	<0.0001
Depression	44.0%	26.6%	<0.0001

- Elderly tend to have more cardiovascular comorbidities
- Disabled tend to have more sleep apnea and depression
- More than half of the elderly and disabled have Type II diabetes

Medtronic analysis of Medicare data

BARIATRIC SURGERY OUTCOMES IN THE MEDICARE POPULATION HAVE SIGNIFICANTLY IMPROVED OVER TIME

NATIONWIDE INPATIENT SAMPLE 2001-2010

Patient characteristics	Medicare, 2001–2005 (n = 46,210)	Medicare, 2006–2010 (n = 79,005)	p Value
Age, y, mean ± SD	45 ± 12*	48 ± 14	<0.01
Outcomes			
Length of stay, d	4*	3	<0.01
In-hospital mortality, %	0.56*	0.23	<0.01
Serious morbidity, %	9.92*	6.98	<0.01
Anastomotic leak, %	2.34*	1.69	0.04
Sepsis, %	0.41	0.45	0.73
Wound complications, %	1.53*	0.66	<0.01
Ileus, %	0.88	1.03	0.25
Bowel obstruction, %	0.06	0.11	0.39
Urinary tract infection, %	1.42*	0.89	<0.01
Pneumonia, %	1.16*	0.59	<0.01
Respiratory failure, %	3.42*	1.34	<0.01
Acute renal failure, %	2.46	2.37	0.69
Cardiac complications, %	1.33*	0.89	<0.01
CVA, %	0.01	<0.01	0.79
DVT, %	0.09	0.08	0.91
Postoperative bleeding, %	1.66	1.46	0.25
Total charge, $, mean ± SD**	33,152 ± 36,903*	39,486 ± 38,530	<0.01

*p Value <0.05 compared with Medicare 2001 through 2005. ** Not adjusted for inflation and case mix

Significant Improvement

Medicare bariatric cases before NCD had higher rates of risk-adjusted in-hospital mortality (OR=2.32; 95% CI, 1.49-3.70) and serious morbidity (1.25; 1.13-1.39)

Young et al. A Decade Analysis of Trends and Outcomes of Bariatric Surgery in Medicare Beneficiaries. J Am Coll Surg 2014;219:480e488.

KEY RANDOMIZED STUDIES ON BARIATRIC SURGERY

Study	Setting	Population	Follow up	Key findings
SG versus medical management				
Kashyap et al. 2013	US	Patients with uncontrolled type 2 diabetes (mean HbA1c 9.7%) and moderate obesity (mean BMI 36 kg/m^2) SG n=19; Medical management n=17	2 years	Weight loss: 22.3 kg for SG, 0.5 kg medical management (p<0.001) HbA1c reduction: 2.5% with SG versus 1.1% with medical management (p=0.06)
Schauer et al. 2012	US	Patients aged 20–60 years with a diagnosis of type 2 diabetes and a BMI 27–43 kg/m^2 SG n=49; Medical management n=41	1 year	Proportion achieving HbA1c ≤6.0%: 37% for SG, 12% for medical management (p=0.008) Reduction in HbA1c: −2.9% for SG, −1.4% for medical management (p<0.001) Reduction in body weight: 25.1 kg for SG, −5.4 kg for medical management (p<0.001)
RYGB versus medical management				
Ikramuddin et al. 2013	US and Taiwan	Patients with type 2 diabetes with HbA1c≥8.0% and BMI 30–40 kg/m^2 RYGB n=60 Medical management n=60	1 year	HbA1c<7%, LDL<100 mg/dL and SBP<130 mmHg (composite endpoint): achieved by 49% of RYGB group, 19% of medical management group (p<0.05) Reduction in body weight: 26.1% for RYGB, 7.9% for medical management arm (p<0.05)
Kashyap et al. 2013	US	Patients with uncontrolled type 2 diabetes (mean HbA1c 9.7%) and moderate obesity (mean BMI 36 kg/m^2) RYGB n=18; Medical management n=17	2 years	Weight loss: −25.4 kg for RYGB, −0.5 kg for medical management (p<0.001) Change in HbA1c: −3.1% with RYGB versus −1.1% with medical management (p<0.001)
Mingrone et al. 2012	Italy	Patients aged 30–60 years with BMI>35 kg/m^2, a history of at least 5 years of diabetes, and an HbA1c>7.0% RYGB n=20; Medical management n=20	2 years	Diabetes remission: 75% for RYGB, 0 for medical management (p<0.001) Change in HbA1c: reduced in all arms, but greater reduction in the RYGB arm (p=0.003) Reduction in BMI: 15.54 kg/m^2 with RYGB versus 2.55 kg/m^2 with medical management (p<0.001)
Schauer et al. 2012	US	Patients aged 20–60 years with a diagnosis of type 2 diabetes and a BMI 27–43 kg/m^2 RYGB n=50; Medical management n=41	1 year	Patients with HbA1c ≤6.0%: 42% for RYGB, 12% for medical management (p=0.002) Reduction in HbA1c: −2.9% for RYGB, −1.4% for medical management (p<0.001) Reduction in body weight: −29.4 kg for RYGB, −5.4 kg for medical management (p<0.001)
Hofsø et al. 2011	Norway	Morbidly obese patients without known diabetes RYGB n=64; Intensive lifestyle intervention n=55	1 year	Reduction in body weight: 30% for RYGB versus 9% for intensive lifestyle intervention (p<0.001) Measures of beta cell function (disposition index and proinsulin to insulin ratio): improved to a greater extent in the RYGB group than in the intensive lifestyle intervention group (both p<0.05)

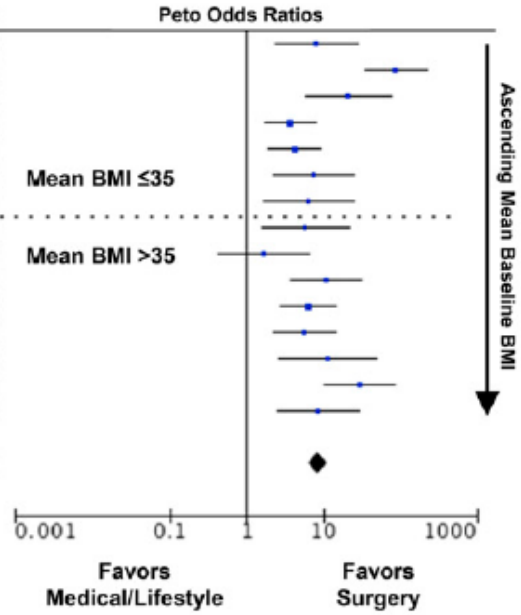
11 RANDOMIZED STUDIES ON METABOLIC EFFECTS SHOW SUPERIORITY OF SURGERY OVER MEDICAL LIFESTYLE

ENDORSED BY AMERICAN DIABETES ASSOCIATION

A

Study (Operation) [Follow-up; HbA_{1c} end point]	Surgery Glyc. Endp.	Surgery N	Medical/ Lifestyle Glyc. Endp.	Medical/ Lifestyle N	Weight	Peto, Fixed, 95% CI
Wentworth 2014 (LAGB) [24 mo; ≤7.0%] (17)	12	23	2	25	4.9%	8.11 [2.37, 27.84]
Liang 2013 (RYGB) [12 mo; ≤7.0% off meds] (16)	28	31	0	70	8.4%	86.76 [33.89, 222.08]
Parikh 2014 (RYGB/LAGB/SG) [6 mo; ≤6.5% off meds] (18)	13	20	0	24	4.5%	21.15 [5.85, 76.51]
Ikramuddin 2013 (RYGB) [12 mo; ≤7.0%] (13)	28	57	11	57	12.5%	3.72 [1.72, 8.04]
Ikramuddin 2015 (RYGB) [24 mo; ≤7.0%] (21)	26	60	8	59	11.8%	4.25 [1.92, 9.38]
Courcoulas 2014 (RYGB/LAGB) [12 mo; ≤6.5% off meds] (14)	18	41	0	17	5.1%	7.51 [2.24, 25.21]
Courcoulas 2015 (RYGB/LAGB) [36 mo; ≤6.5% off meds] (24)	14	37	0	14	4.0%	6.44 [1.65, 25.21]
Halperin 2014 (RYGB) [12 mo; ≤6.5% off meds] (15)	11	19	3	19	4.4%	5.82 [1.59, 21.39]
Ding 2015 (LAGB) [12 mo; ≤6.5%] (22)	6	18	5	22	3.9%	1.68 [0.42, 6.66]
Dixon 2008 (LAGB) [24 mo; ≤6.2% off meds] (10)	22	29	4	26	6.7%	10.83 [3.79, 30.96]
Schauer 2012 (RYGB/SG) [12 mo; ≤6.0%] (12)	34	99	0	41	10.4%	6.39 [2.74, 14.88]
Schauer 2014 (RYGB/SG) [36 mo; ≤6.0%] (19)	27	97	0	40	8.7%	5.73 [2.28, 14.42]
Cummings 2016 (RYGB) [12 mo; ≤6.5% off meds] (23)	9	15	1	17	3.4%	11.48 [2.63, 50.13]
Mingrone 2012 (RYGB/BPD) [24 mo; ≤6.5% off meds] (11)	34	40	0	20	6.4%	30.08 [10.28, 88.06]
Mingrone 2015 (RYGB/BPD) [60 mo; ≤6.5% off meds] (20)	19	38	0	15	4.9%	8.44 [2.46, 29.01]
Fixed-Effects Model		624		466	100.0%	8.45 [6.44, 11.10]

Heterogeneity: $Chi^2 = 45.43$, df = 14 ($P < 0.0001$); $I^2 = 69\%$
Test for overall effect: Z = 15.36 ($P < 0.00001$)



"On the basis of such evidence, metabolic surgery should be recommended to treat T2D in patients with class III obesity (BMI ≥40 kg/m^2) and in those with class II obesity (BMI 35.0–39.9 kg/m^2) when hyperglycemia is inadequately controlled by lifestyle and optimal medical therapy. Surgery should also be considered for patients with T2D and BMI 30.0–34.9 kg/m^2 if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications."

