Appendix A

Literature Search Strategy

Databases: MEDLINE, Cochrane Library, DARE, PsycINFO, CINAHL, EMBASE

Ovid/CINAHL Search Terms:

1. Bariatric Surgery/ or Anastomosis, Roux-en-Y/ or Gastric Bypass/ or Gastrectomy/ or Biliopancreatic Diversion/

2. (bariatric surgery or gastric bypass or gastric band or gastric banding or lap band or lapband or lap-

band or gastrectomy or sleeve gastrectomy or biliopancreatic diversion or duodenal switch).ti,ab 3. 1 or 2

4. Obesity/su or Obesity, Morbid/su or (obes* and surg*).ti,ab

5. 3 and 4

6. Limit 5 to (english language and humans and yr="2000-current")

Embase Search Terms:

1. 'bariatric surgery'/exp OR 'stomach bypass'/de OR 'roux y anastomosis'/de OR 'gastrectomy'/de OR 'biliopancreatic bypass'/de

2. 'bariatric surgery':ab,ti OR 'gastric bypass':ab,ti OR 'gastric band':ab,ti OR 'gastric banding':ab,ti OR lapband:ab,ti OR 'lap band':ab,ti OR gastrectomy:ab,ti OR 'sleeve gastrectomy':ab,ti OR 'biliopancreatic diversion' or 'duodenal switch':ab,ti

3. #1 OR #2

4. 'obesity'/dm_su OR 'morbid obesity'/dm_su OR (obes* NEXT/1 surg*):ab,ti

5. #3 AND #4

6. #5 AND [humans]/lim AND [english]/lim AND [priority journals]/lim AND [embase]/lim AND [2000-2014]/py

Include:

- **Population**: adults and children/adolescents with some classification of obesity (moderate, severe, morbid) with or without comorbidities
- Interventions: Roux-en-Y gastric bypass; laparoscopic adjustable gastric banding; vertical sleeve gastrectomy; and biliopancreatic diversion (with or without duodenal switch)
- **Comparator**: surgery types mentioned above compared to one another OR conventional weight-loss treatment
- **Outcomes**: at least one outcome of interest: weight loss; changes in BMI; resolution or reduction of comorbidities and/or associated reductions in medication use; rates of complications; surgical revision/reversal; improvements in health-related quality of life; procedure-related morbidities (e.g., malabsorption); mortality
- **Sources**: systematic reviews, meta-analyses, RCTs, comparative studies, case series with at least 100 patients (25 for adolescent populations) and ≥2 years of follow-up

Exclude:

- **Population**: non-obese subjects (BMI <30)
- Interventions: surgical procedures other than the 4 procedures previously mentioned (e.g., jejunoileal bypass, ileal interposition, vertical banded gastroplasty); body-contouring/excessive skin removal surgeries (unless specifically tied to an outcome of interest)
- **Comparator**: no intervention or non-obese/overweight/healthy control
- **Outcomes**: any outcome not included in categories listed above
- Sources: case reports; conference abstracts; letters; reviews (not systematic); dissertations

Appendix B

Evidence Tables for RCTs and Comparative Cohort Studies

Table B1. Good Quality Studies

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Angrisani 2007	RCT	1) LAGB 2) RYGB	N=51 1) 27 2) 24	5 years	BMI >35 & <50 Age >16 & <50 No hiatal hernia No previous major abdominal operations	Mean age 34 18% male Mean BMI 43.6 Mean weight 117.6kg	Mean BMI at 5 years 1) 34.9 2) 29.8 Mean %EWL at 5 years 1) 47.5 2) 66.6 Mean weight at 5 years (kg) 1) 97.9 2) 84.0 All outcomes p<0.001 All comorbidities (T2D, sleep apnea, hyperlipidemia) present before surgery had resolved after 5 years	Reoperations 1) 4/26 (15.2%) 2) 3/24 (12.5%) Early complications 1) 0 2) 2 Late complications 1) 2 2) 1 No deaths in either group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Arterburn 2014	Retro- spective cohort	1) RYGB 2) LAGB	N=7,457 1) 5,950 2) 1,507	2.3 years	Not reported	Mean age 46 17% male Mean BMI 44.17	BMI reduction (%) 1) 14.8 2) 8.0 p<0.001	30 day major adverse event Hazard ratio LAGB vs. RYGB: 0.46; p=0.006 Subsequent hospitalization Hazard ratio LAGB vs. RYGB: 0.73; p<0.001
Benaiges 2012	Prospective cohort	1) RYGB 2) VSG	N=102 1) 51 2) 51	12 months	1991 NIH criteria Age 18-55	Mean age 46 18% male Mean BMI 45.2 Mean weight 120.4kg	BMI at 12 months 1) 29.1 2) 28.5 p=NS Mean %EWL at 12 months 1) 45.0 2) 43.6 p=NS	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Bowne 2006	Prospective	1) RYGB	N=106	16.2 months	1991 NIH criteria	Mean age 43	Length of stay	Conversion to open
	cohort	2) LAGB	1) 46			20% male	(days)	surgery
			2) 60			Mean BMI 56	1) 3.5	1) 0
						Mean weight	2) 1.8	2) 1
						153.1kg	p<0.002	
								Early complications
							Mean change in	1) 8
							BMI	2) 11
							1) -26.5	p=NS
							2) -9.8	
							p<0.001	Late complications
								1) 11
							Mean %EWL	2) 43
							1) 52	p<0.05
							2) 31	
							p<0.001	Reoperations
								1) 3
							RYGB had more	2) 15
							significant	p=0.04
							resolution of T2D	
							(p=0.05) and sleep	Mortality
							apnea (p=0.01)	1) 0
							compared to LAGB	2) 1

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Campos 2011	Retro- spective cohort	1) LAGB 2) RYGB	N=200 1) 100 2) 100	1 year	1991 NIH criteria	Mean age 47 14% male Mean BMI 1) 45.7 ± 25 2) 46 ± 28 Mean weight (kg) 1) 128kg 2) 129kg	Mean %EWL 1) 36 2) 64 p<0.01 Resolution of T2D 1) 17 (50%) 2) 26 (76%) p=0.04 QoL (MA II): Individual self- esteem,	Early complications 1) 2 2) 11 p=0.02 Late complications 1) 9 2) 3 p=NS Reoperations 1) 12 2) 2
							physical, and social measures were significantly better for the RYGB group (p<0.001)	p=0.009 No deaths in either group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Carlin 2013	Retro-	1) VSG	N=8847	≤3 years	Not specified	Mean age 46	Mean %EWL at 3	Overall complications
	spective	2) RYGB	(2949 in			26% male	years	(%)
	cohort	3) LAGB	each			Mean BMI 47.5	1) 56	1) 6.3
			group)				2) 67	2) 10.0
							3) 44	3) 2.4
							p<0.0004	p<0.0001
							Comorbidity	Serious complications
							remission at 1 year	(%)
							(%)	1) 2.4
							1) 40-66	2) 2.5
							2) 45-80	3) 1.0
							3) 18-37	p<0.0001
							No differences in	Reoperations (within
							QoL; patient	30 days) (%)
							satisfaction	1) 1.4
							significantly worse	2) 1.6
							for LAGB at 3 years	3) 0.4
							(p=0.0001)	1 & 2 vs. 3, p<0.0001
								Mortality (%)
								1) 0.07
								2) 0.10
								3) 0.07
								p=NS

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Courcoulas 2014	RCT	1) RYGB 2) LAGB 3) intensive lifestyle weight-loss intervention (ILWLI)	N=69 1) 24 2) 22 3) 23	12 months	T2D diagnosis Age 25-55 BMI 30-40	Mean age 47 19% male Mean BMI 35.5	Mean change in BMI 1) -9.7 2) -6.2 3) -3.6 p<0.001 Mean change in weight (%) 1) -27.0 2) -17.3 3) -10.2 p<0.001 Cease antidiabetic meds (n) 1) 14 2) 8 3) 1 p<0.001 Partial remission of T2D (%) 1) 50 2) 27 3) 0 p<0.001 Complete remission of T2D (%) 1) 17 2) 23 3) 0	Serious adverse events: 1) 1 2) 2 3) 0 No deaths in any group

Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
1) LAGB 2) life-style change	N=60 1) 30 2) 30	2 years	BMI 30-40 Age 20-60 T2D ≥2 years	Mean age 47 47% male Mean BMI 37.1 Mean HbA1c 7.7%	Mean weight Loss (kg) 1) 21.1 2) -1.5 p<0.001 Mean %EWL 1) 62.5 2) 4.3 Mean change in BMI 1) -7.4 2) -0.5 T2D remission (%) 1) 73 2) 13 p<0.001 HbA1c (%) 1) -1.81 2) -0.38	No major complications in either group Reoperations (LAGB) 2 revisional surgery 1 reversal surgery Mortality not reported
C II 1 2 cl	omparators/ nterventions) LAGB) life-style hange	comparators/ nterventions# of Patients) LAGB) life-style hangeN=60 1) 30 2) 30	omparators/ nterventions# of PatientsTime to Follow-up) LAGB) life-styleN=60 1) 30 2) 302 years	comparators/ nterventions# of PatientsIntent/Wedian Time to Follow-upEntry Criteria) LAGB () life-style hangeN=60 1) 30 2) 302 yearsBMI 30-40 Age 20-60 T2D ≥2 years	comparators/ interventions# of PatientsInterventionEntry CriteriaBaseline Characteristics0 LAGB b) life-style hangeN=60 1) 30 2) 302 yearsBMI 30-40 Age 20-60 T2D >2 yearsMean age 47 47% male Mean BMI 37.1 Mean HbA1c 7.7%	oomparators/ nterventions# of PatientsTime to Time to Follow-upEntry CriteriaBaseline CharacteristicsMain Outcomes) LAGB bilife-style hangeN=60 2) 302 yearsBMI 30-40 Age 20-60 T2D >2 yearsMean age 47 47% male Mean BMI 37.1 Mean HbA1c 7.7%Mean weight Loss (kg) 1) 21.1 2) -1.5 p<0.001

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Dixon 2012	RCT	1) LAGB	N=60	2 years	Age 18-60 years	Mean age	Mean weight loss	Complications
		weight loss	2) 30		Diagnosed with	2) 50 0	(NB) 1) -27 8	1) 1 2) NR
		treatment	2,50		sleep appea >6	2, 50.0	2) -5.1	27 111
					months OR AHI	18% male	p<0.001	No deaths in either
					≥20 events/hour			group
					At least 3 prior	Mean BMI	Mean weight loss	
					weight loss	1) 46.3 ± 6.0	(%)	
					attempts	2) 43.8 ± 4.9	1) 20.6	
							2) 2.9	
						Mean weight	p<0.001	
						1) 134.9	Maan DML at 2	
						2) 120.0	vears	
						AHI (events/hour)	1) 36 6	
						1) 65.0	2) 42.3	
						2) 57.2	,	
						-	AHI	
							1) -25.5	
							2) -14.0	
							p=NS	
							QOL (SF 36):	
							general health	
							vitality.	
							physical component	
							summary was	
							significantly better	
							for LAGB (p=0.04)	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Galvani 2006	Retro- spective cohort	1) RYGB 2) LAGB	N=590 1) 120 2) 470	3 years	1991 NIH criteria Age 17-65	Mean age 41 18% male Mean BMI 47.5	Mean %EWL 1) 63 2) 55	Both groups had similar rates of complications and reoperations
							p=NR No significant difference between groups for resolution of comorbidities	Mortality 1) 1 2) 0
Hedberg 2012	RCT	1) RYGB 2) BPD	N=47 1) 23 2) 24	4 years	BMI >48	Mean age 39 53% male Mean BMI 54.4	Mean change in BMI 1) -16.2 2) -23.2 p<0.001 %EBMIL 1) 51 2) 80 p<0.001	Revisions/Reoperations /Mortality 1) 0/2/1 2) 0/1/0

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Ikramuddin 2013	RCT	1) RYGB 2) lifestyle- medical management	N=120 1) 60 2) 60	12 months	HbA1c ≥8% BMI 30-39 Age 30-67	Mean age 49 24% male Mean HbA1c 9.6% Mean weight 97.4kg	HbA1c <7% (%) 1) 32 2) 43 OR 4.8; 95% CI, 1.9- 11.7 Mean weight loss 1) 26.1% 2) 7.9% 17.5%; 95% CI, 14.2%-20.7%	Postop complications 1) 2 (leaks) 2) 0 Serious adverse events 1) 22 2) 15 No deaths in either group
Liang 2013	RCT	 usual care ususal care + exanatide RYGB 	N=108 1) 36 2) 34 3) 31	1 year	T2D diagnosis BMI >28 Hypertension 5- 10 years Insulin + oral therapy for 1 year HbA1c > 7% Age 30-60 years	Mean age 1) 51.75 2) 50.94 3) 50.81 65% male Mean BMI 1) 30.94 2) 30.28 3) 30.48 Mean HbA1c 1) 10.88 2) 10.52 3) 10.47	Mean change in BMI 1) -0.56 2) -3.44 3) -5.97 1 vs. 3, p<0.01 2 vs. 3, p<0.05 HbA1c 1) -3.74 2) -3.42 3) -4.49 1 vs. 3 and 2 vs. 3, p<0.05	No serious adverse events including death, hospitalization, disability, life- threatening experience, or any that required medical or surgical intervention

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Mingrone	RCT	1) conventional	N=60	2 years	BMI ≥35	Mean Age	Mean change in	Late complications
2012		medical	1) 20		T2D duration ≥5	1) 43.5	HbA1c (%)	2) 6
		therapy	2) 20		years	2) 42.8	1) -0.8	3) 3
		2) BPD	3) 20		HbA1c≥7%	3) 43.9	2) -3.9	
		3) RYGB					3) -2.2	Reoperations
						47% male	1 vs. 2, p<0.001	2) 1
							1 vs. 3, p=0.003	3) 1
						Mean BMI	2 vs. 3, p=0.001	
						1) 45.6		No deaths in any group
						2) 45.1	Mean change in	
						3) 44.9	BMI	
							1) -2.6	
						Mean weight (kg)	2) -16.0	
						1) 136.4	3) -15.5	
						2) 137.9	1 vs. 2, 1 vs. 3, 2 vs.	
						3) 129.8	3, all p=0.001	
						Mean HbA1c	Mean weight loss	
						1) 8.5	(kg)	
						2) 8.9	1) 4.7	
						3) 8.6	2) 33.8	
							3) 33.3	
							1 vs. 2, 1 vs. 3, 2 vs.	
							3, all p=0.001	
							Reduction in anti-	
							hypertensive	
							therapy (%)	
							1) 70	
							2) 85	
							3) 80	
							p=NR	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
O'Brien 2006	RCT	1) LAGB 2) low-calorie diet, pharmaco- therapy and lifestyle change	N=80 1) 40 2) 40	24 months	Age 20-50 years BMI 30-35 Obesity-related comorbidity, severe physical limitations, and/or clinically significant psychosocial problems Previous unsuccessful weight loss attempts during the last 5 years	Mean age 1) 41.8 2) 40.7 % male 1) 25 2) 23 Mean BMI 1) 33.7 2) 33.5 Mean weight (kg) 1) 95.0 2) 94.8	Mean weight loss (kg) 1) 74.5 2) 89.5 Mean change in BMI 1) -26.4 2) -31.5 Mean %EWL 1) 87.2 2) 21.8 All above outcomes p<0.001 Metabolic syndrome remission 1) 1/15 (24%) 2) 8/15 (3%) p<0.002	No perioperative complications occurred Surgical revision 1) 4 2) N/A Port site infection 1) 1 2) N/A Mortality not reported

Design Interv	ntions Patients	Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
O'Brien 2010 RCT 1) LAGE 2) lifest interver	N=50 1) 25 ion 2) 25	24 months	Age 14-18 years BMI >35 with comorbidities >3 years attempting to lose weight by lifestyle means	Mean age 1) 16.5 2) 16.6 % male 1) 36 2) 28 Mean BMI 1) 42.3 2) 40.4 Mean weight (kg) 1) 120.7 2) 115.4	Mean change in BMI 1) -29.6 2) -39.2 Mean weight loss (%) 1) 28.2 2) 3.1 Mean weight loss (kg) 1) 34.6 2) 3.0 Mean %EWL 1) 78.8 2) 13.2 All outcomes	Adverse events 1) 13 2) N/A Reoperations 1) 8 2) N/A Hospital admissions 1) 1 2) 1

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
O'Brien 2013	RCT (follow-up to 2002 study)	1) LAGB 2) non-surgical therapy 3) cross-over (to LAGB)	N=80 B/L (51 follow-up) 1) 40 B/L (31 follow-up: 5 WL only, 27 complete) 2) 40 B/L (10 follow-up) 3) 10	10 years	Age 20-50 years BMI 30-35 Obesity-related comorbidity, severe physical limitations, and/or clinically significant psychosocial problems Previous unsuccessful weight loss attempts during the last 5 years	Mean age 1) 53.58 2) 53.30 3) 52.00 % male 1) 16.1 2) 40.0 3) 30.0 Mean BMI 1) 33.6 2) 33.8 3) 33.8 Mean weight (kg) 1) 94.7 2) 95.1 3) 96.2	Mean weight loss (kg) 1) 80.53 (b) 2) 94.72 (a) 3) 84.19 Mean change in BMI 1) 25.83 (b) 2) 33.12 (a) 3) 29.70 Mean %EWL 1) 63.04 (b) 2) -2.63 (a, c) 3) 48.15 (b) Metabolic syndrome remission 1) 10 2) +1 3) 5 a: p<0.05 compared to (1); b: p<0.05 compared to (2); c: p<0.05 compared to (3)	Surgical revision 1) 19 2) N/A 3) 5 Band reversal 1) 4 2) N/A 3) 3

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Raffaelli 2014	Prospective cohort	1) RYGB 2) Lifestyle intervention and medical therapy for comorbidities	N=40 1) 20 2) 20	12 months	BMI <u>></u> 40 or >35 with T2D Age 30-60 years No sustained weight loss in previous year	Mean weight (kg) 1) 129.1 2) 124.8 43% male Mean BMI 1) 43.80 2) 42.26 Mean HbA1c (%) 1) 7.0 2) 6.3	Mean weight loss (kg) 1) 91.8 2) 116.8 p<0.01 Mean change in BMI 1) -31.7 2) -40.3 p<0.0001	None reported
Ramon 2012	RCT	1) RYGB 2) VSG	N=15 1) 7 2) 8	12 months	BMI >35 with 1 or more comorbidities or 40-50 BMI Age 18-60 years Females only	Mean age 1) 46.1 2) 49.8 Mean BMI 1) 44.2 2) 43.5 Fasting GLP-1 (pg/mL) 1) 7.3 2) 7.4 Fasting PYY (pg/mL) 1) 73.1 2) 61.25 Fasting PP (pg/mL) 1) 32.8 2) 46	Fasting GLP-1 (pg/mL) 1) 5.5 2) 3.6 p=NS Fasting PYY (pg/mL) 1) 75.7 2) 64.2 p<0.05 Fasting PP (pg/mL) 1) 32.4 2) 37.6 p<0.05	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Risstad 2015	RCT	1) RYGB	N=60	5 years	BMI 50-60	Mean age	Mean BMI	Patients with adverse
		2) BPD/DS	1) 31		Age 20-50 years	1) 35	1) 41.2	events (%)
			2) 29			2) 36	2) 33.1	1) 67.7
							p<0.001	2) 79.3
						30% male		p=NS
							Weigh regain (kg)	
						Mean BMI	1) 9.9	Patients with hospital
						1) 54.8	2) 8.7	readmissions (%)
						2) 55.2	p=NS	1) 29
							(720	2) 59
						Mean weight (kg)	Remission of 12D	p=0.02
						1) 162	1) 4/5 (80%)	Dationate with summary
						2) 162	2) 6/6 (100%)	related to precedure
							p=NS	
							Pomission of	(%)
							motabolic	1) 5.7 2) AA Q
							syndromo	2)44.0
							1) 17/20 (85%)	μ=0.002
							2) 22/23 (96%)	One death in the RVGR
							n=NS	group from renal
								cancer

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Romero 2012	Prospective	1) VSG	N=22	6 weeks	T2D diagnosis	Mean age	Mean change in	None reported
	cohort	2) RYGB	1) 6		Severely obesity	1) 49.5	BMI	
		3) T2D controls	2) 6	(controls		2) 49.2	1) -47.0	
		4) Non-T2D	3) 5	evaluated on		3) 50.0	2) -45.1	
		controls	4) 5	single occasion)		4) 48.0		
							Mean weight loss	
						41% male	(%)	
							1) 11.3	
						Mean BMI	2) 13.0	
						1) 52.8		
						2) 50.8	Mean HbA1c (%)	
						3) 46.0	1) 5.0	
						4) 46.4	2) 4.5	
						Mean HbA1c (%)	(within group	
						1) 6.3	comparisons p=NS	
						2) 6.5	for main outcomes)	
						3) 4.5		
						4) 6.5		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Schauer 2012	RCT	1) intensive	n=150	12 months	Age 20-60 years	Mean age	Mean weight loss	Reoperation
		medical	1) 50		T2D diagnosis	1) 49.7	(kg)	1) 0
		therapy (IMT)	2) 50		BMI 27-43	2) 48.3	1) 99.0	2) 3
		2) RYGB	3) 50			3) 47.9	2) 77.3	3) 1
		3) VSG					3) 75.5	
						34% male	a: p<0.001; b:	Adverse event
							p<0.001; c: p=0.50	requiring
						Mean BMI		hospitalization
						1) 36.3	Mean change in	1) 4
						2) 37.0	BMI	2) 11
						3) 36.1	1) -34.4	3) 4
							2) -26.8	
						Mean weight (kg)	3) -27.2	No deaths or life-
						1) 104.4	a: p<0.001; b:	threatening
						2) 106.7	p<0.001; c: p not	complications
						3) 100.6	reported	
						Mean HbA1c (%)	a=RYFB vs. IMT:	
						1) 8.9	b=VSG vs IMT:	
						2) 9.3	c=RYGB vs. VSG	
						3) 9.5		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Schauer 2014	RCT (follow-up to 2012 study)	1) intensive medical therapy (IMT) 2) RYGB 3) VSG	n=137 1) 40 2) 48 3) 49	3 years	Age 20-60 years T2D diagnosis BMI 27-43	Mean age 1) 50.3 2) 48.0 3) 47.8 34% male Mean BMI 1) 36.4 2) 37.1 3) 36.1 Mean weight (kg) 1) 104.5 2) 106.8 3) 100.6 Mean HbA1c (%) 1) 9.0 2) 9.3	Mean weight (kg) 1) 100.2 2) 80.6 3) 79.3 a: p<0.001; b: p<0.001; c: p=0.69 Mean change in BMI 1) -34.8 2) -27.9 3) -29.2 a: p<0.001; b: p=0.006; c: p not reported a=RYFB vs. IMT; b=VSG vs IMT; c=RYGB vs. VSG	No life-threatening complications or deaths
						2) 106.8 3) 100.6 Mean HbA1c (%) 1) 9.0 2) 9.3 3) 9.5	a=RYFB vs. IMT; b=VSG vs IMT; c=RYGB vs. VSG	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Søvik 2010	RCT	1) RYGB	N=60	12 months	BMI 50-60	Mean age	%EBMIL	Early complications
		2) BPD	1) 31		Age 20-50 years	1) 35	1) 54.4	1) 4
			2) 29			2) 36	2) 74.8	2) 7
							p<0.001	
						30% male		Late complications
							Mean change in	1) 5
						Mean BMI	BMI	2) 9
						1) 54.8	1) -38.5	
						2) 55.2	2) -32.5	Reoperations
							p<0.001	1) 2
						Mean weight (kg)		2) 1
						1) 162		
						2) 162		All outcomes above
								p=NS
								No deaths in either
								group
Søvik 2011	RCT	1) RYGB	N=60	24 months	BMI 50-60	Mean age	Mean weight (kg)	Late complications
		2) BPD	1) 31		Age 20–50 years	1) 35	1) 111	1) 9
			2) 29			2) 36	2) 88.3	2) 12
						30% male	Mean BMI	Reoperations
							1) 37.5	1) 3
						Mean BMI	2) 30.1	2) 7
						1) 54.8	p<0.001	
						2) 55.2		
							Both outcomes	
						Mean weight (kg)	p<0.001	
						1) 162		
			1			2) 162		

Table B2. Fair Quality Studies.