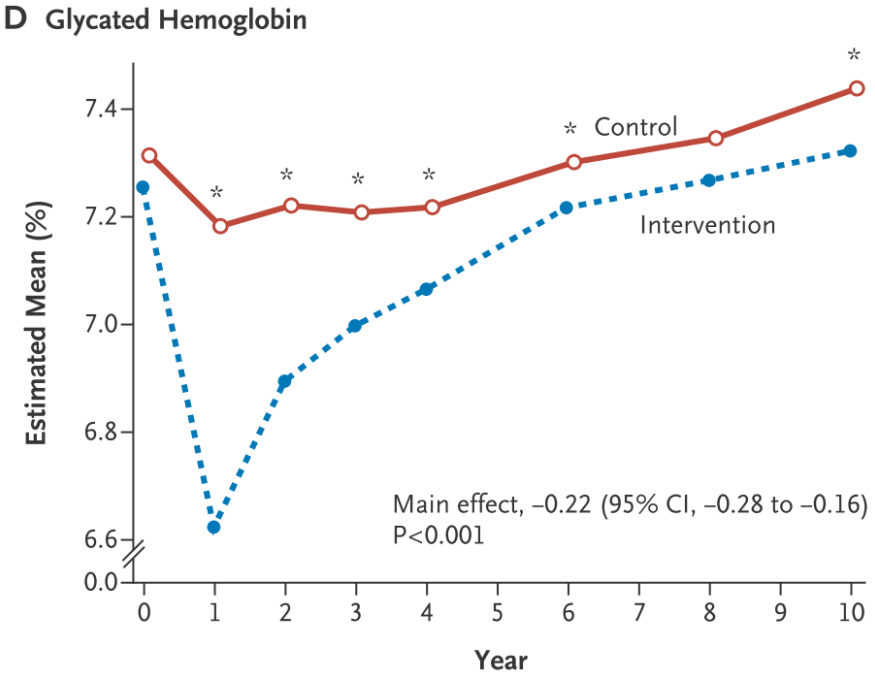
Rubino and associates. Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations. Diabetes Care 2016;39:861–877

LIFESTYLE INTERVENTION IS FUTILE IN OBESE PATIENTS WITH TYPE 2 DIABETES

- The Look AHEAD trial (N= 5,145) was **stopped early** on the basis of futility analysis, **lifestyle intervention** (physical activity and low caloric intake) **did not reduce cardiovascular (CV) events** compared with support and education

- Weight loss was higher with intervention, 6.0% vs. 3.5% at study end

- CV death, myocardial infarction, stroke or angina, occured at 1.83 and 1.92 events per 100 person-years in the intervention and control groups, respectively



- At 1 year, intervention patients showed significantly reduced: weight, HbA1c, waist circumference
- But from year 2 onwards, these tended back toward baseline

The Look AHEAD Research Group. Cardiovascular Effects of Intensive Lifestyle Intervention in Type 2 Diabetes. N Engl J Med 2013; 369:145-154

KEY DATA REFERENCES ADDRESSING MEDCAC & AHRQ QUESTIONS:

Contents:

- Grid with links to key study summaries addressing meaningful primary health outcome studies of bariatric surgery
- Key study summaries
- Predictors of success
- Table of RCT's regarding bariatric surgery vs. medical management
- Table of key prospective and retrospective studies on bariatric surgery outcomes
- Table of meta analyses of bariatric surgery impact on co-morbidities
- Comparative graphic of sleeve gastrectomy vs. bypass for diabetes remission

MEDCAC QUESTIONS

Voting Questions

For each voting question, please use the following scale identifying your level of confidence with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5
Low Confidence — *Intermediate* — *High Confidence*

1. How confident are you that the following are meaningful primary health outcomes in research studies of bariatric surgery:

   a. Weight loss;
   b. Postoperative complications;
   c. Diabetes and metabolic outcomes;
   d. Cardiovascular outcomes;
   e. Respiratory outcomes;
   f. Musculoskeletal outcomes; and
   g. Quality of life.

2. How confident are you that there is sufficient evidence for an intervention (to include open and laparoscopic surgeries and endoscopic procedures) where the benefit outweighs the harm for:

   a. Short term (2 years or less from surgery) weight loss?
   b. Mid-term (more than 2 but 5 or less from surgery) weight loss?
   c. Long-term (more than 5 years after surgery) weight loss?

3. For those outcomes listed in Question 1 with a voting score >2.5, how confident are you that there is sufficient evidence for an intervention (to include open and laparoscopic surgeries and endoscopic procedures) where the benefit outweighs the harm for:

   a. Short term (2 years or less from surgery) outcomes?
   b. Mid-term (more than 2 but 5 or less from surgery) outcomes?
   c. Long-term (more than 5 years after surgery) outcomes?

4. How confident are you that the predictors of success in the Medicare population (such as patient characteristics and pre and post procedure standards of care) for any bariatric therapy is known?

   Discussion: List the predictors of success and the correspondent strength of evidence.

Source: https://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=74

AHRQ KEY QUESTIONS

KQ 1: What are the theorized mechanisms of action of bariatric procedures on weight loss and on type 2 diabetes in the Medicare population?

KQ 2: In studies that are applicable to the Medicare population and enroll patients who have undergone bariatric therapy, what are
a) the characteristics and indications of the patients including descriptives of age, BMI, and comorbid conditions
b) the characteristics of the interventions, including the bariatric procedures themselves as well as pre- and/or post-surgical surgical work-ups (e.g., psychiatric evaluations, behavioral and nutritional counseling)
c) the outcomes that have been measured, including peri-operative (i.e., 90 days or less after bariatric surgery), short-term (2 years or less from surgery), mid-term (more than 2 but 5 or less years), and long-term (more than 5 years after surgery) outcomes?

KQ 3a: In Medicare-eligible patients, what is the effect of different bariatric therapies (contrasted between them or vs. non-bariatric therapies) on weight outcomes (including failure to achieve at least minimal weight loss)?

KQ 3b: What patient- (KQ2a) and intervention-level characteristics (KQ2b) modify the effect of bariatric therapies on weight outcomes (including failure to achieve at least minimal weight loss)?

KQ 3c: In Medicare-eligible patients who have undergone bariatric therapy, what is the frequency and the predictors of failing to achieve at least minimal weight loss?

KQ 4a: In Medicare-eligible patients, what is the comparative effectiveness and safety of different bariatric interventions (contrasted between them or vs. non-bariatric interventions) with respect to the outcomes in KQ2c?

KQ 4b: What patient- (KQ2a) and intervention-level (KQ2b) characteristics modify the effect of the bariatric therapies on the outcomes in KQ2c?

KQ 5a: In Medicare-eligible patients who have undergone bariatric therapy, what is the association between weight outcomes and eligible short- and long-term outcomes (other than weight outcomes)?

KQ 5b: In Medicare-eligible patients, what proportion of the bariatric intervention effect on eligible short- and long-term outcomes (other than weight outcomes) is accounted for by changes in weight outcomes?