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Alam 2011	Prospective cohort	1) RYGB 2) calorie restriction (CR)	N=30 1) 16 2) 14	1) 35.9 days 2) 73.5 days p=0.032	BMI ≥35 <60 years T2D duration <5 years HbA1c <8%	Mean weight (kg) 1) 111.1 2) 113.3 Mean BMI 1) 43.7 2) 43.9 DPP-4 activity 1) 529.5 2) 464.1	Mean weight loss (kg) 1) -11.1 2) -10.9 DPP-4 activity 1) -61.5 2) -5.5 It is unlikely that the decrease in DPP-4 activity after GBP is related to CR or weight loss.	None reported
Alley 2012	Retro- spective cohort	1) VSG 2) LAGB	N=108 1) 69 2) 39	9.3 months	BMI >40 or 35- 39.9 with comorbidities	Mean age 49 20% male Mean BMI 42.5	Mean %EWL 1) 47.2 2) 29.5 p=0.0003 %EBIL 1) 58.1 2) 36.9 p=0.0009 BQL Composite Score 1) 66.5 2) 57.9 p=0.0009	Overall complications 1) 11 2) 6 Clavien Grade 1 1) 6 2) 2 Clavien Grade 2 1) 3 2) 1 Reoperation 1) 2 2) 3 No deaths in either group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Angrisani 2013	RCT	1) LAGB 2) RYGB	N=51 1) 27 2) 24	10 years	BMI >35 & <50 Age >16 & <50 No hiatal hernia No previous major abdominal operations	Mean Age 34 18% male Mean BMI 43.6	BMI at 10 years 1) 36 ± 7 2) 30 ± 5 Mean %EWL at 10 years 1) 46 2) 69 p=0.03 Mean weight at 10 years 1) 101 ± 22 2) 83 ± 18	Reoperations 1) 9/22 (40.9%) 2) 6/21 (28.6%) Early complications 1) 0 2) 2 No deaths in either group
Ballantyne 2006	Retro- spective cohort	1) LAGB 2) RYGB	N=117 1) 56 2) 61	45.5 days	NIH 1991 criteria	Median age 41 24% male Median BMI 45.0	Mean change in BMI 1) -4 2) -6 p<0.05 Mean %EWL 1) 24.1 2) 51.4 p<0.05 Median postop insulin (U/mI): 1) 12.3 2) 9.1 p<0.05 p=NS for HbA1c or glucose	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Bayham 2012	Retro- spective cohort	1) RYGB 2) VSG	N=109 1) 38 2) 71 N=262 for character- istics and harms (n=123 and n=139 for RYGB and LAGB)	8 weeks	Obese patients with T2D on hypoglycemic meds	Mean age 49 30% male Mean BMI 47.5	Discontinued T2D medications 1) 30 2) 59	Major complications (%) 1) 24.7 2) 3.6 Minor complications (%) 1) 22.8 2) 6 Mortality 1) 1 2) 0
Benaiges 2011	Prospective cohort	1) RYGB 2) VSG	N=140 1) 95 1) 45	12 months	1991 NIH criteria Age 18-55	Mean age 45 18% male Mean BMI 45.7	Mean %EWL at 12 months 1) 82.7 2) 80.9 p=NS 40-50% reduction in CV risk via FRS and REGICOR; p=NS between groups Resolution of HTN (%) 1) 74.4 2) 64.3 p=0.NS Resolution of HLD (%) 1) 100 2) 75 p=0.014	Perioperative complications (%) 1) 16.8 2) 8.9 p=NS Readmission rate (%) 1) 1.1 2) 2.2 p=NS No deaths in either group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Benaiges 2013	Prospective cohort	1) RYGB 2) VSG	N=193 1) 115 2) 78	24 months	1991 NIH criteria Age 18-55	Mean age 45 17% male Mean BMI 45.1	Resolution of insulin resistance (%) 1) 92.9 2) 87.5 p=NS T2D resolution (%) 1) 62.1 2) 60 p=NS	None reported
Brunault 2011	Prospective cohort	1) LAGB 2) VSG	N=131 1) 102 2) 29	12 months	Not reported	Mean age 40 18% male Mean BMI 49.5	Mean change in BMI: 1) -7.9 2) -12.1 p=NR Mean %EWL: 1) 34.8 2) 43.8 p=0.02 Significant (p=0.0048) improvement in psychosocial QoL forV VSG, but no other differences	Reoperations 1) 20 2) 5 p=NS Postoperative fistula 1) 0 2) 3 p=0.01 No deaths reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Busetto 2007	Cross- sectional	1) LAGB 2) weight management intervention	N=1642 1) 821 2) 821	1) 5.6 ± 1.9 years 2) 7.2 ± 1.2 years	BMI >40	Mean age 1) 38.2 2) 42.8 25% male Mean BMI 1) 48.7 ± .4 2) 48.1 ± .5	Mean BMI at 3 years 1) 38.6 ± 7.3 2) NR Mean %EWL 1) 40.9 ± 21.7 2) NR	Reoperations 1) 107 (13%) 2) N/A Mortality 1) 8 (0.97%) 2) 36 (4.38%)
Chen 2013	Retro- spective cohort	1) VSG 2) LAGB	N=32 (16 in each group	1 year	T2D diagnosis Age 30-60 BMI 25-35	Mean age 45.3 34% male Mean BMI 30	T2D remission 1) 1 (50%) 2) 9 (100%) P=0.002 Partial remission 1) 7 2) 7 Significant reductions in selected UKPDS risks with both procedures	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Cottam 2006	Prospective	1) RYGB	N=362	Up to 3 years	Not reported	Mean age 42.5	Mean %EWL at 1	Minor reoperation
	cohort	2) LAGB	(181 in			16% male	year	1) 25
			each			Mean BMI 47.2	1) 76	2) 28
			group)				2) 48	p=NS
							p<0.001	
								Major reoperation
							T2D resolution (%)	1) 10
							1) 78%	2) 15
							2) 50%	p=NS
							p=0.010	
								Downward trend over 3
							HLD resolution (%)	years significant in
							1) 61	favor of LAGB
							2) 40	
							p=0.009	No deaths in either
								group
							HTN resolution (%)	
							1) 81	
							2) 56	
							p=0.003	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Coupaye 2013	Retro- spective cohort	1) RYGB 2) VSG	N=60 (30 in each group)	6 months	Not reported	Mean age 46.6 27% male Mean BMI 49.7	Mean BMI at 6 months 1) 39.6 ± 7.4 2) 40.4 ± 9.4 p=NS Weight loss (kg) 1) -31.8 ± 10.2 2) -29.1 ± 13.9 p=NS	None reported
Cutolo 2012	Retro- spective cohort	1) RYGB 2) VSG	N=31 1) 16 2) 15	Up to 24 months	T2D diagnosis	Mean age 45 45% male Mean BMI 49.5	Mean change in BMI 18-24 months (%) 1) 33 ± 11 2) 29 ± 8 p=NS Mean %EWL 1) 52 ± 19 2) 53 ± 16 p=NS D/C antidiabetics 1) 14 2) 13 p=NR	Concomitant surgery 1) 4 2) 3 p=NR Reoperation 1) 3 2) 3 p=NR

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
del Genio 2007	Retro- spective cohort	1) RYGB 2) dietary and lifestyle correction	N=40 1) 20 2) 20	1) 6 weeks 2) 6 months	Not reported	Mean age 37.6 45% male Mean BMI 50.3 Mean weight 138.5kg Mean fat mass 48.6%	Weight loss (kg) 1) -14 2) -22 p=NR Fat mass (%) 1) -0.2 2) -5.2 Change only significant in group 2 (p=0.002)	None reported
Demaria 2010	Retro- spective cohort	1) RYGB 2) LAGB	N=218 (109 in each group)	90 days	T2D present BMI 30-34.9	Mean age 52.4 23.4% male Mean BMI 33.8	BMI at 90 days 1) 30.6 ± 3.0 2) 31.6 ± 2.5 p=0.018 %EBW 1) 41.7 ± 15.0 2) 40.6 ± 46.8 p=NS D/C antidiabetics (%) 1) 37.5 2) 21.1 p=0.016	Any complication through 90 days 1) 20 2) 3 p<0.05 Serious complications 1) 3 2) 1 No deaths in either group

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Deveney 2004	Retro- spective cohort	1) RYGB 2) BPD	N=93 1) 57 2) 36	Up to 2 years	No prior failed bariatric surgery	Mean age 45 22% male Mean BMI 60	%EBW at 12 months 1) 54 ± 16	Wound infection* 1) 47 2) 25
							2) 53 ± 11 %EBW at 24 months 1) 67 ± 18 2) 63 ± 21	p=NS Postop anastomotic leak* 1) 8 2) 7
							p=NS for both comparisons Hospital LOS*	Mortality 1) 2 2) 1
							2) 8.7d p<0.05	*from full sample only
Dixon 2007	RCT	1) LAGB 2) low-energy diet	N=23 1) 26 2) 27	2 years	Age 20-50 BMI 30-35 & comorbidities Weight loss attempt in last 5 years	Mean Age 41.4 25% male Mean BMI 33.4 Mean Weight 94.5kg	Mean weight loss (kg) 1) 20.3 2) 5.9 p<0.001	None reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Dolan 2004	Retro- spective cohort	1) BPD 2) LAGB	N=46 1) 23 2) 23	24 months 1) 30 2) 34	BMI 40-50	Mean age 1) 41 2) 39 30% male Mean BMI 1) 56.9 2) 55.9	Mean change in BMI 1) -22.3 2) -17 p=0.04 Mean %EWL 1) 64.4 2) 48.4 p=0.02 Resolution of obstructive sleep apnea 1) 4/5 2) 2/3 Fishers exact 0.64 Resolution of hypertension 1) 4/6 2) 4/6 Fishers exact 0.60 Resolution of T2D 1) 2/2 2) 2/3	Complications 1) 13 (56.5%) 2) 2 (8.7%) p=0.001 Reoperations 1) 7 (30.4%) 2) 2 (8.7%) No deaths in either group
						Mean BMI 1) 56.9 2) 55.9	Mean %EWL 1) 64.4 2) 48.4 p=0.02 Resolution of obstructive sleep apnea 1) 4/5 2) 2/3 Fishers exact 0.64 Resolution of hypertension 1) 4/6 2) 4/6 Fishers exact 0.60 Resolution of T2D 1) 2/2 2) 2/3 Fishers exact 0.65	Reoperations 1) 7 (30.4%) 2) 2 (8.7%) No deaths in either group

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Dorman 2012	Retro- spective cohort	1) medical management (NSC) 2) LAGB 3) BPD/DS	N=172 1) 29, 29 2) 30, 30 3) 27, 27 Each group was compared to the same # of patients who under- went RYGB	1 year	BMI >35 with T2D diagnosis b/w 2001-2008	Mean age 1) 52.3 2) 54.0 3) 51.4 38% male Mean BMI 1) 41.3 2) 46.6 3) 51.5 Mean HbA1c 1) 7.2 2) 7.1 3) 7.7	BMI (NSC vs. RYBG) no change vs 14.8, p<0.001 Mean %EWL (NSC vs. RYBG) -37.4% > than NSC, p<0.001 Mean change in HbA1c (NSC vs. RYBG) no change vs1.3, p<0.001 Mean change in BMI (RYBG vs. LAGB) -14.8 vs6.5, p<0.001 Mean %EWL (RYBG vs. LAGB) 20.8% < RYGB, 95% CI: 17.3–24.3 Mean change in HbA1c (RYBG vs. LAGB) -0.8 vs. no change, p=0.009 HbA1c (RYGB vs. BPD/DS) -2.4 vs1.3, n=0.001	Readmissions for RYGB, LAGB, and DS = 11.6%, 6.7%, and 14.8% Overall complication rates for RYGB, LAGB, and DS = 15.1%, 10%, and 40.7% Reoperation range for RYGB, LAGB, and DS = 2, 1, and 0 No mortality

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
DuPree 2014	Retro-	1) RYGB	N=38699	6 months	>17 years old	Mean age	Resolution of GERD	New onset GERD
	spective	2) VSG	1) 33867			1) 45.4	1) 62.8%	1) 2.2%
	cohort		2) 4832			2) 46	2) 15.9%	2) 8.6%
							p0<0.001	p<0.05
						% male		
						1) 20.9	The percentage of	Postoperative
						2) 26.7	patients who	complications (15.1%
							experienced	vs 10.6%),
						Mean BMI	resolution	gastrointestinal
						1) 47.6	of comorbidities	adverse events (6.9% vs
						2) 47.9	was decreased in the VSG patients	3.6%), and increased need for revisional
						Preoperative GERD	who had	surgery (0.6% vs 0.3%)
						1) 50.4%	preoperative GERD	were higher for VSG (all
						2) 44.5%		p<0.05).
								Mortality
								1) 61 (0.2%)
								2) 3 (0.1%)

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Garrido-	Prospective	1) BPD/DS	N=31	90 days	Not reported	Mean age	BMI	None reported
Sanchez 2012	cohort	2) VSG	1) 18			1) 40.06	1) -7.98	
			2) 13			2) 43.15	2) -7.98	
							p=NS	
						23% males		
							HbA1c	
						Mean BMI	1) -1.81	
						1) 50.05	2)81	
						2) 48.01	p<0.01	
						Mean HbA1c	Mean Cholesterol	
						1) 6.75	1) -1.62	
						2) 6.56	2)12	
							p<0.001	
						Mean Cholesterol		
						1) 5.06	Mean Triglycerides	
						2) 5.02	1)22	
							2)37	
						Mean Triglycerides	p=NS	
						1) 1.63		
						2) 1.68		
Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
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Gehrer 2010	Prospective cohort	1) VSG 2) RYGB	N=136 1) 86 2) 50	24.4 months	Not reported	Mean age 1) 41.9 2) 43.5 28% male Mean BMI 1) 46.5 2) 44.2	Mean change in BMI 1) -10.8 2) -13.8 %EBMIL 1) 60 2) 79 Vit. B deficiency (%) 1) 18 2) 58 p<0.0001 Vit. D deficiency (%) 1) 32 2) 52 p=0.02 Iron deficiency (%) 1) 18 2) 28 p=NS	None reported
Halperin 2014	RCT	1) RYGB 2) T2D and weight management	N=38 1) 19 2) 19	12 months	T2D >1year BMI 30-42 Age 21-65	Mean age 51.7 39% male Mean BMI 36.3 Mean fat mass 44kg Mean HbA1c 8.5%	Fat Mass (kg) 1) -22.7 2) -6.2 p<0.001 HbA1c <6.5% (%) 1) 58 2) 16 p=0.03	None reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Helmio 2012	RCT	1) RYGB 2) VSG	N=238 1) 117 2) 121	30 days	BMI >40 or BMI >35 w/comorbidities Age 18-60 Supervised and failed diet & exercise program	Mean Age 49 30.4% male Mean BMI 44.6	Only complications reported.	Major complications (%) 1) 7.4 2) 5.8 p=NS Minor complications (%) 1) 17.1 2) 7.4 p=0.023 Overall morbidity (%) 1) 26.5 2) 13.2 p=0.01 Reoperation (%) 1) 3.4 2) 2.5 p=NS No deaths in either group

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Himpens 2006	RCT	1) LAGB	N=80	3 years	Not reported	Mean Age 38	Mean weight loss	GERD occurrence (%)
		2) VSG	1) 40			20% male	(kg)	1) 8.8
			2) 40			Median BMI 38	1) 17	2) 21.8
							2) 29.5	p=NS
							p<0.0001	
								All reoperations
							Mean %EWL	1) 9
							1) 48	2) 4
							2) 66	
							p=0.0025	Revisions
								1) 4 (to RYGB)
							Mean change in	2) 2 (to DS)
							BMI	
							1) -18.0	Overall complications
							2) -27.5	1) 16
							p=0.0004	2) 6
								No deaths reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Hutter 2011	Prospective	1) VSG	N=28616	1 year	Not reported	Mean age	Mean change in	30-day reoperations
	cohort	2) LAGB	1) 944			1) 46.52	BMI	1) 28 (2.97%)
		3) RYGB (lap)	2) 12193			2) 44.31	1) -11.87	2) 112 (0.92%)
		4) RYGB (open)	3) 14491			3) 44.6	2) -7.05	3) 728 (5.02%)
			4) 988			4) 45.52	3) -15.34	4) 50 (5.06%)
						23% male	T2D resolution (%)	30-day morbidity
							1) 55	1) 53 (5.61%)
						Mean BMI	2) 44	2) 175 (1.44%)
						1) 46.24	3) 83	3) 857 (5.91%)
						2) 43.91		4) 148 (14.98%)
						3) 46.07	Hypertension	
						4) 48.80	resolution (%)	Mortality
							1) 68	1) 2 (0.21%)
							2) 44	2) 10 (0.08%)
							3) 79	3) 49 (0.34%)
								4) 11 (1.11%)
							OSA resolution (%)	
							1) 62	
							2) 38	
							3) 66	
							GERD resolution	
							(%)	
							1) 50	
							2) 64	
							3) 70	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
lesari 2013	Prospective	1) diet-induced	N=20	6 months	No T2D	Mean age	Mean weight loss	None reported
	cohort	weight loss	1) 10		diagnosis	1) 41.2	1) 14.7 (p<0.01)	
		2) BPD	2) 6			2) 38	2) 29.9 (p<0.01)	
						25% male	Mean change in BMI	
						Mean Weight	1) -5.2 (p<0.05)	
						1) 132.1	2) -10.5 (p<0.05)	
						2) 134.2		
							FBG (mmol/L)	
						Mean BMI	1) -0.17	
						1) 49	2) -1.28	
						2) 49.7	p<0.001	
						FBG (mmol/L) 1) 5.31		
						2) 5.41		

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Inabet 2012	Retro- spective cohort	1) LAGB 2) RYGB 3) VSG 4) BPD/DS (only patients with metabolic syndrome were analyzed) 1a) With metabolic syndrome 2b) Without metabolic syndrome	N=23106 1) 7357 2) 14329 3) 1081 4) 339 N=186576 1) 23106 2) 163470	90 days	Age 18-75 years BMI >35	Mean age 45.5 43% male Mean BMI 46.9	Only complications reported	90-day reoperation 1) 134 (1.8%) 2) 754 (5.3%) 3) 38 (3.5%) 4) 28 (8.3%) 1 vs. 4, p<0.0001 90-day serious complication 1) 67 (0.9%) 2) 445 (3.1%) 3) 24 (2.2%) 4) 22 (6.5%) 2 vs. 1, p<0.0001 90-day mortality 1) 5 (0.1%) 2) 53 (0.4%) 3) 3 (0.3%) 4) 4 (1.2%) Remission rate of T2D was least for gastric banding (28%) compared with the other procedures (RYGB 62%, VSG 52%, BPD/DS 74%.

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Jan 2007	Retro-	1) LAGB	N=898	5 years	BMI ≥40 or BMI	Mean age	Mean %EWL	Complications (%)
	spective	2) RYGB	1) 406		≥35 with	1) 47	1) 49	1) 24
	cohort		2) 492		comorbidities	2) 44	2) 58.6	2) 32
								p=0.002
						17% male	Mean weight loss	
							(kg)	Adverse events (%)
						Mean BMI	1) 48.1	1) 5
						1) 51	2) 47.7	2) 9
						2) 49		p=NS
							Mean change in	
							BMI	Reoperation rate (%)
							1) 16.2	1) 17
							2) 18	2) 17
								p=NS
							No significant	
							differences	One death in RYGB
							between	group
							procedures	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Karlsen 2013	Prospective cohort	1) RYGB 2) intensive lifestyle intervention (ILI)	N=139 1) 76 2) 63	1 year	None reported	Mean age 1) 43 2) 47 30% male Mean BMI 1) 46	Change from baseline: Physical 1) 16.8 2) 4.9 p<0.001 95% CL 8.6 (4.6	None reported
						2) 43 QoL Scores (SF 36): Physical 1) 34 2) 39	 95% Cl, 8.8 (4.8, 12.6) Mental 1) 9.6 2) 3.5 p=0.007 5.4; 95% Cl, 1.5- 	
						Mental 1) 41 2) 2 Emotional 1) 32 2) 42	9.3 Emotional 1) 42.7 2) 15.7 p<0.007 25.2; 95% CI, 15.0-	
							35.4 RYGB was more effective at improving all HRQL- dimension scores	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Kashyap 2013	RCT	1) intensive medical management (IMT) 2) RYBG + IMT 2) VSG + IMT	N=60 1) 20 2) 20 3) 20	24 months	Not reported	Mean age 48.4 47% male Mean BMI 36.1 Mean HbA1c 9% Mean weight 104.3kg Mean T2D duration 8.4 years	Mean change in HbA1c 1) -1.1 2) -3.1 3) -2.5 1 vs. 2, p<0.001 Mean weight loss (kg) 1)5 2) -25.4 3) -22.5 2 & 3 vs. 1, p<0.001 Mean change in BMI 1) -0.2 2) -8.7 3) -8.2 2 & 3 vs. 1, p<0.001 Triglycerides (mg/dL) 1) -56 2) -56 3) -2 p=NS HDL (mg/dL) 1) 4.8 2) 13.8 3) 16.8 1 vs. 2 & 3, p=0.002	No deaths in any group

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Kehagias 2011	RCT	1) RYGB 2) VSG	N=60 1) 30 2) 30	3 years	BMI <50	Mean Age 34.9 40% male Mean BMI 45.4	Mean change in BMI 1) -14.5	Early morbidity (%) 1) 10 2) 13
			,				2) -15.3 p=NS	p=NS
							%EBMIL	Late morbidity (%) 1) 10
							1) 61.4 2) 68.2	2) 10 p=NS
							p=NS	Reoperations
							Mean %EWL	1) 1
							2) 68.5	2) 1
							p=NS	No mortality
							No significant	
							differences were seen for resolution	
							of comorbidities between groups	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Kim 2006	Retro-	1) RYGB	N=392	18 months	BMI ≥40 or BMI	Mean Age	Mean %EWL	Early complications (%)
	spective	2) LAGB	1) 232		≥35	1) 38.5	1) 68	1) 5.2
	cohort		2) 160		w/comorbidities	2) 41.7	2) 47.5	2) 0.6
							p=NS	
						17% male		Late complications (%)
							Mean %EWL for	1) 0.4
						Mean BMI	BMI >50	2) 3.7
						1) 47.2	1) 50.5	
						2) 47.1	2) 40.7	Overall complications
							p=NS	were not significantly
								different.
							Significant	
							improvement of	No deaths in either
							comorbidities	group
							including,	
							hypertension, T2D,	
							hyperlipidemia,	
							arthritis, GERD,	
							and stress urinary	
							incontinence were	
							not statistically	
							different between	
							groups.	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Kokkinos 2013	Prospective cohort	1) RYGB 2) VSG	N=37 1) 14 2) 23	6 months	Not reported	Mean age 1) 38 2) 40.3 Mean BMI 1) 47.9 2) 51.6	BMI 1) -13.4 2) -13.3 p=0.05 No significant differences for systolic or diastolic BP between the two groups Both procedures proved to be similarly effective in inducing improvement of cardiovascular indices.	None reported
Kruger 2014	Retro- spective cohort	1) RYGB 2) LAGB 3) VSG	N=3640 1) 2966 2) 352 3) 118	~5 years	Age 18-74 BMI 34-80 BMI>40 or BMI>35 with significant comorbidities	17% male Mean age 44 Mean BMI 1) 47.1 2) 43.9 3) 45.3	Mean %EWL over 5 years 1) 55 2) 45 3) 62 p=NR	Major complications (%) 1) 6.9 2) 2.8 3) 12.7 1 vs. 2, p<0.0001 1 vs. 3, p<0.005 2 vs. 3, p<0.05 Reoperation (%) 1) 2.33 2) 1.42 3) 3.39 Mortality 1) 3 2) 0 3) 0

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Laferrere 2008	Prospective cohort	1) RYGB 2) hypocaloric diet	N=19 1) 9 2) 10	1 month	Females with T2D	Mean Age 45.6 Mean Weight 112kg Mean BMI 43.3 Mean T2D duration 26.6 months Mean HbA1c 6.6	Mean weight loss (kg) 1) 10.0 2) 9.8 p=NS Mean change in BMI 1) -3.8 2) -3.7 p=NS Fasting glucose (mmol/l) 1) -1.53 2) -1.50 p=NS All patients in the RYGB group discontinued their T2D medications vs. 2 in the diet group	No serious adverse events in any group.
Leonetti 2012	Prospective cohort	1) VSG 2) conventional therapy	N=60 1) 30 2) 30	18 months	Morbid obesity with T2D	Mean age 1) 53.0 2) 56.0 Mean BMI 1) 41.3 2) 39.0 Mean HbA1c (%) 1) 7.9 2) 8.1	Mean BMI 1) 28.3 2) 39.8 <i>p</i> <0.001 Mean HbA1c (%) 1) 6.0 2) 7.1 <i>p</i> <0.001	None reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Leyba 2011	Prospective cohort	1) RYGB 2) VSG	N=117 1) 75 2) 42	1 year	BMI 35-49.9	Mean Age 1) 38.6 2) 34.6 19% male Mean BMI 1) 42.1 2) 41.1	Mean %EWL 1) 86.0 2) 78.8 p=NS	Minor complications 1) 0 2) 4 p<0.02 Major complications 1) 7 2) 2 P=NS No deaths in either group
Lim 2014	Retro- spective cohort	1) VSG 2) RYGB	N=454 1) 226 2) 228	5 years	All patients were military retirees or family members of active duty service personnel; no patients were on active duty	Median age 1) 47.2 2) 45.6 9% male Mean BMI 1) 41 2) 41	Mean %EWL 1) 54 2) 57 p=NS	None reported
Lips 2013	Prospective cohort	1) LAGB 2) RYGB	N=27 1) 11 2) 16	3 months	Obese females eligible for dietary and surgical treatment	Mean age 47.4 Mean BMI 1) 43.1 2) 44.2 Mean weight (kg) 1) 118.6 2) 128.2	Mean weight (kg) 1) 106.6 (p<0.05) 2) 108.1 (p<0.05) Mean BMI 1) 38.4 (p<0.05) 2) 37.1 (p<0.05) Mean weight loss (%) 1) 10.2 (p<0.05) 2) 15.7 (p<0.05)	None reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Lips 2014	Prospective	1) LAGB (non-	N=54	3 weeks	(1), (2), (3), (4):	Mean age	Mean weight (kg)	None reported
	cohort	T2D)	1) 11		fulfilled	1) 46.3	1) 113.1	
		2) RYGB (non-	2) 16		international	2) 48.6	2) 119.4	
		T2D)	3) 15		criteria for	3) 51.3	3) 112.5	
		3) RYGB (T2D)	4) 12		bariatric surgery;	4) 50.8	4) 105.3	
		4) very low-			(4): eligible for			
		calorie diet			dietary	Mean BMI	Mean BMI	
		(T2D)			treatment and	1) 43.1	1) 40.5	
					did not wish to	2) 44.2	2) 40.9	
					undergo surgery	3) 43.5	3) 40.4	
						4) 40.2	4) 37.7	
						Mean weight (kg)	3 & 4 vs. 1 & 2,	
						1) 118.6	p=NS for both	
						2) 128.2	outcomes	
						3) 121.3		
						4) 112.0		

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Martins 2011	Prospective	1) RYGB 2) residential	N=179	1 year	Not reported	Mean age	Weight loss (kg)	None reported
	conort	intermittent	2) 27			2) 40.2	2) 21.7	
		program	3) 56			3) 38.4	3) 17.6	
		3) commercial weight loss	4) 46			4) 41.4	4) 6.7	
		camp 4) hospital				29% male	Weight loss (%) 1) 30.5	
		outpatient				Mean BMI	2) 14.8	
		program				1) 45.2	3) 13.0	
						2) 45.3	4) 5.3	
						3) 48.3		
						4) 44.3	1 vs. 2, 3 or 4 for	
							both outcomes,	
							p<0.0001	
							There were no	
							differences in	
							changes in total or	
							LDL cholesterol,	
							triacylglycerol or	
							glucose between	
							groups	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Messiah 2013	Prospective	1) RYGB	N=890	1 year	Aged 11-19	25% male	Mean change in	120 total complications
	cohort	2) LAGB	1) 454				BMI	1) 98
			2) 436			Mean BMI	1) -17.1	2) 22
						1) 53.6	2) -6.9	
						2) 49.14	p<0.001	Readmissions
								1) 45
						Mean weight	Mean weight loss	2) 10
						1) 167.58	(kg)	
						2) 155.66	1) 48.6	Reoperations
							2) 19.8	1) 29
							p<0.001	2) 8
							Hyperlipidemia	1 death after RYGB (cardiac failure)
							1) 58.8	
							2) 23.3	
							p<0.05	
							P	
							T2D, hypertension,	
							asthma, and OSA	
							improved in both	
							groups but were	
							not statistically	
							different b/w them	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Mingrone 2002	RCT	1) diet protocol 2) BPD	N=79 1a) 21 women 1b) 12 men 2a) 31 women 2b) 15 men	1 year	Age 30-45 Morbidly obese	34% male Mean weight 1a) 121.6 1b) 147.3 2a) 125.3 2b) 151.8 Mean BMI 1a) 48.4 1b) 47.8 2a) 48.3 2b) 48.0	Weight loss 1a) 7.1 1b) 9.1 2a) 35.1 2b) 52.1 BMI 1a) -4.6 1b) -3 2a) -13.1 2b) -17.6 Between-group differences were not assessed but only BPD groups had a significant changes from baseline	None reported
Müller 2008	Retro- spective cohort	1) LAGB 2) RYGB	N=104 1) 52 2) 52	3 years	BMI>40 or BMI>35 with significant comorbidities History of obesity >5 years Failed conservative treatment	Mean age 1) 40.1 2) 40.7 13% male Mean BMI 1) 45.7 2) 45.3 Mean weight (kg) 1) 124 2) 122	Mean change in BMI 1) -15.3 2) -12.2 p=0.036 QoL (MA II) 1) 1.35 2) 1.28 p=NS Overall satisfaction with procedure (%) 1) 97 2) 83 p=NS	None reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Nanni 2012	Prospective	1) RYGB	N=79	24 months	Met 1991 NIH	Mean age	Mean BMI	Early complications
	cohort	2) BPD	1) 20		guidelines for	1) 42.1	1) 29.2	1) 2
		3) Transoral	2) 30		bariatric surgery	2) 40.2	2) 29.6	2) 0
		endoscopic	3) 29					
		vertical	(results			14% male	Total weight loss	Late complications
		gastroplasty	excluded				(%)	1) 0
			from			Mean BMI	1) 34.7	2) 5
			table)			1) 44.8	2) 37.1	
						2) 47.5		No deaths in any group
							EBMIL (%)	
							1) 81.1	
							2) 79.1	
							Mean weight loss	
							(kg)	
							1) 45	
							2) 48	
							p=NR for any	
							outcome	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Nelson 2012a	Retro-	1) BPD	N=78951	≥2 years	Not reported	Mean age	Mean change in	Early reoperation (%)
	spective	2) RYGB	1) 1545			1) 45.4	BMI	1) 1.5
	cohort		2) 77406			2) 45.3	1) -36	2) 3.3
							2) -43	p<0.001
						% male	p<0.05	
						1) 21.6		Late reoperation (%)
						2) 26	>50 BMI subgroup	1) 1.3
						-,	Mean %FWL	2) 1.1
						Mean BMI	1) 79	n=NS
						1) 52	2) 67	p no
						2) /8	p < 0.01	Any reoperation (%)
						2)40	p<0.01	1) 11 5
							Comorbidity	2) 7 2
							control of T2D	2) 7.2
							control of 12D,	p<0.001
							hypertension, and	
							sleep apnea were	Similar rates for >50
							all superior with	BIMI.
							the DS (all p<0.05)	
								Overall Mortality (%)
								1) 1.2
								2) 0.3
								p<0.001
								Mortality for >50 BMI
								(%)
								1) 0.4
								2) 1 8
								p<0.001