EVIDENCE GRID & MEDCAC QUESTIONS

Click on green link for study details

Outcomes	Short-term (≤2 years)	Mid-term (2-5 years)	Long-term (5+ years)
Weight loss	RCT: STAMPEDE*, CROSSROADS*, DSS*		VA-Arterburn, SOS
Post-operative complications	Young, Sanni	Chang	
Diabetes & metabolic	CROSSROADS*, DSS*	STAMPEDE*	VA data, SOS
Cardiovascular	Benotti		SOS
Respiratory	Sarkhosh		SOS
Musculoskeletal	King, Gill, Lidar		SOS
Quality of Life	STAMPEDE*		SOS

Predictors of outcomes: Clinical and Behavioral

Procedures in scope: Laparoscopic sleeve gastrectomy, Laparoscopic roux-en-Y gastric bypass

* Includes BMI 30-35

TRENDS IN MEDICARE BARIATRIC OUTCOMES
NATIONWIDE INPATIENT SAMPLE 2001-2010

Table 1. Patient Demographics and Comorbidities for Medicare vs Non-Medicare Patients, 2001 Through 2010

	Medicare (n = 125,322)	Non-Medicare (n = 649,718)	p Value
Age, y, mean	46*	43	<0.01
Sex, %			
Male	19.3*	18.8	<0.01
Female	80.7	81.2	0.10
Race or ethnicity, %			
White	68.8*	77.6	<0.01
Black	16.9*	12.0	<0.01
Hispanic	10.8*	6.0	<0.01
Asian or Pacific Islander	0.2*	0.5	<0.01
Native American	0.3*	0.5	<0.01
Other	2.9*	3.4	<0.01
Comorbidities			
Comorbidity score	2*	1	<0.01
Congestive heart failure, %	4.20*	1.0	<0.01
Chronic pulmonary disease, %	25.30*	15.30	<0.01
Diabetes, %	40.50*	26.0	<0.01
Hypertension, %	58.70*	49.10	<0.01
Liver disease, %	8.70*	8.0	<0.01
Peripheral vascular disorder, %	0.90*	0.40	<0.01
Renal failure, %	1.90*	0.50	<0.01

*p Value <0.05 compared with non-Medicare.

After 2006 NCD, there was significant reduction of in-hospital mortality (0.56% vs 0.23%; p < 0.01) and serious morbidity (9.92% vs 6.98%; p< 0.01) for Medicare

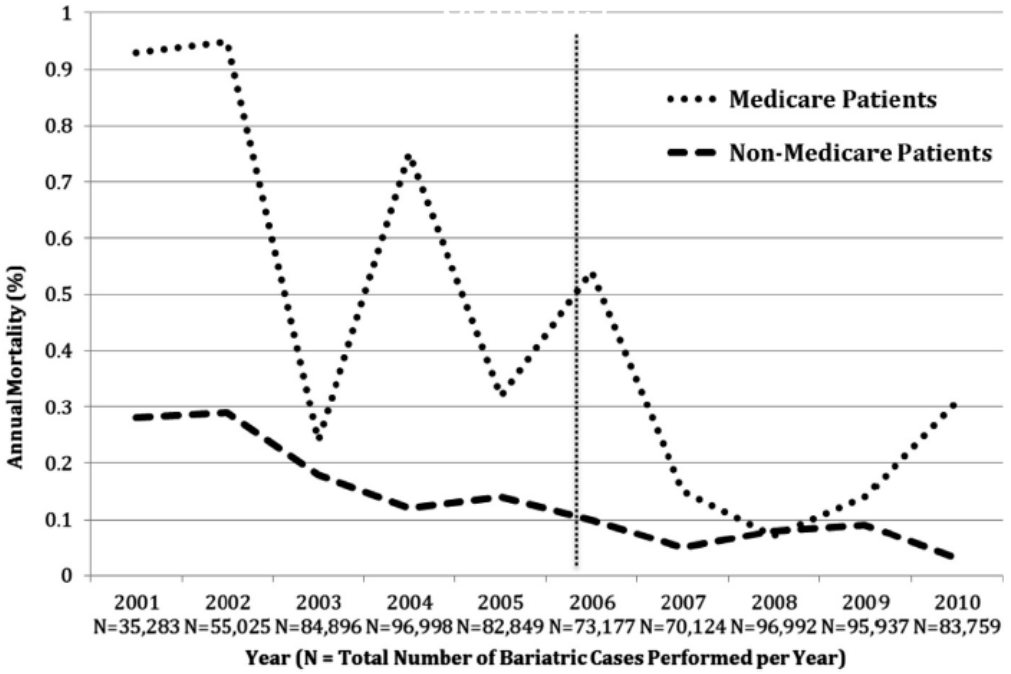


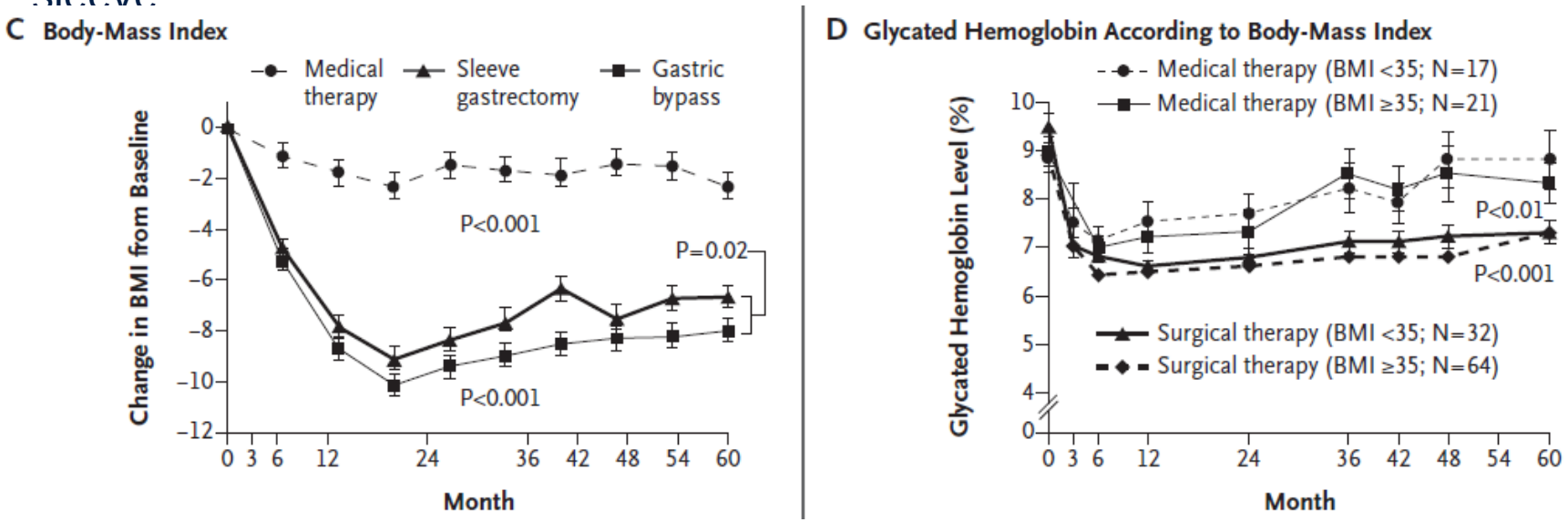
Figure 1. Annual mortality rate for Medicare and non-Medicare patients who underwent bariatric surgery before and after the 2006 national coverage determination (dashed vertical line).

Young et al. A Decade Analysis of Trends and Outcomes of Bariatric Surgery in Medicare Beneficiaries. J Am Coll Surg 2014;219:480e488.

Evidence Grid

STAMPEDE RCT: MEDICAL VS. BYPASS VS. SLEEVE

- 134 patients; Mean age of 49 (±8) years; BMI: 27-43; 5 years follow up
- Primary endpoint (HbA1c ≤6%): 5% in medical group, 29% in bypass, 23% in sleeve



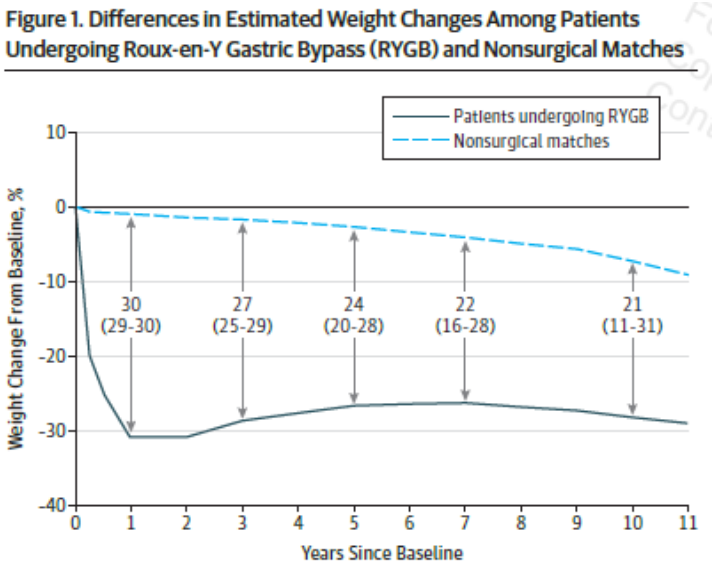
Changes in bypass and sleeve groups were superior to changes in medical group with respect to triglycerides (−40%, −29%, −8%), HDL cholesterol (32%, 30%, 7%), quality-of-life measures (general health score increases of 17, 16, and 0.3; higher scores indicating better health) ($p<0.05$ for all comparisons).

Schauer et al. Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 5-Year Outcomes. N Engl J Med 2017;376:641-51.

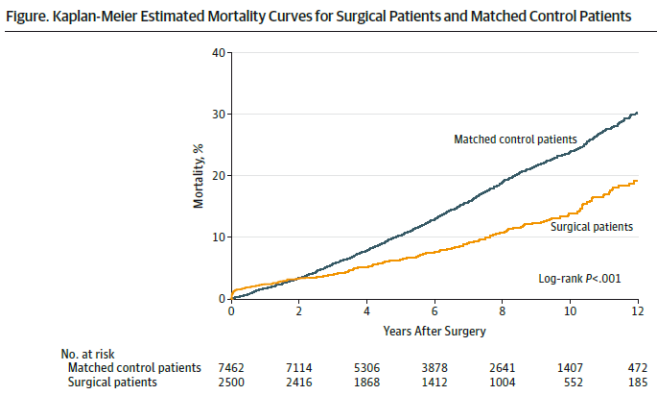
Evidence Grid

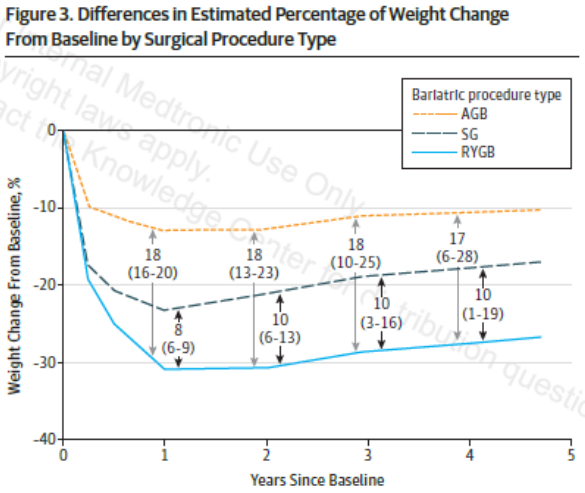
BARIATRIC SURGERY & LONG TERM SURVIVAL
VETERANS AFFAIRS DATA

- 1787 RYGB patients had mean (SD) age of 52.1 (8.5) years and 5305 nonsurgical matches had mean age of 52.2 (8.4) years
- 71.8% RYGB cases had more than 20% estimated weight loss at 10 years vs. 10.8% of matches
- Only 3.4% RYGB cases regained weight back to within an estimated 5% of their baseline weight by 10 years



Long term mortality





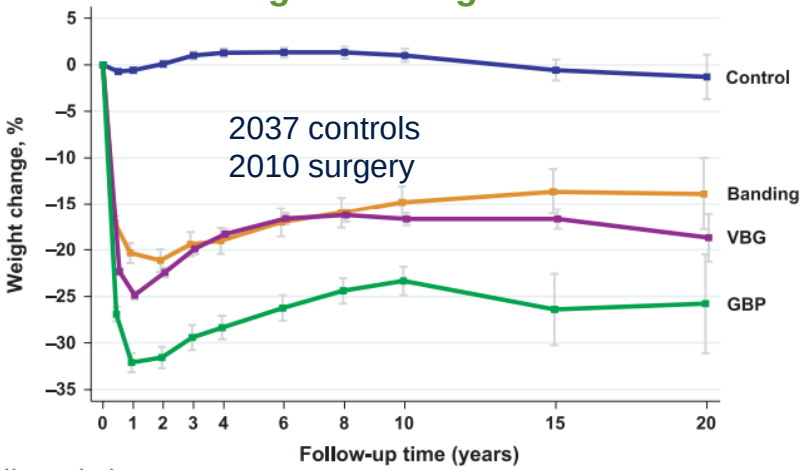
Maciejewski et al. Bariatric Surgery and Long-term Durability of Weight Loss. *JAMA Surg*. doi:10.1001/jamasurg.2016.2317
Arterburn et al. Association Between Bariatric Surgery and Long-term Survival. *JAMA*. 2015;313(1):62-70.

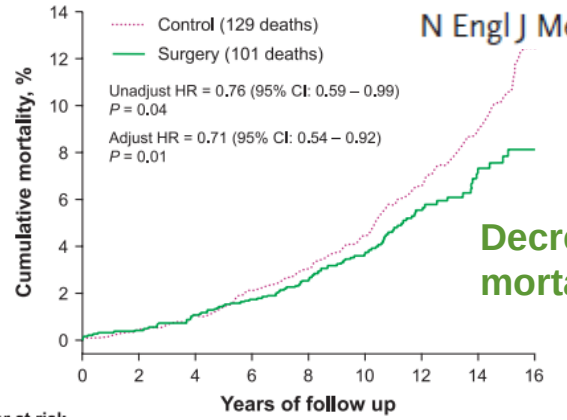
SWEDISH OBESE SUBJECTS (SOS) STUDY (I)

JAMA The Journal of the American Medical Association 2012;307(1):56-65

Bariatric Surgery and Long-term Cardiovascular Events

Long-term weight loss





N Engl J Med 2007;357:741-52.

Decreased overall mortality

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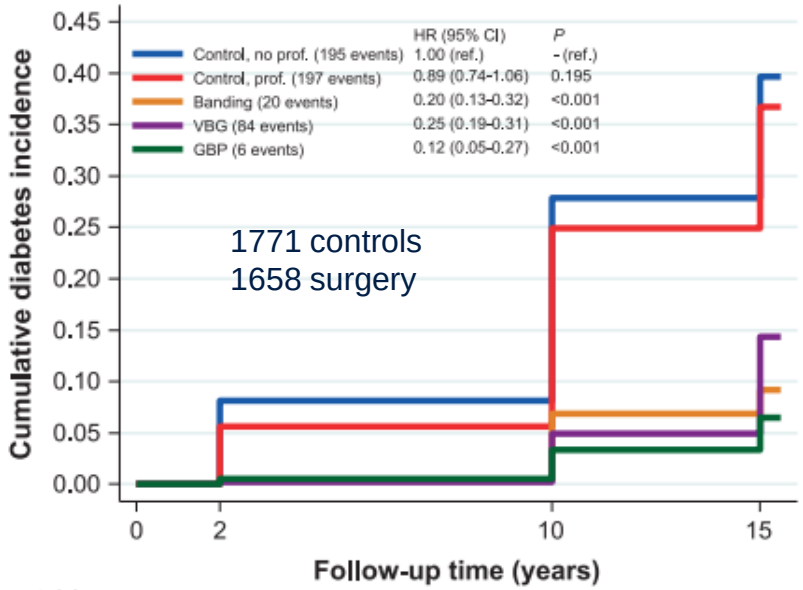
Bariatric Surgery and Prevention of Type 2 Diabetes in Swedish Obese Subjects



Type 2 Diabetes developed among:

- **Controls: 28.4 cases** /1000 person-years
- **Surgery: 6.8 cases** /1000 person-years

Evidence Grid

SWEDISH OBESE SUBJECTS (SOS) STUDY (II)

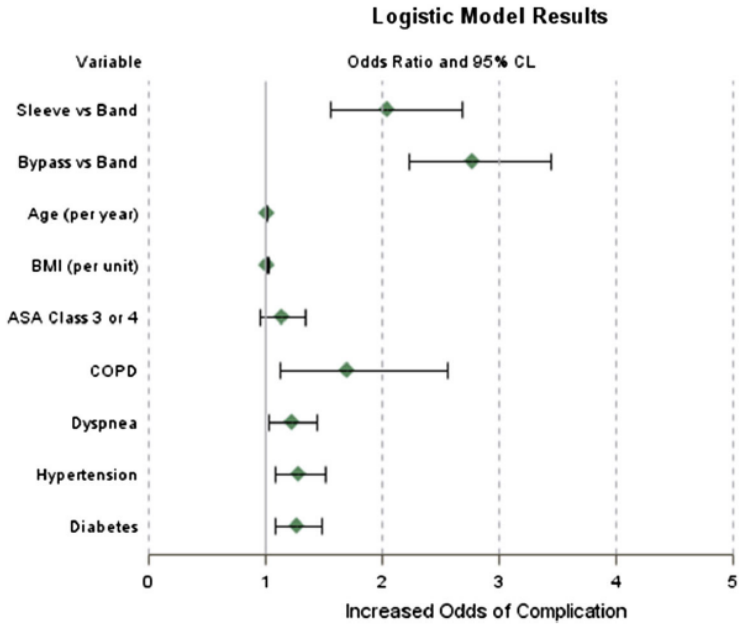
Effect	Conclusion	Year
Cardiovascular	Surgery reduced CV deaths (surgery: 28 of 2010 patients; controls: 49 of 2037 patients; HR: 0.47; 95%CI, 0.29-0.76). First time CV events (myocardial infarction / stroke) was lower in surgery group (N=199) vs. controls (N=234; HR, 0.67; 0.54-0.83)	2012
Comorbidities	Odds ratio at 2 years for hypertension among surgical vs. controls was 0.38 (0.22-0.65); hypertriglyceridemia: 0.10 (0.04-0.25)	2012
Sleep apnea	Surgery: 23% at baseline; 8% at 2 years after surgery Controls: corresponding values were 22% and 20%	2006
Cancer	Among women, cancers incidence was significantly lower in surgery group (HR: 0.58, 95%CI: 0.44–0.77; p=0.0001)	2009
Joint Pain	Recovery after surgery was better in knee and ankle joints amongst men, and in neck, back. hip, knee and ankle joints amongst women	2013
Healthcare Use	Surgical patients used more inpatient and outpatient care during first 6-year period but not thereafter, drug costs from years 7-20 were lower for surgery	2012
Productivity	Compared to controls, surgical group had 35% more days of sickness during 1st year after treatment, 10-14% fewer sickness days during years 2-3	1999