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Nguyen 2009	RCT	1) RYGB	N=197	4.2 years	BMI 40-60 or 35	Mean age	Mean %EWL	Early complications
		2) LAGB	1) 111		with	1) 41.4	1) 68.4	1) 17 (15.3%)
			2) 86		comorbidities	2) 45.8	2) 45.5	2) 4 (4.7%)
					Age 18-60		p<0.05	p=0.02
						23% male		
							Mean change in	Late complications
						Mean BMI	BMI	1) 15 (13.5%)
						1) 47.5	1) -17	2) 0 (0%)
						2) 45.5	2) -15	p<0.01
							p<0.05	
								Reoperations
							Mean %EWL ≥50	1) 14
							vs. BMI <50 (RYGB)	2) 11
							61.0% vs. 70.9%,	p=NS
							p<0.05	(LAGB had more late
								reoperations than
							Mean %EWL ≥50	RYGB but the
							vs. BMI <50 (LAGB)	difference was not
							34.3 vs. 49.7,	significant)
							p<0.05	
								30- and 90-day and
							QoL after 1 year	mortality was
							(SF-36)	zero for both groups
							scores for all 8	
							health domains	1 year mortality
							comparable with	1) 1 (0.9%) (unrelated
							that of US norms	to surgery)
							and were not	2) 0 (0.0%)
							significantly	
							different between	
							groups	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Nocca 2011	Retro-	1) VSG	N=68	1 year	>35 BMI	Mean age	Mean %EWL	Perioperative morbidity
	spective	2) RYGB	1) 35		All patients	1) 46.5	1) 60.12	1) 1 (2.9%)
	cohort		2) 33		undergoing T2D	2) 47.5	2) 56.35	2) 2 (5.8%)
					therapy			
						Mean weight (kg)	Mean change in	No deaths in either
						1) 139.4	BMI (%)	group
						2) 131.40	1) -29.80	
							2) -29.75	
						Mean duration T2D		
						(years)	T2D remission	
						1) 6.7	1) 35/35 (100%)	
						2) 7.8	2) 31/33 (91.4%)	
						Mean HbA1c	p=NS for all	
						1) 7.9	outcomes	
						2) 8.2		

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Norstrand 2012	Prospective cohort	1) RYGB 2) lifestyle intervention	N=90 1) 49 2) 41	12 months	Participant in Clinical trial NCT00273104 who underwent 24-hour ambulatory monitoring of BP; ≥10 daytime or ≥5 nighttime recordings (See Hofso 2010)	Mean age 1) 44.4 2) 47.5 32% male Mean BMI 1) 45.5 2) 42.3 Mean weight (kg) 1) 134 2) 122 Nocturnal hypertension 1) 42 (86%) 2) 29 (71%) Daytime hypertension 1) 37 (76%) 2) 27 (66%)	Mean weight loss (kg) 1) -41 ($p \le 0.001$) 2) -10 ($p \le 0.001$) Nocturnal hypertension change 1) -28 (67%) ($p \le 0.001$) 2) -2 (7%) ($p = NS$) Daytime hypertension change 1) -24 (65%) ($p \le 0.001$) 2) -3 (11%) ($p = NS$)	None reported
Olsen 2012	RCT	1) RYGB 2) BPD	N=30 1) 16 2) 14	24 months	BMI 50-60 Age 20-50 years	Mean age 1) 34.1 2) 36.3 33% male Mean BMI 1) 55.1 2) 56.34 Mean weight (kg) 1) 160.1 2) 164.1	Mean weight (kg) 1) 110.1 2) 88.6 p=0.003 Mean BMI 1) 37.7 2) 30.4 p<0.001	None reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Ortega 2012	Retro-	1) RYGB	N=407	12.5 months	BMI >40 or 35-	Mean age	Mean %EWL	None reported
	spective	2) VSG	1) 307		40 with major	1) 43	1) 76	
	cohort		2) 100		obesity-	2) 46	2) 68	
					associated		p<0.0001	
					comorbidities	24% male		
					2 or more			
					physician-	Mean BMI		
					supervised	1) 46		
					weight	2) 53		
					loss attempts			
					within preceding	Mean weight (kg)		
					3 years	1) 122		
					No previous	2) 138		
					weight loss			
					surgery			
Padwal 2014	Prospective	1) RYGB	N=500	2 years	BM <u>></u> 40 or <u>></u> 35	Mean age	Mean weight loss	None reported
	cohort	2) intensive	1) 150		with at least 1	1) 43.5	(kg)	
		medical	2) 200	Subjects	comorbidity	2) 43.9	1) -22.0	
		management	3) 150	progressed from		3) 43.6	2) -4.1	
		3) wait-listed		wait list to IMT			3) -1.5	
		controls		to surgery and didn't remain in		12% male	p<0.0001	
				original study		Mean BMI	Mean weight loss	
				groups for		1) 46.2	(%)	
				duration of study		2) 48	1) -16.3	
						3) 49.4	2) -2.8	
							3) -0.9	
						Mean weight (kg)	p<0.0001	
						1) 128		
						2) 132	Mean change in	
						3) 134	BMI	
							1) -7.8	
						Mean HbA1c (%)	2) -1.5	
						1) 5.9	3) -0.6	
						2) 6.3	p<0.0001	
						3) 6.2		

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Paluszkiewics	RCT	1) VSG	N=72	12 months	BMI <u>></u> 40 or <u>></u> 35	Mean age	Mean %EWL	Major/minor
2012		2) RYGB (open)	1) 36		with at least 1	1) 43.9	1) 67.6	complications (%)
			2) 36		comorbidity	2) 44.9	2) 64.2	1) 8.3/10.1
					Age 18-60 years			2) 0.0/16.6
						32% male	Mean change in	p=NS for both
							BMI	
						Mean BMI	1) 32.8	Reoperations
						1) 46.1	2) 33.8	1) 0 (0.0%)
						2) 48.6		2) 1 (5.5%)
							Mean weight (kg)	p=NS
						Mean weight (kg)	1) 91.7	
						1) 130.7	2) 96.8	No deaths in either
						2) 137.7		group
							Hypertension	
							remission	
							1) 17 (47.2%)	
							2) 19 (52.7%)	
							T2D remission	
							1) 6 (16.7%)	
							2) 5 (13.9%)	
							Dyslipidemia	
							remission	
							1) 26 (72.2%)	
							2) 18 (50.0%)	
							p=NS for all	
							comparisons	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Parikh 2005	Retro- spective cohort	1) LAGB 2) RYGB 3) BPD	N=332 1) 192 2) 97 3) 43	3 years	BMI >50 undergoing a primary bariatric operation	Mean age 1) 43 2) 42 3) 41 21% male Mean BMI 1) 55.3 2) 54.8 3) 57	Mean %EWL 1) 49.5 (b) 2) 56.8 3) 77.4 (a) a: p<0.05 compared to (1); b: p<0.05 compared to (2); c: p<0.05 compared to (3)	Conversion to open (%) 1) 0.5 2) 2.1 3) 7.0 Perioperative complications (%) 1) 4.7 2) 11.3 3) 16.3 p=0.02 Reoperations 1) 2 2) 3 3) 2 No deaths in any group
Parikh 2006	Retro- spective cohort	1) LAGB 2) RYGB 3) BPD	N=780 1) 480 2) 235 3) 65	1) 12.5 months 2) 12.4 months 3) 14.5 months	BMI >40 or >35 with at least 1 comorbidity Failed prior medical therapy to lose weight	Mean age 1) 41.8 2) 41.2 3) 41.1 20% male Mean BMI 1) 46.1 2) 47.5 3) 52.6	Only complications reported.	Reoperations 1) 0 2) 5 (2 revision) 3) 3 Complications 1) 42 (8.8%) 2) 54, (23.0%) 3) 16 (24.6%) 1 vs. 2 and 3, p<0.001 Mortality 1) 0 2) 1 3) 0

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Peterli 2012	RCT	1) RYGB	N= 23	12 months	Non-diabetic	Mean age	Mean weight (kg)	None reported
		2) VSG	1) 12		patients from	41.4	1) 87.3	
			2) 11		study center (subgroup of	35.2	2) 86.3	
					ongoing "Swiss	26% male	Mean BMI	
					Multicenter		1) 31.1	
					Bypass or Sleeve Study")	Mean weight (kg) 1) 133.3	2) 32.0	
						2) 120.2	Mean %EBMIL	
							1) 77.0	
						Mean BMI	2) 65.6	
						1) 47.6		
						2) 44.7	p=NS for all	
							outcomes	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Peterli 2013	RCT	1) VSG 2) RYGB	N=217 1) 107 2) 110	2 years	Fulfilled criteria for bariatric surgery in Switzerland (BMI >40 or >35 with at least 1 comorbidity Age 18-65 years Failure of conservative treatment in prior two years	Mean age 1) 43.0 2) 42.1 28% male Mean BMI 1) 43.6 2) 44.2 Female (n) 1) 77 2) 79	Mean %EBMIL 1) 63.3 2) 72.8 p=NR Mean BMI 1) ~33 2) ~32 <i>Resolution or</i> <i>improvement of</i> <i>comorbidities (%)</i> Hypertension 1) 32/94 2) 32/89 Dyslipidemia 1) 45/95 2) 25/84 T2D 1) 66/95 2) 56/99 OSA 1) 32/99 2) 51/95 Back/joint pain 1) 16/87 2) 21/88 Depression 1) 5/88 2) 16/94	Reoperations 1) 5/110 (4.5%) 2) 1/107 (.9%) p=NS Conversion rate (%) 1) 0.9 2) 0.9 Perioperative morbidity 1) 9 (8.4%) 2) 19 (17.2%) p=NS Mortality 1) 0 2) 1

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Pohle-Krauza	Retro-	1) RYGB	N=294	42 months	Not reported	Mean age	Mean %EWL	None reported
2011	spective	2) LAGB	1) 215			1) 44.7	1) 46	
	cohort		2) 79			2) 48.1	2) 65	
							p=NS	
						17% male		
							Mean BMI	
						Mean BMI	1) 32.1	
						1) 48.7	2) 35.7	
						2) 45.3	p=NS	
Prachand 2006	Retro-	1) BPD	N=350	36 months	BMI >50	Mean age	Mean BMI	60-day reoperation
	spective	2) RYGB	1) 198			1) 40.4	1) 33.6	rate (%)
	cohort		2) 152			2) 40.5	2) 37.2	1) 4.0
							p=0.05	2) 5.3
						17% male		p=NS
							Mean %EWL	
						Mean weight (lb)	1) 68.9	Other complications
						1) 368.2	2) 54.9	not reported
						2) 346.3	p<0.05	
								30 day mortality
						Mean BMI	Mean weight loss	1) 1
						1) 58.8	(lb)	2) 0
						2) 56.4	1) 173.5	
							2) 118.0	
							p<0.01	

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Puzziferri 2008	Prospective cohort	1) RYGB 2) LAGB	N=1733 1) 1102 2) 631	24 months	1991 NIH criteria Age 18-65 years	Mean age 1) 43.1 2) 44.8 15% male Mean BMI 1) 51.1 2) 48.6 Mean weight (lb) 1) 316.2 2) 300.7 Mean excess weight (lb) 1) 168.0 2) 152.7	Mean %EWL 1) 75.06 2) 43.53 p<0.001	None reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Romy 2012	Retro- spective cohort	1) LAGB 2) RYGB	N=442 1) 221 2) 221	6 years	BMI >40 and <50 or >35 with at least 1 severe comorbidity Failed conservative therapy Complete evaluation by a multidisciplinary team Underwent prior primary bariatric procedure	Groups were matched according to sex ratio, age, baseline BMI, and follow-up rates at 6 years (values not reported)	Maximal Mean %EWL 1) 64.8 2) 78.5 Mean nadir BMI 1) 29.4 2) 26.7 Maximal weight loss (months) 1) 36 2) 18 Mean %EWL 1) 18.5 2) 27.1	Major complications 1) 47 (21.3) 2) 0 (0.0%) p<0.001 Overall complications 1) 92 (41.6%) 2) 42 (19.0%) p<0.001 Reoperations 1) 59 (26.7%) 2) 28 (12.7%) p<0.001 Total patients with reversal 1) 47 (21.3%) 2) 0 (0.0%) p<0.001 No deaths reported

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Scopinaro	Prospective	1) BPD	N=68	12 months	T2D diagnosis	Mean age	Mean BMI	Conversions
2011	conort	2) medical	1) 30 2) 29		for at least 3	1) 56.4	1) 25.3 ($p < 0.05$)	1) U 2) N/A
		T2D	2) 38		Age 35-70 years	2) 55	2) 50.2 (p=N3)	2) N/A
					BMI 25-34.9	71% male	Resolution of T2D	Early postoperative
					HbA1c <u>></u> 7.5%		1) 9 (30%)	complications
						Mean BMI	2) NR	1) 5
						1) 30.6		2) N/A
						2) 30.2	Improvement of	
							T2D (%)	Major late
						Mean HbA1c (%)	1) 17	postoperative
						1) 9.3	2) NR	complications
						2) 8.3	Control of T2D /n	1) 0
								2) N/A
							70) 1) 75 92	No dooths in aithar
							1) 23, 03 2) ND	group
								group

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Skroubis 2011	Retro- spective cohort	1) VSG 2) RYGB 3) BPD 4) VBG 5) RYGB (open) 6) Reoperation	N=1162 1) 151 2) 137 3) 699 4) 35 5) 90 6) 50 Results from 4, 5, & 6 not represent- ed here	62.7 months	Not reported	Mean age 1) 32.8 2) 36.7 3) 37.3 Mean BMI 1) 43.3 2) 46.4 3) 57.5 Mean weight (kg) 1) 124.1 2) 124.4 3) 159 T2D (%) 1) 5.8 2) 13.3 3) 19.5 Dyslipidemia (%) 1) 26 2) 28.9 3) 30 Hypertension (%) 1) 4.9 2) 13.3 3) 29 2	Mean %EWL 1) 52.7 (in year 4) 2) 60.2 3) 70.4 T2D (%) 1) 7.1 (in year 4) 2) 0 3) 1.5 Dyslipidemia (%) 1) 14.3 (in year 4) 2) 7.5 3) 3 Hypertension (%) 1) 14.3 (in year 4) 2) 10 3) 9.1	Early complications 1) 11 (7.28%) 2) 10 (7.3%) 3) 57, 8.15% Early reoperations 1) 8 (5.3%) 2) 7 (5.11%) 3) 27 (3.86%) Late complications 1) 2 (1.32%) 2) 9 (6.57%) 3) 249 (35.62%) Late reoperations 1) 2 (1.3%) 2) 9 (6.57%) 3) 224 (32.05%) Mortality 1) 0 2) 1 3) 20
Spaniolas 2014	Retro- spective cohort	1) RYGB 2) VSG	N=1005 1) 850 2) 155	30 days	Aged ≥65	31% male Mean BMI 44	Not reported	No differences for 30- day mortality, serious morbidity, or overall morbidity (even after controlling for preoperative diabetes)

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Strain 2009	Prospective	1) RYGB	N=221	1) 19.1 months	1991 NIH criteria	Mean age	Mean BMI	None reported
	cohort	2) BPD	1) 101	2) 27.5 months		1) 44.3	1) 32.5	
		3) LAGB	2) 49	3) 21.4 months		2) 43.9	2) 27.8	
		4) VSG	3) 41	4) 16.7 months		3) 39.8	3) 39.5	
			4) 30			4) 41.9	4) 37.2	
							p<0.001	
						31% male		
							Mean %EWL	
						Mean BMI	1) 70	
						1) 46.7	2) 84	
						2) 53.2	3) 38	
						3) 44.3	4) 49	
						4) 61.4	p<0.0001	
te Riele 2008	Retro-	1) LAGB	N=106	1) 23 months	1991 NIH criteria	Median age	Median Mean	Minor complications
	spective	2) RYGB	1) 53	2) 18 months		1) 40.3	%EWL	1) 5
	cohort		2) 53			2) 38.0	1) 43.4	2) 3
							2) 59.9	
						17% male	p<0.001	Severe complications
								1) 1
						Median BMI	Median BMI	2) 9
						1) 50.9	1) 38.3	
						2) 51.3	2) 34.0	Reoperations
							p=NR	1) 2
						Median weight (kg)		2) 10
						1) 147.0		
						2) 151.0		No deaths in either
								group

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Viana 2013	Prospective	1) RYGB	N=48	12 months	21-59 years old;	Mean age	Mean weight (kg)	None reported
	cohort	2) VSG	1) 24		BMI between 40	1) 33.8	1) 74.3	
			2) 24		and 45; history	2) 37.2	2) 74.6	
					of multiple			
					unsuccessful	Mean weight (kg)	Mean BMI	
					attempts to	1) 115.1	1) 27.2	
					reduce weight;	2) 106. 8	2) 69.6	
					female			
						Mean BMI	p=NS for all	
						1) 42.0	outcomes	
						2) 42.7		

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Vidal 2013	Retro-	1) RYGB	N=249	24 months	1991 NIH criteria	Mean age	Mean %EWL	Reoperations
	spective	2) VSG	1) 135		Age 18-60 years	1) 44.5	1) 66	1) 6
	cohort		2) 114			2) 44.8	2) 65	2) 4
							p=NS	p<0.001
						17% male		
							Mean BMI	Conversions to open
						Mean BMI	1) 30.8	1) 3
						1) 45.4	2) 29.2	2) 2
						2) 44.8	p=NS	
								No deaths in either
						Major comorbidities	Resolution/	group
						(n, %)	improvement of	
							comorbidities 1	
						Dyslipidemia	year after surgery	
						1) 79, 58.5	(%)	
						2. 57, 50		
							Hypertension	
						Hypertension	1) 72	
						1) 50, 37	2) 71	
						2) 38, 33.3		
							T2D	
						Sleep apnea	1) 92	
						1) 27, 20	2) 95	
						2) 42, 36.8		
							Dyslipidemia	
						T2D	1) 68	
						1) 39, 28.8	2) 58	
						2) 24, 21		
							OSA	
							1) 95	
							2) 90	
Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
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Vilarrasa 2013	Retro- spective cohort	1) RYGB 2) VSG	N=66 1) 33 2) 33	12 months	Not reported	Mean age 1) 49.7 2) 45.8	Mean BMI 1) 30.94 2) 31.46	None reported
						Mean BMI 1) 46.87 2) 49.06	1) 67.51 2) 67.01 p=NS for all	
							comparisons	
Vix 2013	RCT	1) VSG 2) RYGB	N=100 1) 55 2) 45	12 months	BMI <u>></u> 40 and <u><</u> 60 Age 18-60 years	Mean age 1) 35.13 2) 35.23 18% male	Mean %EWL 1) 82.97 2) 80.38 p=NR	None reported
						Mean BMI 1) 45.57 2) 47.09		

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Weber 2004	Prospective	1) RYGB	N=206	24 months	BM I>40 or >35	Mean age	Mean BMI	Conversion to open
	cohort	2) LAGB	1) 103		with	1) 40.1	1) 31.9	1) 1
		-	2) 103		comorbidities	2) 39.6	2) 36.8	2) 0
			-		History of		p<0.02	
					obesity >5 years	18% male		Early reoperations
					Failed		Mean %EWL	1) 11
					conservative	Mean BMI	1) 54	2) 1
					treatment >2	1) 47.8	2) 42	p=0.003
					vears	2) 48.0	p<0.05	
					, Age 18-60 years	,	'	Late reoperations
					old	Excess weight (kg)	Hypertension	1) 4
						1) 72.3	1) 12	2) 26
						2) 73.0	2) 18	p<0.001
						,	p=NS	
						Hypertension	'	Conversion to RYGB
						1) 54	T2D	1) N/A
						2) 62	1) 6	2) 17
						,	2) 18	,
						T2D	p=0.007	No deaths in either
						1) 38	1	group
						2) 45	Dyslipidemia	0 1
						,	1) 35	
						Dyslipidemia	2) 64	
						1) 75	p=0.001	
						2) 64	P	
Zerrweck 2014	Retro-	1) RYGB	N=77	12 months	BMI 50-59.9	Mean BMI	Mean %EWL	Major complications
	spective	2) VSG	1) 32			1) 52.7	1) 63.9	1) 2
	cohort	,	2) 45			2) 53.87	2) 43.9	2) 2
			,			,	p<0.05	,
						72% male	F	Reoperations
							Mean BMI	1) 0
						Mean age	1) 34.8	2) 1 (trocar-site
						1) 35.4	2) 40.9	bleeding)
						2) 37.5	p<0.05	0,
								No deaths in either
								group

Author/Year	Study Design	Comparators/ Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Zuegel 2012	Retro-	1) LAGB	N=620	>5	Not reported	Mean age	Mean %EWL	Conversion to RYGB
	spective	2) RYGB	1) 204			1) 36	1) 52.6	1) 37
	cohort		2) 416			2) 37	2) 79.9	2) N/A
							p<0.0001	
						22% male		Mortality
							Mean BAROS	1) 0
						Mean BMI	1) 3.71	2) 2
						1) 46	2) 4.04	
						2) 46	p=0.02	

Table B3. Poor Quality Studies.

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Albeladi 2013	Retro-	1) RYGB	N=70	18 months	BMI>40 or	Mean Age	Mean %EWL	Early complications
	spective	2) VSG	1) 36		BMI>35 with	1) 39.7	1) 77.6	1) 9 (25%)
	cohort		2) 34		significant	2) 38.3	2) 57.1	2) 3 (8.8%)
					comorbidities		p=0.003	
					Age 18-60 years	61% male		Late complications
					Supervised and		BMI	1) 13 (36.1%)
					failed diet &	Mean BMI	1) -16.31	2) 7 (20.6%)
					exercise	1) 46.31	2) -10.21	
					program	2) 50.39	p<0.05	Complications were not
								significantly between
							Resolution of T2D	groups.
							(%)	
							1) 85.7	Reoperations
							2) 100	1) 3
								2) 1
							Resolution of	
							hypertension (%)	No deaths in either
							1) 46.7	group after 1 year
							2) 53.8	
							Differences in	
							resolution of	
							comorbidities were	
							not significant	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Batsis 2009	Retro- spective cohort	1) RYGB 2) nutritional counseling program	N=236 1) 148 2) 88	1) 3.8 years 2) 4.0 years	Not reported	Mean Age 1) 46 2) 44 Mean Weight (kg) 1) 132 ± 24 2) 124 ± 20 Mean BMI 1) 47 ± 7 2) 43 ± 6	Mean weight (kg) 1) 90 ± 19 2) 124 ± 29 Mean BMI 1) 32 ± 6 2) 43 ± 9 Mean %EWL 1) 59 2) -2 T2D resolution 1) 20/50 2) 24/18 Hypertension resolution 1 32/126 2) 3/69 Dyslipidemia resolution 1) 39/107 2) 2/63 QOL (SF-12) Physical 1) 54 2) 47 Mental 1) 49 2) 45	Not reported
							All outcomes p<0.001	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Bekheit 2014	Retro- spective cohort	 1) RYGB 2) LAGB 3) Vertical banded gastroplasty (results not reported here) 	N=640 1) 39 2) 289 3) 312	6 years	Patients who had surgery ≥5 years before November 2011	Mean BMI 1) 45.3 2) 42.5 Male/Female (n) 106/534 Mean age 38	% EWL (Males/Females) 1) 50.76/44.82 p=0.3 2) -0.59/36.9 p=0.003	Not reported
Biertho 2003	Retro- spective cohort	1) LAGB 2) RYGB	N=1261 1) 805 2) 456	12 months	1991 NIH criteria	Mean age 41.4 20.9% male Mean BMI 44.2	Mean %EWL at 12 months 1) 33 2) 67 P=NR Mean %EWL for BMI 30-40 1) 37 2) 75 Mean %EWL for BMI 40-50 1) 32 2) 72 Mean %EWL for BMI 50-60 1) 26 2) 57	Major intraoperative complications 1) 10 2) 9 p=NS Major in-hospital complications 1) 15 2) 14 p=0.02 Conversions 1) 24 2) 9 p=NS Perioperative mortality 1) 0 2) 2 p=NS