Review of the key results from the Swedish Obese Subjects

Journal of INTERNAL MEDICINE 2013 http://onlinelibrary.wiley.com/doi/10.1111/joim.12012/pdf

POSTOPERATIVE COMPLICATIONS
ACS NSQIP DATA (2010-2011)

Variable	LGBP ($N = 11,617$)	LSG ($N = 3,069$)	LAGB ($N = 5,622$)	P value
Morbidity, n (%)	589 (5.1 %)	98 (1.4 %)	114 (3.7 %)	**<0.0001**
Mortality, n (%)	19 (0.2 %)	3 (0.1 %)	3 (0.1 %)	0.1401
Reoperation, n (%)	255 (2.2 %)	48 (1.6 %)	55 (1.0 %)	**<0.0001**
Op time, mean mins (sd)	126.5 (50.6)	93.3 (45.9)	64.2 (31.5)	**<0.0001**
LOS, median days (IQR)	2.0 (1.0)	2.0 (1.0)	1.0 (1.0)	**<0.0001**



Increased risk of short term (30 day) morbidity for bypass / sleeve vs. banding

Sanni et al. Postoperative complications in bariatric surgery using age and BMI stratification: a study using ACS-NSQIP data. Surg Endosc (2014) 28:3302–3309.

RISKS AND EFFECTIVENESS OF BARIATRIC SURGERY
META-ANALYSIS

Table 3. Meta-analyses of Surgery Risk and Comorbidities Remission Outcomes[a]

	Mean (95% CI)		
	GB	AGB	SG
Complication rates			
RCT			
Estimates, %	21.00 (12.00-33.00)	13.00 (5.20-26.00)	13.00 (0.70-44.00)
Study/arm/No. of patients	10/14/649	7/11/855	2/2/137
OBS			
Estimates, %	12.00 (7.30-17.00)	7.80 (3.90-13.00)	8.90 (5.60-13.00)
Study/arm/No. of patients	19/28/71 020	22/24/36 778	8/20/4987
Reoperation rates			
RCT			
Estimates, %	2.56 (0.61-5.36)	12.23 (4.46-24.46)	9.05 (0.77-34.56)
Study/arm/No. of patients	6/8/512	8/10/502	2/2/161
OBS			
Estimates, %	5.34 (4.48-6.48)	7.01 (3.99-11.24)	2.96 (1.70-4.71)
Study/arm/No. of patients	6/8/23 688	18/21/30 314	7/7/2912

164 studies
37 RCTs, 127 observational
161,756 patients; mean age: 44.6 years; mean BMI: 45.6

In RCTs, mortality within 30 days was 0.08%; mortality after 30 days was 0.31%

Complication rate = 17%
Reoperation rate = 7%

- Bypass was more effective in weight loss but associated with more complications
- Banding had lower mortality and complication rates; yet, the reoperation rate was higher and weight loss was less substantial than bypass
- Sleeve appeared to be more effective in weight loss than banding and comparable with bypass

Chang et al. The Effectiveness and Risks of Bariatric Surgery An Updated Systematic Review and Meta-analysis, 2003-2012. *JAMA Surg*. 2014;149(3):275-287.

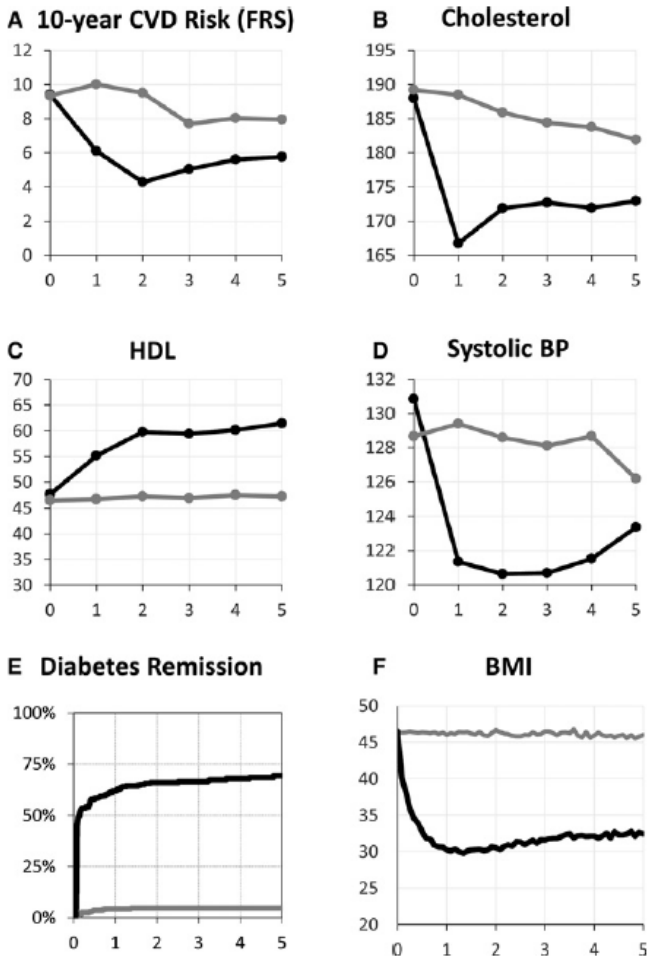
CARDIOVASCULAR OUTCOMES
GEISINGER HEALTH SYSTEM

	RYGB (n=1724)	Control (n=1724)	*P* Value
Used in matching criteria			
Age, y—mean (SD)	45.0 (10.6)	45.1 (10.6)	0.986*
Sex			
Female, % (n)	87% (n=1493)	87% (n=1493)	NA
Male, % (n)	13% (n=231)	13% (n=231)	
BMI, kg/m^2—mean (SD)	46.5 (6.0)	46.5 (6.1)	0.930*
Diabetes mellitus, % (n)	28% (n=486)	28% (n=486)	NA
10-y CVD risk (FRS), %—mean (SD)	9.40 (8.11)	9.35 (8.05)	0.851*

Table 2. Cox Regression Models for Severe CVD, Stroke, MI, and CHF Comparing RYGB to Controls

	Severe Composite CVD (N=173)		Stroke (N=80)		MI (N=29)		CHF (N=79)	
	HR [95% CI]	*P* Value	HR [95% CI]	*P* Value	HR [95% CI]	*P* Value	HR [95% CI]	*P* Value
Unadjusted	0.69 [0.50–0.94]	0.018	0.77 [0.49–1.21]	0.251	0.85 [0.41–1.79]	0.675	0.53 [0.33–0.85]	0.0089
Adjusted*	0.58 [0.42–0.82]	0.0018	0.73 [0.45–1.17]	0.188	0.89 [0.41–1.92]	0.764	0.38 [0.22–0.64]	0.0003

Gastric bypass is associated with a reduced risk of major cardiovascular events and the development of congestive heart failure



Change from baseline to 5 years after RYGB matched with controls. P<0.0001 in each outcome for overall difference between RYGB and controls across time.
FRS, Framingham Risk Score

Benotti et al. Gastric Bypass Surgery Produces a Durable Reduction in Cardiovascular Disease Risk Factors and Reduces the Long-Term Risks of Congestive Heart Failure. J Am Heart Assoc. 2017;6:e005126. DOI: 10.1161/JAHA.116.005126.

RESPIRATORY OUTCOMES: SLEEP APNEA
SYSTEMATIC REVIEW

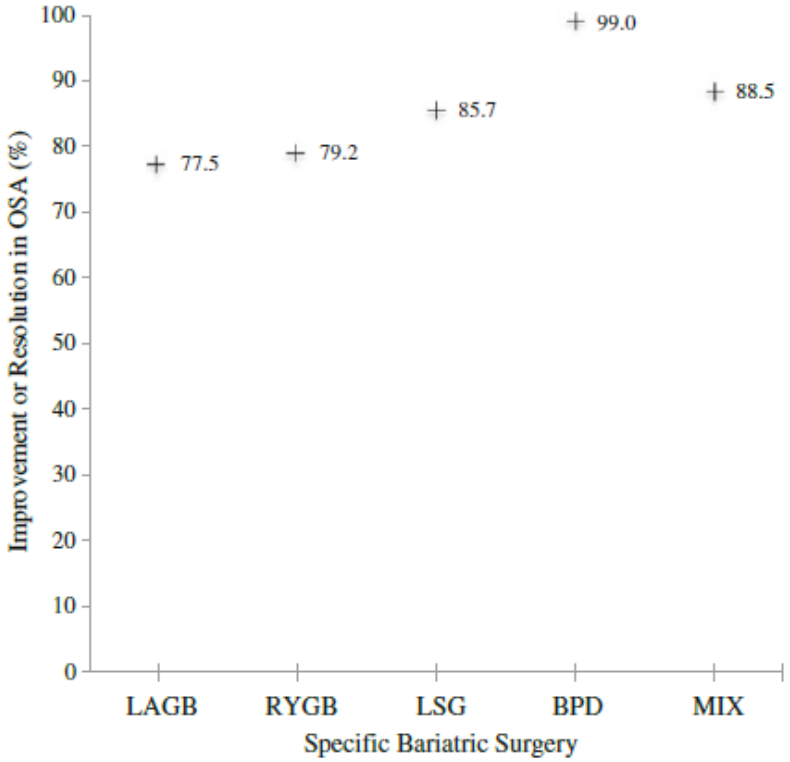


Fig. 2 Percentage improvement or resolution in OSA of the specific bariatric surgeries. *OSA* obstructive sleep apnea, *LSG* laparoscopic sleeve gastrectomy, *LAGB* laparoscopic adjustable gastric banding, *RYGB* Roux-en-Y gastric bypass, *MIX* Studies with mixed procedures

- 69 studies with 13,900 patients
- All procedures achieved profound effects on OSA, as over 75% of patients saw at least an improvement in their sleep apnea
- BPD was most successful procedure in improving or resolving OSA, with lap banding being the least
- Bariatric surgery is a definitive treatment for obstructive sleep apnea, regardless of the specific

Sarkhosh et al. The Impact of Bariatric Surgery on Obstructive Sleep Apnea: A Systematic Review. OBES SURG (2013) 23:414–423.

Evidence Grid

MUSCULOSKELETAL OUTCOMES
LITERATURE REVIEW

LABS-2 data:

- 2458 cases, median age: 47; BMI: 46; 70% RYGB
- Year 1: 57.6% improvement in bodily pain, 76.5% in physical function, 59.5% in walk time; ~3/4th had improvements in knee (77.1%) and hip function (79.2%)
- Year 1-3: improvement rates for walk time, knee and hip pain, and knee and hip function did not decrease

Low Back Pain:

- From pre-surgical height of 6±1.3 mm, L4-L5 disc space increased to 8±1.5 mm at 1 year post surgery (p<0.001)
- Axial and radicular back pain decreased

Author, year	Joint studied	Change in BMI (kg m^{-2}) or weight (kg)	Outcome
Parvizi *et al.*, 2000 (15)	Knee, hip	–20 kg m^{-2}	I. Improved from 103.6 to 148.9 II. Improved from 40 to 67.5 III. A total of 13/14 patients satisfied with arthroplasty results
Peltonen *et al.*, 2003 (19)	Knee, hip	Male: –29.5 kg Female: –27.6 kg	Knee: (Male) OR 3.01* (Female) OR 2.90* Hip: (Male) OR 1.93 (Female) OR 1.70*
Abu-Abeid *et al.*, 2005 (16)	Knee	–6.3 kg m^{-2}	I. Left knee: improved 0.6 mm Right knee: improved 0.7 mm II. Pain: improved from 39.7 to 45.5 Function: improved from 79.9 to 91.4
Hooper *et al.*, 2007 (17)	Hip, knee	–41 kg	I. Hip: improved from 29% to 15% (NS) II. Knee: improved from 75% to 44% ($P < 0.01$)
Korenkov *et al.*, 2007 (18)	Knee	–14.2 kg m^{-2}	I. Decrease in frequency of knee pain in 47% to 38% of patients ($P < 0.001$) II. Intensity of knee pain decreased from median of 3 to 1 ($P < 0.001$)
Richette *et al.*, 2011 (9)	Knee	–10 kg m^{-2}	I. Improvement in pain score (VAS) from 50 to 24.5 ($P < 0.001$) II. Improvement of severity of knee OA from 51.6 to 25.3 ($P < 0.001$)

King et al. Change in Pain and Physical Function Following Bariatric Surgery for Severe Obesity. *JAMA*. 2016;315(13):1362-1371.
Gill et al. The benefits of bariatric surgery in obese patients with hip and knee osteoarthritis: a systematic review. Obesity reviews (2011) 12, 1083–1089.
Lidar et al. Intervertebral Disc Height Changes After Weight Reduction in Morbidly Obese Patients and Its Effect on Quality of Life and Radicular and Low Back Pain. Spine 2012 ; 37 : 1947 – 1952

Evidence Grid

CLINICAL PREDICTORS OF DURABLE WEIGHT LOSS

- Outcome: diabetes remission
- MarketScan claims data on RYGB
- 18 months follow up
- Regression models

- Increasing age reduced odds of remission (OR: 0.976)
- Procedure year improved remission (1.11)
- Preop insulin use (0.14), sulfonylurea use (0.616), other antidiabetic medication use reduced odds (0.747)

- Outcome: weight loss
- Geisinger data on RYGB
- 7-12 years follow up

- Preoperative insulin use was strongly associated with better long-term %WL

- Preoperative hyperlipidemia, higher body mass index, and older age were associated with poorer %WL

Hatoum et al. Clinical Factors Associated With Remission of Obesity-Related Comorbidities After Bariatric Surgery. *JAMA Surg*. 2016;151(2):130-137.
Wood et al. Evaluation of the Association Between Preoperative Clinical Factors and Long-term Weight Loss After Roux-en-Y Gastric Bypass. *JAMA Surg*. 2016;151(11):1056-1062.

BEHAVIORAL PREDICTORS OF DURABLE WEIGHT LOSS
LABS-2 DATA

- 2022 participants
- Median age, 47 years [IQR: 38-55]
- Median BMI, 46 [IQR: 42-51])
- Follow up: 3 years

- Participants with positive changes on 3 critical behaviors were predicted to lose a mean of 38.8% of their baseline weight

- This is about 14% greater weight loss compared with participants who made no positive changes in these variables (−24.6%; *P* < .001)

Table 1. Modifiable Practices and Behaviors

Category	Practice or Behavior
Weight loss practices	Self-weigh at least weekly
	See nutritionist or dietitian
	See personal trainer or exercise specialist
	Keep a food diary
	Count fat grams
	Decrease fat intake
	Reduce number of calories eaten
	Use a very low-calorie diet
	Cut out between-meal snacking
	Eat fewer high-carbohydrate foods
	Eat special low-calorie diet foods
	Eat or drink meal replacements
	Increase fruits and vegetables
	Cut out sugar-sweetened beverages
Alcohol, smoking, and illegal drugs	Alcohol use disorder
	Current smoker
	Illegal drug use
Eating behaviors and problems	Eat breakfast regularly
	Eat breakfast, lunch, and dinner regularly
	Eat when feeling full, more than once a week
	Eat when not hungry, more than once a week
	Eat continuously during the day or part of the day
	Binge-eating disorder
	Loss-of-control eating
	Night eating syndrome
	Evening hyperphagia
	Night eating

3 critical behaviors

Mitchell et al. Postoperative Behavioral Variables and Weight Change 3 Years After Bariatric Surgery. *JAMA Surg.* 2016;151(8):752-757.