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Boza 2010	Prospective cohort	1) RYGB 2) LAGB	N=153 1) 91 2) 62	5 years	1991 NIH criteria	Mean age 35.5 13.7% male Mean BMI 38.6	Mean %EWL 1) 92.9% 2) 52.1% p<0.001 Resolution or better control of T2D, insulin resistance, HLD, HTN: 1) 80-100% 2) 25-40% Not statistically tested	Early complications 1) 12 2) 1 p=0.014 Early reoperations 1) 8 2) 1 p=NS Late complications 1) 33 2) 17 p=NR Late reoperations 1) 9 2) 15 p=NS No deaths in either group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Breznikar 2009	Retro- spective cohort	1) LAGB 2) VSG 3) RYGB	N=246 1) 180 2) 30 3) 36	≤3 years	1991 NIH criteria	Mean age 42.0 13.8% male Mean BMI 44.0	Mean %EWL at 1 year 1) 52.4% 2) 57.9% 3) 77.9% Change in BMI at 1 year 1) -7.9 2) -15.1 3) -14.2 Resolution of T2D, HLD, HTN 1) 59-73% 2) 75-100% 3) 71-75% No statistical testing done	Reoperation 1) 9/120 2) N/A 3) 2/36 No deaths reported
Chen 2013	Retro- spective cohort	1) VSG 2) LAGB	N=417 1) 85 2) 332	54 months	No prior urinary calculi	Not reported	Not reported	Rate of urinary calculi per 1,000 P-Y: 1) 5.25 2) 3.40 p-value NR No deaths reported
Christ-Crain 2006	Prospective cohort	1) RYGB 2) LAGB 3) Nonsurgical controls	N=20 1) 5 2) 8 3) 7	2 years	BMI >37	Mean age 44.9 20% male Mean BMI 42.0	Mean BMI at 2 years: 1) 32.9 2) 33.2 3) 41.0 p<0.01	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Christou 2009	Retro- spective cohort	1) RYGB 2) LAGB	N=1035 1) 886 2) 149	Up to 7 years	1991 NIH Criteria	Mean age 40.4 26.8% male Mean BMI 50.2	BMI at 1 year 1) 32.8 2) 36.2 p=NR Mean %EWL at 1 year 1) 70.4 2) 42.8 p=NR	Overall complications 1) 135 2) 35 p=0.041 Early complications 1) 74 2) 11 p=0.86 Late complications 1) 61 2) 24 p=0.002 Early reoperations 1) 32 2) 0 p=NR Late reoperations 1) 27 2) 23 p=NR Mortality 1) 3 2) 0
Conason 2013	Retro- spective cohort	1) RYGB 2) LAGB	N=155 1) 100 2) 55	24 months	Not reported	Mean age 40 15% male Mean BMI 46	Not reported	Frequency of alcohol use at 24 months vs. baseline 1) 3.08 vs. 1.86, p=0.011 2) 3.08 vs. 3.00, p=NS

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Coupaye 2009	Prospective cohort	1) RYGB 2) LAGB	N=70 1) 49 2) 21	1 year	Not reported	Mean age 40.6 10% male Mean BMI 47.2 Mean Weight 125.8kg	Weight loss (kg) 1) 40 ± 13 2) 16 ± 8 p<0.001 Requiring vitamins 1) 47% 2) 0% p=NR	Symptoms of nutritional deficits 1) 29 (59%) 2) 6 (29%) p=NR Prevalence of deficiencies was decreased 1 year after GBP in patients taking multivitamin supplements.
Cozacov 2014	Retro- spective cohort	1) RYGB 2) VSG	N=18 1) 8 2) 10	55.2 months	Adolescent patients 11-19 years old; at least 12 months of follow-up data available	Mean age 17.5 18% male Mean BMI 47.2 Mean weight 293.1kg	Mean BMI 1) 28.9 2) 32.5 Comorbidity resolution Diabetes: 1/1 Hypertension: 2/2 Sleep apnea: 3/6 (3 lost to follow-up)	No postoperative complications or mortality

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
De Gordejuela 2011	Retro- spective cohort	1) RYGB 2) VSG	N=90 1) 60 2) 30	Up to 2 years	T2D present RYGB: BMI 40-50 or duodenal switch contraindicated VSG: BMI >60, BMI >50 with comorbs, or standalone	Mean age 50 BMI 46.2 for RYGB, 56.2 for VSG	Mean %EWL (%) at 2 years 1) 72.3 2) 72.4 p=NS EBMIL (%) 1) 71.0 2) 74.8 p=NS D/C antidiabetics (%) 1) 91.8 2) 88.9	None reported
DiGiorgi 2008	Retro- spective cohort	1) RYGB 2) LAGB	N=534 1) 403 2) 131	24 months	Vitamin D levels available No prior obesity surgery	Mean age 41 18.6% male Mean BMI 49	p=NS Vitamin D deficient at 25 months (%) 1) 40 2) 33 p=NS Elevated PTH (%) 1) 50 2) 0 p<0.05	None reported
Dittmar 2003	Retro- spective cohort	1) LAGB 2) Metformin control	N=35 1) 26 2) 9	17 months	Prior unsuccessful medical management	Mean age 40 31.4% male Mean BMI 48.5	Significant effects (p<0.05) of interaction of surgery and time on body weight, BMI, and fat mass	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Ducarme 2013	Retro- spective cohort	1) LAGB 2) RYGB	N=94 1) 63 2) 31	2.1 years (interval from surgery to conception)	Women who became pregnant after surgery	Mean Age 30.8 Mean BMI 34.1	Birth weight (g) 1) 3253 2) 2993 p=0.02	Pre-term labor according to timing of pregnancy 1) within 1 year: 13.9% 2) after 1 year: 5.9% p=NS
Eldar 2012	Retro- spective cohort	1) VSG 2) RYGB 3) VSG + RYGB (staged approach)	N=49 1) 26 2) 11 3) 12	Mean 17.4 months 1) 14 2) 12.5 3) 29.3	BMI ≥70	Mean age 40.6 41% male Mean BMI 80.7	Mean change in BMI 1) -13.6 2) -21.6 3) -31.4 p=0.02 Mean %EWL 1) 25.4 2) 43.8 3) 54.5 1 vs. 3, p=0.002	Early morbidity 1) 5 (18.5%) 2) 2 (18.2%) 3) 3 (27.3%) p=NS ≥80 BMI vs. <80 BMI 31.8% vs. 11.1%, p=NS Late morbidity 1) 2 (7.4%) 2) 3 (27.5%) 3) 4 (36.45) p=NS ≥80 BMI vs. <80 BMI 22.2% vs. 13.6%, p=NS No early (<30 days) mortality in any group Late mortality 1) 1 (3.7%) 2) 0 (0.0%)

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Facchiano	Retro-	1) LAGB	N=36 (42)	18 months	Women who	Mean age	Gestational age	Complications
2012	spective	2) RYGB	1) 19 (22)		became	1) 30.4	(weeks)	1) 2
	cohort		2) 17 (20)		pregnant after	2) 31.2	1) 38.7	2) 4
			Patients		surgery		2) 38.9	
			(preg-			Mean BMI (before		No reoperations
			nancies)			surgery)	Birth weight (g,	
						1) 42.7	total)	No deaths reported
						2) 50.5	1) 3224.8	
							2) 2983.5	
						BMI at conception		
						1) 33.9	Pregnancy-induced	
						2) 32.9	hypertension	
							1) 1	
						BMI after pregnancy	2) 0	
						1) 36.9		
						2) 35.1	Preterm labor	
							1) 3	
						weight at conception	2) 1	
						1) 92.7	No differences in	
						2) 87.5	No differences in	
						Woight after	pregnancy	
						programov	statistically	
						1) 101 2	significant	
						2) 93 7	Significant.	
						2, 55.7		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Fenske 2013	Prospective cohort	1) RYGB 2) LAGB 3) VSG	N=34 1) 10 2) 13 3) 11	12 months	BMI >35 aged 18-65	17% male Mean weight 124.1 Mean BMI 44.6 Systolic BP 142.9 Diastolic BP 87.1	Mean %EWL 1) 48.7 2) 45.0 3) 47.8 p=NS Mean change in systolic BP 1) -18.4 2) -16 3) -21.7 p=NS Mean change in diastolic BP 1) -13.8 2) -10.9 3) -13.4 n=NS	None reported
Fredheim 2013	Prospective cohort	1) intensive lifestyle intervention (ILI) 2) RYGB	N=133 1) 74 2) 59	1 year	BMI>40 or BMI>35 with significant comorbidities	Mean age 1) 47.4 2) 42.7 30 % male Mean BMI 1) 43 2) 46.8 Mean weight 1) 124 2) 138	Mean change in BMI 1) -4.2 2) -14 p<0.001 Weight loss 1) -12.1 2) -42.0 p<0.001 Remission of OSA 1) 16/40 (40%) 2) 29/44 (66%) p=0.028	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Fridman 2013	Retro-	1) RYGB	N=2199	17 months	None reported	Mean age	Mean change in	Reoperations
	spective	2) VSG	1) 1327			1) 46.3	BMI	1) 88 (0 conversions)
	cohort	3) LAGB	2) 619			2) 46.1	1) -14.8	2) 11 (5 conversions)
			3) 253			3) 48.1	2) -11.2	3) 26 (10 conversions)
							3) -5.6	
						47% male	1 vs. 2 OR 1 & 2 vs.	
							3, p<0.01	
						Mean BMI		
						1) 48.1		
						2) 44.2		
						3) 42.2		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Friedrich 2013	Prospective	1) VSG	N=54	12 months	Aged 18-65	Mean Age	Mean %EWL	None reported
	cohort	2) multi-	1) 27		BMI >30	1) 45.4	1) 64.5%	
		disciplinary	2) 27			2) 45.3	2) 38.3%	
		intervention					p<0.001	
		program (MIP)				Mean weight (kg)		
						1) 149.2	Mean weight loss	
						2) 132.9	(kg)	
							1) 48.8	
						26% male	2) 21.7	
							p=NS	
						Mean BMI		
						1) 51.7	BMI	
						2) 44.8	1) -16.6	
							2) -7.2	
						Hypertension	p=NS	
						1) 67%		
						2) 63%	Body fat	
							composition	
						T2D	1) -36.5	
						1) 41%	2) -14.4	
						2) 7%	p=NR	
						Body fat composition	Prevalence of	
						1) 73.7	hypertension	
						2) 62.8	1) 38%	
							2) 44%	
							p=NS	
							Prevalence T2D	
							1) 4%	
							2) 7%	
							p=NS	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Gan 2007	Prospective	1) LAGB	N=72	13 months	HbA1c >6%	Mean BMI	% patients not	Major complications
	cohort	2) VSG	1) 9			1) 45.6	taking T2D	1) 0
		3) RYGB	2) 11			2) 52.8	medications	2) 1
			3) 20			3) 43.5	1) 17%	3) 2
							2) 33%	
						43% male	3) 69%	No deaths in any group
							2 & 3 vs. 1,	
						Mean HbA1c	p<0.0001	
						1) 8.9		
						2) 8.0	Mean HbA1c	
						3) 8.0	1) 1.7	
							2) 1.4	
							3) 1.6	
							p=NS	
							Mean %EWL	
							1) 34.2	
							2) 35.9	
							3) 66.2	
							1 vs. 2, p=NS	
							3 vs. 1 & 2,	
							p<0.001	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Gothberg 2014	Prospective	1) adolescent	N=243	2 years	Aged 13-18	Mean age	Mean weight loss	Surgical complications
	cohort	RYGB	1) 81		years	1) 15.6	(%)	were comparable to the
		2) conventional	2) 81		BMI >40 or >35	2) 15.8	1) 32	adult group, but only
		care	3) 81		with	3) 39.7	2) -3	reported in detail for
		3) adult RYGB			comorbidities		3) 31	adolescents.
						35% male	p=NR	
								No postoperative
						Mean BMI	There were no	mortality
						1) 45.5	significant	
						2) 42.0	differences in the	
						3) 42	weight loss	
							between genders.	
						Mean weight		
						1) 133		
						2) 124		
						3) 127		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Gracia-Solano	Retro-	1) BPD- S	N=437	7 years	Not reported	Mean age	Mean BMI @ 5	Mortality (<30 days)
2011	spective	(Scopinaro)	1) 150			1) 39.9	years	1&2) 3/265 (1.1%)
	cohort	2) BPD - M	2) 115			2) 44.8	1) 26.9	3) 1/152 (0.7%)
		(modified)	3) 152			3) 42.2	2) 28.9	
		3) RYGB					3) 31.5	Early complications
						24% male		(<30 days)
							Mean %EWL @ 5	1&2) 75/265 (28.3%)
						Mean BMI	years	3) 45/152 (29.6%)
						1) 52.7	1) 85%	p=NS
						2) 52.8	2) 76%	
						3) 44.7	3) 68%	Iron deficiency (>30
						,	,	days)
							Metabolic	1) 62%
							syndrome @ 7	2) 40%
							vears	3) 32.9%
							, 1) 7/125 (5.6%)	p=0.05
							2) 4/50 (8%)	
							3) 12/40 (30%)	Reoperations
							, , , ,	1) 8 (3.2%)
							Hypertension	2) 0 (0.0%)
							resolution @	3) 1 (0.8%)
							midpoint	-, (,
							1&2) 87%	
							3) 70%	
							-,	
							Dyslipidemia	
							resolution @	
							midpoint	
							1&2) 100%	
							3) 70%	

Author/Year Stud Desig	Comparators/ n Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Hofso 2010 Prospec cohort	ive 1) RYGB 2) intensive lifestyle intervention (ILI)	N=145 1) 80 2) 66	1 year	Aged 19-66 years Patients qualifying for either surgery or lifestyle intervention	Mean age 1) 42.8 2) 47 33% male Mean weight 1) 137 2) 125 Mean BMI 1) 46.7 2) 43.3	Mean weight loss (%) 1) 30% 2) 8% Mean %EWL 1) 67% 2) 23% Mean change in BMI 1) -14 2) -3.7 All weight measures, p<0.001. T2D remission 1) 11/14 (78.6%) 2) 0/6 (0%) p=0.027 Hypertension remission 1) 20/40 (50%) 2) 9/41 (22%) p=0.016 Metabolic syndrome 1) 76% to 17% 2) -70% to 50%	No mortality 1 early complication 4 late complications 2 reoperations Gastrointestinal symptoms 1) 33/69 (48%) 2) 4/59 (7%) p<0.001