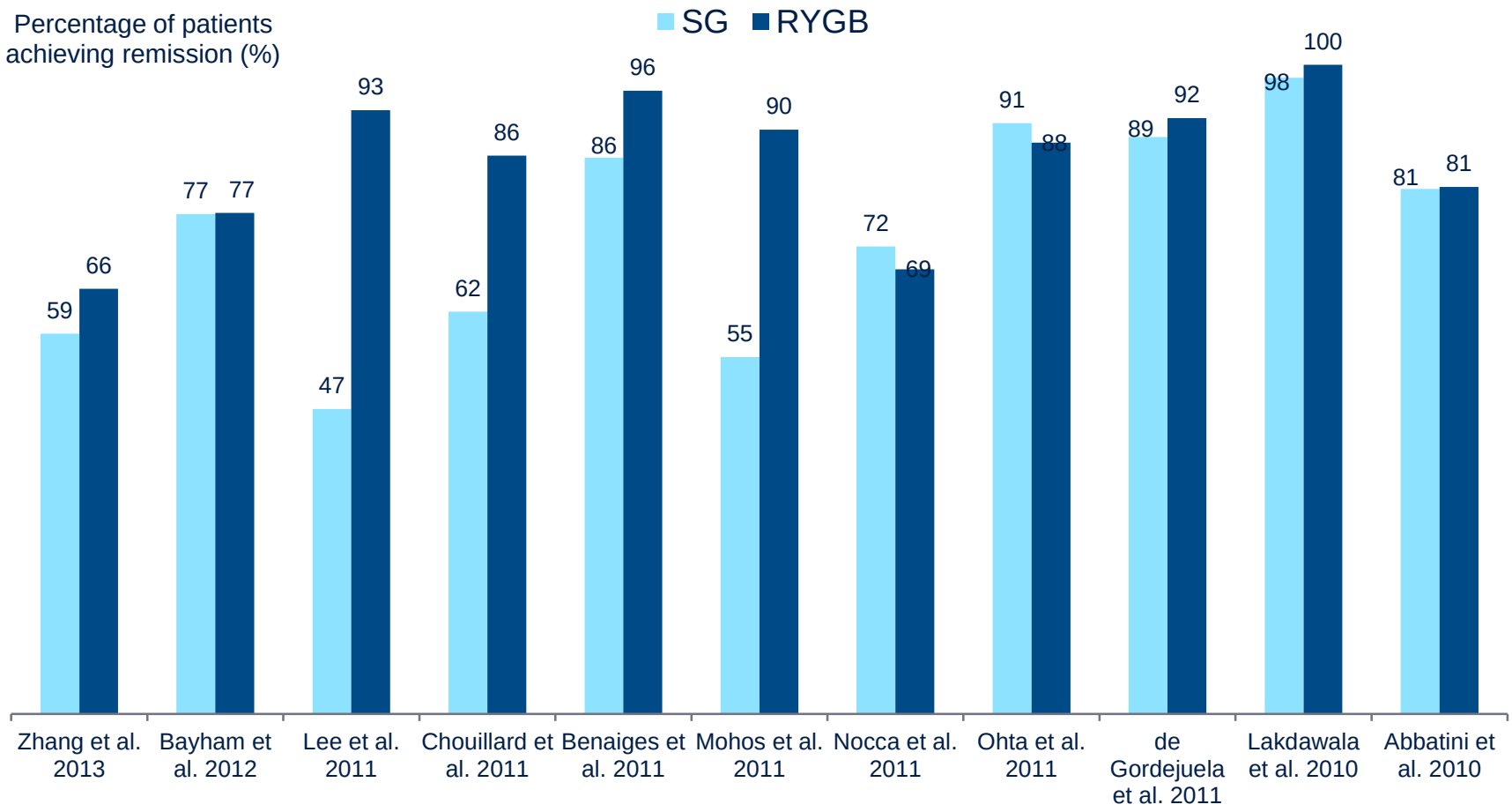
PROSPECTIVE / RETROSPECTIVE STUDIES

Study	Population	Follow up	Key findings	Study design
Adams et al. 2012	Patients with a BMI≥35 kg/m^2, who sought and received surgery, sought but did not receive surgery (control group 1), or did not seek surgery (control group 2) RYGB n=418; Control group 1 n=417; Control group 2 n=321	6 years	Weight loss: 27.7% of bodyweight for RYGB versus 0.2% gain for control group 1 and 0% in control group 2 (p<0.05 versus both control groups) Maintenance of weight loss: 94% and 76% of RYGB group maintained at least 20% weight loss 2 and 6 years after surgery, respectively (p value not presented) Remission of diabetes at 6 years: 62% for RYGB versus 8% in control group 1, and 6% in control group 2 (p<0.001)	Prospective controlled study
Leslie et al. 2012	Patients aged 18–67 with type 2 diabetes with BMI≥35 kg/m^2 RYGB n=152 Routine medical management n=115	2 years	Change in BMI: BMI decreased from 47.4 kg/m^2 to 32.4 kg/m^2 in the RYGB group, versus no significant change for medical management group (p<0.001) Change in HbA1c: HbA1c fell from 7.6% to 6.4% in the RYGB group, versus no significant change in the medical management group (p<0.01) Composite endpoint of HbA1c<7%, LDL<100 mg/dL, SBP<130 mmHg: 38.2% of patients in the RYGB group versus 17.4% in the medical management group (p<0.01)	Retrospective cohort
Al Harakeh et al. 2010	Patients evaluated for RYGB who underwent or were denied surgery due to an insurance-related reason RYGB n=587 Denied surgery n=189	3 years	Decrease in BMI: Mean BMI fell from 48.5 kg/m^2 (baseline) to 30.5 kg/m^2 at 2 years for RYGB and from 47.3 kg/m^2 to 46.8 kg/m^2 in the denied surgery group (p value for difference between arms not presented) Incidence of new onset complications: greater incidence of new-onset diabetes, hypertension, obstructive sleep apnea, gastroesophageal reflux disease, and lipid disorders were observed in the denied group versus the RYGB group (all p<0.001)	Retrospective cohort
Mumme et al. 2009	Patients aged 18–67 with type 2 diabetes with BMI>35 kg/m^2 RYGB n=51 Conventional treatment n=51	3 years	Change in HbA1c (at 3 years): decrease from 7.8% to 6.1% for RYGB group versus an increase from 7.1% to 7.8% for conventional treatment (p=0.01) Remission of diabetes (at 1 year): 59% in the RYGB group versus 5% in the conventional treatment group (p value not presented) Remission of diabetes (at 3 years): 54% in the RYGB group and 3% in the conventional treatment group (p value not presented)	Retrospective cohort
Adams et al. 2007	Patients undergoing RYGB and patients with BMI≥35 kg/m^2 applying for a driver's license or identification card RYGB n=9,949 Control group n=9,628	Mean 7.1 years	Deaths per 10,000 patient years: 37.6 for surgery patients versus 57.1 in the control group (p<0.001) Deaths due to diabetes: 0.4 versus 3.4 per 10,000 patient years for bariatric surgery group versus control group (p=0.005) (92% reduction) Deaths due to cancer: 5.5 versus13.3 per 10,000 patient years for bariatric surgery versus control group (p<0.001) (60% reduction) Deaths not due to disease: 11.4 versus 6.1 per 10,000 patient years for bariatric surgery versus control group (p=0.04)	Retrospective cohort
Bolen et al. 2012	Patients with BMI>35 kg/m^2 Surgery n=22,693 Medical management n=22,263	5 years	Outcomes: bariatric surgery patients more likely to have a serious (OR 1.9, p<0.05) or less serious (OR 2.5, p<0.05) clinical outcome during the first 365 days following surgery; this risk remained elevated until year 4 post-surgery Co-morbidities: bariatric surgery group had a 55% lower likelihood of having an obesity-related co-morbidity diagnosis 1 year post-surgery (OR 0.4, p<0.05) versus controls, which remained lower throughout 5 years of follow-up	Retrospective cohort
Johnson et al. 2012	Patients aged 40–79 years, with a diagnosis code of morbid obesity, a primary surgical procedure of interest, and a cardiovascular event history Surgery n=349 Controls n=903	Surgery mean 28.1 months Controls mean 35.2 months	Mortality: surgery associated with significantly lower all-cause mortality (HR 0.60, 95% CI 0.36–0.99) Cardiovascular mortality: no significant difference in deaths due to cardiovascular (HR 0.63, 95% CI, 0.29–1.38) and non-cardiovascular causes (HR 0.58, 95% CI, 0.30– 1.13)	Retrospective cohort
Maciejewski et al. 2011	Veterans undergoing bariatric surgery and nonsurgical controls Surgery n=850 Nonsurgical unmatched controls n=41,244	Mean follow-up 6.7 years	Mortality: crude mortality rates at 1, 2 and 6 years were 1.5% (p=0.17), 2.2% (p<0.001), and 6.8% (p<0.001) for bariatric surgery group versus 2.2%, 4.6%, and 15.2% for nonsurgical controls Mortality: in Cox regressions bariatric surgery was associated with reduced mortality (unadjusted HR 0.64, p<0.001; adjusted HR 0.80, p=0.45) Mortality: in propensity-matched patients, bariatric surgery not significantly associated with reduced mortality in unadjusted and time-adjusted Cox regressions (p values not presented)	Retrospective cohort

META-ANALYSES ON COMORBIDITY RESOLUTION

Study	Details	Key findings
Washington State HTA 2015	N=275 studies including RCTs, prospective cohort studies and case series (of which 100 were rated as “good” or “fair” in quality) Number of patients not presented	BMI change: pooled mean (95% CI) difference in BMI between bariatric surgery and non-surgical management was 7.4 (6.2, 8.6) kg/m^2 (p<0.001) BMI change: in a comparison of RYGB versus SG, mean (95% CI) difference was 0.296 (−0.828, 1.421) kg/m^2 in favor of SG, which was not significant (p=0.605) Diabetes resolution in studies exclusively in type 2 diabetes patients: OR (95% CI) for resolution of diabetes with bariatric surgery versus non-surgical management was 3.62 (2.49, 4.74) (p<0.001)
Tee et al. 2013	N=6 observational studies N=51,740 patients Random effects model	Cancer risk: RR (95% CI) for obese patients undergoing bariatric surgery was significantly reduced versus those not undergoing surgery at 0.55 (0.41, 0.73) (p<0.0001) Gender and cancer risk: reduction in cancer risk was significant for women (RR [95% CI] 0.68 [0.60, 0.77] p<0.0001) but not for men (RR [95% CI] 0.99 [0.74, 1.32] p=0.930)
Vest et al. 2012	N=73 studies including randomized and non-randomized studies N=19,543 patients Fixed and random effects models used	Percentage excess weight loss: overall excess weight loss was 54% Resolution of co-morbidities: overall rates of resolution/improvement were 73.2% for diabetes, 62.5% for hypertension and 65.2% for hyperlipidemia Resolution of co-morbidities: RR (95% CI) for hypertension for obese patients who underwent bariatric surgery versus those not undergoing surgery was 0.36 (0.31, 0.42) (p=0.000), the corresponding value for diabetes was 0.24 (0.20, 0.30) (p=0.000) and for hyperlipidemia this value was 0.32 (0.26, 0.40) (p=0.000)
Padwal et al. 2011	N=31 RCTs in severely obese adults (≥40 kg/m^2 or ≥35 kg/m^2 with ≥1 obesity-related co-morbidity) N=2,619 patients, Bayesian NMA	Change in BMI, relative to standard care: differences (95% CI) from baseline in BMI were greatest for BPD at −11.2 (−15.7, −6.9) kg/m^2 followed by SG at −10.1 (−17.8; −2.6) kg/m^2, then RYGB at −9.0 (−15.1; −3.1) kg/m^2 and AGB at −2.4 (−9.1; 3.9) kg/m^2 (p values not presented) Length of stay: AGB associated with significantly shorter length of hospital stay versus RYGB; mean (95% CI) difference of −1.7 (−2.00, −1.30) days (p value not stated)
Buchwald et al. 2009	N=621 studies including trials, observational studies and case series N=135,246 Random effects model	Mean (95% CI) reduction in BMI: −10.62 (−11.36, −9.89) kg/m^2 for AGB, −16.33 (−17.08, −15.58) kg/m^2 for RYGB and −18.72 (−21.17, −16.27) kg/m^2 for BPD-DS (p values not presented) Mean (95% CI) reduction in BMI in patients with diabetes: −8.34 (−10.61, −6.08) kg/m^2 for AGB, −16.14 (−16.86, −15.42) kg/m^2 for RYGB and −16.47 (−26.06, −6.89) kg/m^2 for BPD-DS (p values not presented) Diabetes resolution rate (in studies in patients with diabetes only): 62.7 (55.4, 70.0)% for AGB, 80.5 (74.8, 86.2)% for AGB and 99.4 (98.3, 100.0)% for BPD-DS (p values not presented) Mean (95% CI) change in HbA1c (in studies in patients with diabetes only): −1.40 (−3.20, 0.40)% for AGB, −2.18 (−2.71, −1.65)% for RYGB (data not presented for BDP-DS) (p values not presented)
Greenburg et al. 2009	N=12 studies including trials, observational studies and before/after studies N=342 patients	Mean (95% CI) change in BMI: −17.9 (16.5, 19.3) kg/m^2 Reduction in apnea hypopnea index: bariatric surgery associated with a significant reduction (by 38.2 [31.9, 44.4] events per hour in the random effects model; in an analysis of individual patient data this improvement was 49.4 events per hour
Mummadi et al. 2008	N=15 studies (prospective and retrospective) with paired liver biopsies N=766 patients with non-alcoholic fatty liver disease	Improvement or resolution of steatohepatitis (95% CI): 81.3 (61.9, 94.9)%; proportion (95% CI) of patients with complete resolution of steatohepatitis was 69.5 (42.4, 90.8)% Improvement in fibrosis (95% CI): 65.5% (38.2, 88.1)% patients with liver biopsies showed improvement of fibrosis following bariatric surgery

METABOLIC OUTCOMES
TYPE 2 DIABETES REMISSION



Medtronic

BARIATRIC SURGERY PROCEDURE TRENDS
PREMIER DATA 2008-2014

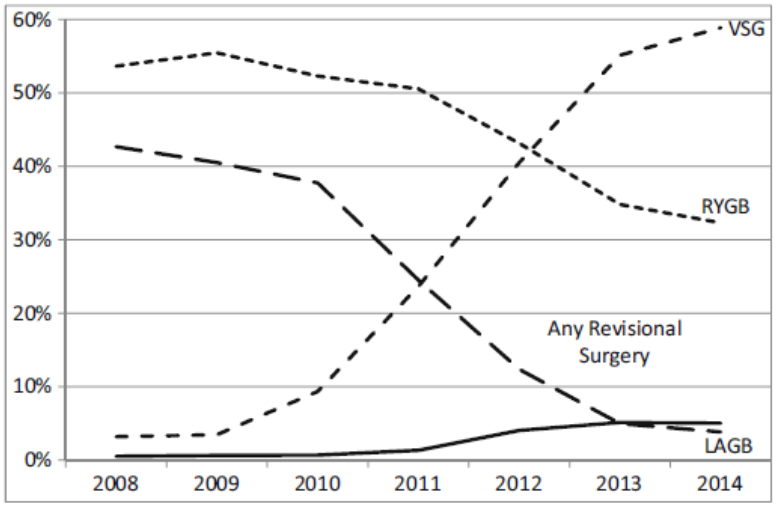


Fig. 1 Contribution of VSG, RYGB, LAGB, and revisional surgeries to yearly bariatric procedures

MORE MEDICARE DISABLED UNDERGO BARIATRIC SURGERY THAN ELDERLY

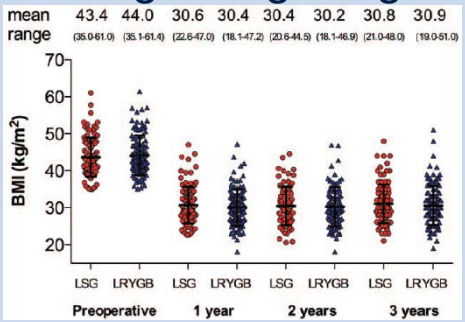
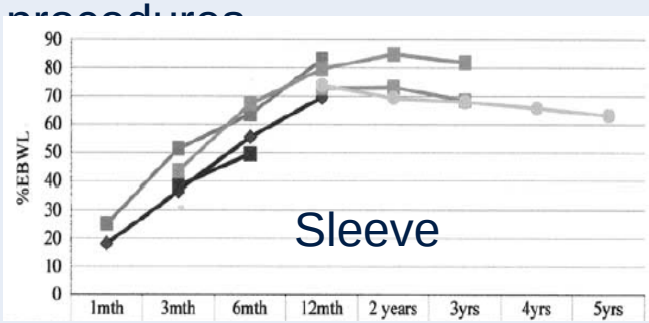
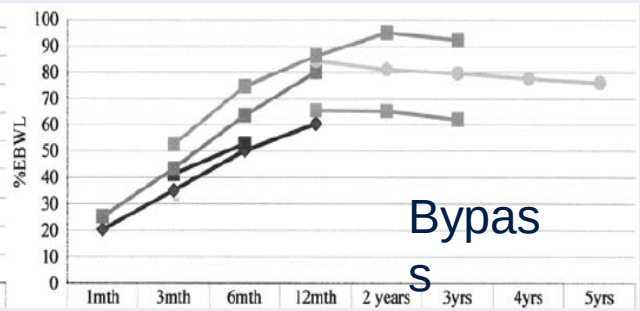
	Total cohort	LAGB	RYGB	VSG	Revisional surgery
N	114,655	27,960	53,365	30,601	2729
Mean Age	44	45	44	44	47
Greater than 65 years	4.8 %	6.6 %	4.3 %	3.9 %	7.7 %
Diabetes, type II	32 %	28 %	38 %	27 %	20 %
Insurance status					
Medicare	13 %	14 %	15 %	9.5 %	16 %
Medicaid	8.4 %	5.1 %	9.9 %	9.0 %	5.8 %
Managed care	69 %	72 %	66 %	73 %	69 %
Uninsured	3.9 %	3.6 %	2.5 %	6.7 %	3.8 %

From 2008-2014, Medicare was payer for 13% of the total surgical cohort

- ~37% of Medicare beneficiaries were above 65 years (or 4.8% of the total cohort)
- ~63% of Medicare beneficiaries were disabled or had ESRD (or ~8.2% of the total cohort)

Abraham et al. Trends in Bariatric Surgery: Procedure Selection, Revisional Surgeries, and Readmissions. OBES SURG DOI 10.1007/s11695-015-1974-2

SLEEVE VS. BYPASS: WHICH IS BETTER?
BROADLY COMPARABLE

Study	Outcome
Swiss Multicentre Bypass Or Sleeve Study; SM-BOSS 3 year RCT data	LSG and LRYGB are equally efficient regarding weight loss, quality of life, and complications 
Systematic review and meta-analysis (9 RCTs, 865 patients)	12 month EWL: LSG=69.7-83%, LRYGB=60.5-86.4% Slow weight regain in 2nd and 3rd years (1.4-4.2% EWL) Trend continues in 5th year (8-10% EWL) for both procedures  

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Evidence Grid