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Jimenez 2012	Prospective cohort	1) RYGB 2) VSG	N=153 1) 98 3) 55	35.4 months	T2D ≥6 months Patients were considered for surgery based on current guidelines	Mean age 50.6 38% male Mean BMI 46.5 Mean T2D duration (years) 5.9 HbA1c 7.5% Mean waist circumference 133.5	No T2D resolution (%) 1) 31.4 2) 20.4 p=NS T2D reoccurrence (%) 1) 10.31 2) 16.2 p=NS Mean %EWL 1) 65.4 2) 61.2 p=NS	None reported
Jimenez 2014	Retro- spective cohort	1) RYGB 2) VSG	N=232 1) 121 2) 111	48.7 months	T2D for at least 6 months prior to surgery; follow- up for at least 2 years	Mean age 51.5 36% male Mean BMI 46 Mean HbA1c 6.7%	Mean %EWL 1) 76.4 2) 70.2 p=0.017 Weight regain (%) 1) 16.5 2) 10.5 p=NS T2D remission (%) 1) 80.2 2) 65.8 p=0.013 T2D relapse (%) 1) 23.7 2) 23.3 p=NS	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Johnson 2013	Prospective cohort	1) RYGB 2) lifestyle intervention	N=126 1) 72 2) 54	1 year	BMI ≥40 or BMI ≥35 w/comorbidities	Mean age 1) 42.6 2) 46.8 30% male Mean weight 1) 136 2) 123 Mean BMI 1) 46.2 2) 42.6	Mean weight loss (%) 1) 30 2) 8 Fiber intake below recommendation (%) 1) 68% 2) 30% % with <30% intake from fat 1) 10 to 18% 2) 9 to 44% p=0.002	None reported
Karamanakos 2008	RCT	1) RYGB 2) VSG	N=32 1) 16 2) 16	12 months	Not reported	Mean Age 33.8 16% male Mean Weight 123.7 Mean BMI 45.9 Mean Glucose 97	Mean %EWL (%) 1) 60.5 2) 69.7 p=0.05 Mean weight loss (kg) 1) 15.1 2) 16.1 p=NS Mean change in glucose (mg/dL) 1) -9 2) -12 p=NS	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Keidar 2013	RCT	1) RYGB 2) VSG	N=37 1) 19 2) 18	12 months	BMI ≥35 w/T2D Age 18-65	Mean Age 49.6 55% male Mean BMI 42.2 Mean Weight 167.1kg Mean HbA1c 8%	HbA1c (%) 1) -1.48 2) -2.37 p=0.034 from baseline Mean change in BMI 1) -10.6 2) -12.1 p=NS Mean weight loss (kg) 1) 25.9 2) 28.4 p=NS	No deaths in either group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Khoo 2014	Prospective	1) T2D support	N=61	12 months	T2D diagnosis	Mean age	Mean weight loss	No postoperative
	cohort	and education	1) 31		BMI ≥40 or BMI	1) 47.4	(kg)	complications in
		(DSE)	2) 30		≥35	2) 49.6	1) 0.6	surgery group
		2) RYGB			w/comorbidities		2) 33.6	
					18-60 years	33% male		Mortality not reported
							BMI	
						Mean weight	1) 0.3	
						1) 114.3	2) -12.2	
						2) 120.1		
							Waist	
						Mean BMI	circumference	
						1) 40.1	1) -1.0	
						2) 43.4	2) -26.6	
						Mean HbA1c (%)	HbA1c	
						1) 7.51	1) 0.4	
						2) 7.53	2) -1.2	
						Mean waist	All p<0.001	
						circumference		
						1) 122.7		
						2) 130.3		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Korner 2009	Retro- spective cohort	1) LAGB 2) RYGB	N=43 1) 15 2) 28	1 year	>21 years old scheduled to undergo either surgery	Mean age 1) 47.1 2) 45.0 19% male Mean weight (kg) 1) 112 2) 128 BMI 1) 41 2) 48	Mean weight loss (%) 1) 15 2) 30 p<0.001 Ghrelin levels were not statistically difference b/w groups. Glucose (mg per 100 ml) 1) -7 2) -13 p<0.05	None reported
Lee 2010	Retro- spective cohort	1) RYGB 2) LAGB	N=76 1) 25 2) 51	3 years	Met the 2005 APBVSG bariatric surgery criteria for Asian morbidly obese patients	Mean age 1) 29 2) 33 25% male Mean BMI 1) 41 2) 40	Mean %EWL (%) 1) 85.8 2) 63.3 p<0.05	Overall morbidity 1) 8 2) 6 Reoperations 1) 4 2) 3 Overall mortality 1) 0 2) 0

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Lee 2012	Retro- spective cohort	1) RYGB 2) LAGB	N=55 1) 33 2) 23	2 years	15-19 years 1991 NIH criteria	Mean age (year) 1) 18.6 2) 17.2 Male/Female (n) 1) 9/23 2) 6/17 Mean BMI (kg/m2) 1) 50.6 2) 47.0	Mean %EWL (%) 1) 83.4 2) 29.7 p<0.01 Resolution of T2D 1) 3/3 2) 0/0 p=NR Resolution of dyslipidemia 1) 2/2 2) 1/2 n=NR	Revisions 1) 0 2) 2
Lennerz 2014	Retro- spective cohort	1) LAGB 2) RYGB 3) VSG	N=345 (167 with follow-up) 1) 66 2) 50 3) 37	544 days	Aged 8-21	Mean age 19.2 33% male Mean BMI 47.4	Mean BMI reduction (%) 1) 20.0 2) 32.9 3) 29.4 1 vs. 2 & 3, p<0.001 Mean weight loss (kg) 1) 28 2) 50 3) 46 1 vs. 2 & 3, p<0.001	Specific postoperative complications (%) 1) 0.8 2) 1.7 3) 7.8 3 vs. 1 & 2, p=0.019 No differences for intraoperative or general complications No deaths in any group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Leslie 2012	Retro-	1) RYGB	N=267	2 years	Complete follow-	Mean age	Mean %EWL	Adverse events/Re-
	spective	2) routine	1) 152		up at 2 annual	1) 51.4	1) 61.6	admissions/ED visits
	cohort	medical	2) 115		visits	2) 53.1	2) -1.6	(related to surgery)
		management			BMI ≥35 and T2D		p<0.01	21/82/36
		(RMM)				37% male		
							Mean weight loss	No mortality within 90
						Mean BMI	(%)	days
						1) 47.4	1) 31.4	
						2) 40.7	2) +.7	
							p<0.01	
						LDL		
						1) 93.1	Mean change in	
						2) 97.4	LDL (mm/dl)	
							1) -10.2 (p<0.05)	
						SBP	2) -6.9 (p=NS)	
						1) 138		
						2) 132	Mean change in	
							SBP	
							1) -14.1 (p<0.01)	
							2) -2.5 (p=NS)	
Li 2009	Retro-	1) RYGB	N=548	1) 27 months	Not reported	Mean age	Weight loss >24%	Incidence of
	spective	2) VSG	1) 496	2) 17 months		1) 42.9	1) 79.4	complicated gallstones
	cohort		2) 52			2) 40.5	2) 13	(%)
							p=NS	1) 1.8
						25% male		2) 1.9
								p=NS
						Mean BMI		
						1) 48.5		Symptomatic gallstones
						2) 43.0		(%)
								1) 8.7
								2) 3.8
								p=NS

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Matsuo 2013	Prospective cohort	1) RYGB	N=29	1) 12 months	Age 12-19	Mean age (year)	Mean weight (kg) $1 \times 105 6$ (p<0.05)	None reported
	conort	3) Healthy	2) 10	2) 0 11011113		2) 13.2	2) 79.8 (p<0.05)	
		normal weight control	3) 14			3) 14.3	Mean BMI (kg/m2) 1) 34 8 (n<0 05)	
						38% male	2) 29.4 (p<0.05)	
						Mean BMI (kg/m2)		
						1) 59.2 2) 34 9		
						3) 19.1		
						Mean weight (kg)		
						2) 92.7 2) 52 5		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Miranda 2013	Retro-	1) RYGB	N=19	1) 4.2 years	Patients with	Mean age	Mean weight loss	None reported
	spective	2) nutrition	1) 13	2) 2.4 years	heart failure	1) 62	(kg)	
	cohort	clinic	2) 6		BMI >35	2) 69	1) 47 (p<0.001)	
		management			Age >18 years		2) -8 (p<0.001)	
						31% male		
							Mean change in	
						Mean BMI	BMI	
						1) 55	1) -15 (p<0.001)	
						2) 42	2) +5 (p<0.001)	
						Mean weight (kg)	Hypertension	
						1) 146	1) 13	
						2) 132	2) 6	
						Hypertension	Dyslipidemia	
						1) 12	1) 8	
						2) 6	2) 6	
						Dyslipidemia	T2D	
						1) 11	1) 6	
						2) 5	2) 3	
							p=0.049	
						T2D		
						1) 10	Smoker	
						2) 2	1) 1	
							2) 0	
						Smoker		
						1) 4	QoL scores	
						2) 2	1) 7 (p=0.001)	
							2) 6 (p=NS)	
						QoL scores	p=0.06	
						1) 3		
						2) 4.5		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Mognol 2005	Retro- spective cohort	1) LAGB 2) RYGB	N=290 1) 179 2) 111	18 months	>50 BMI	Mean age 40 22% male Mean weight 1) 145 2) 162 Mean BMI 1) 54 2) 59	Mean %EWL 1) 46% 2) 73% Mean change in BMI 1) -13 2) -21 BMI <35 (%) 1) 23 2) 58 p<0.01	Major intraoperative complications 1) 1 2) 0 Early post-op complications 1) 5 2) 11 p<0.01 Late post-op complications 1) 44 (36 due to band slippage) 2) 18 p<0.05 Mortality 1) 1 (0.6%) 2) 1 (0.9%) p=NS

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-u <u>p</u>	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Mohos 2011 Ret spe coh	ective hort	1) RYGB 2) VSG	N=94 1) 47 2) 47	1) 38.3 months 2) 15.7 months	BMI>40 or BMI>35 with significant comorbidities Failure of previous weight loss treatment	Mean age 1) 38.8 2) 46 26% male Mean BMI 1) 46.1 2) 50.3 Mean weight 1) 132.8 2) 141	QoL (SF 36) 1) 671 points 2) 602 points p=NS QoL (MA II) 1) 2.09 2) 1.7 Mean change in BMI 1) -18 2) -16.8 p=NS Mean %EWL 1) 88% 2) 70% p=0.0001 Resolution of T2D 1) 9/10 (90%) 2) 7/13 (55%) Resolution of GERD 1) 14/19 (73%) 2) 10/23 (43%) Resolution of OSA 1) 5/7 (72%) 2) 1/16 (6%)	Postop Operations 1) 15 (32%) 2) 4 (8%) p=NR No deaths reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Moon 2014	Retro-	1) RYBG	N=586	1) 15 months	NIH 1991 criteria	Mean age	Mean %EWL	Symptomatic
	spective	2) VSG	1) 367	2) 11.6 months		1) 42.6	1) 67.3%	cholelithiasis
	cohort	3) LAGB	2) 115	3) 18.6 months		2) 43.7	2) 59.9%	1) 21 (5.7%)
			3) 104			3) 45.8	3) 31.2%	2) 7 (6.1%)
							p<0.01	3) 0.0 (0.0%)
						24% male		1 vs. 2, p=NS
								3 vs. 1 and 2, p=0.02
						Mean BMI		
						1) 47.1		Cholecystectomy in first
						2) 46.0		year after surgery
						3) 41.5		1) 11 (53%)
								2) 5 (71%)
								p=NS

Author/Year Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Musella 2014 Retro- spective cohort	1) LAGB 2) VSG	N=10 1) 6 2) 4	5 years	>60 years old ≥5 years of follow-up	Mean age 1) 65.8 2) 66.2 Mean BMI 1) 45.4 2) 48.2	Mean %EWL @ 1 year 1) 14.2 2) 13.9 Mean %EWL @ 5 years 1) 34.6 2) 37.2 Mean BMI @ 1 year 1) 39.0 2) 41.4 Mean BMI @ 5 years 1) 28.7 2) 30.4 p=NS for all outcomes Complete resolution of all comorbidities in bath groups	No deaths or complications in either group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Nelson 2012b	Retro-	1) BPD/DS	N=130	2 years	Not reported	Mean age	Weight loss (kg)	RR score
	spective	2) VSG	1) 42			1) 38	1) 21	1) -2.7
	cohort	3) RYGB	2) 40			2) 46	2) 12	2) -1.9
			3) 48			3) 45	3) 16	3) -1.4
								1 vs. 2 and 3, p=0.005
						12% male	BMI (%)	
							1) -42	
						Mean BMI	2) -27	
						1) 52	3) -35	
						2) 43	1 vs. 2 and 3,	
						3) 44	p<0.01	
						ReynoBPD Risk Score	BPD had a	
						(for cardiovascular	significantly	
						risk)	greater reduction	
						1) 4.7	in cardiovascular	
						2) 3.9	risk scores	
						3) 3.8	compared to VSG	
							or RYGB (p=0.005)	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Nguyen 2013	Retro- spective cohort	1) RYGB 2) LAGB	N=1295 1) 609 2) 686	1) 2 years 2) 1.6 years	Per recommendatio ns of ASMBS	Mean age 1) 42.4 2) 37.2 19% male Mean BMI 1) 46.8 2) 40.4	BMI 1) -14.8 2) -2.9 p<0.001 No difference in weight loss between genders during the first 3- year post-surgery, but male LAGB patients had greater BMI reduction than females (-8.2 vs. -3.9, p=0.02) T2D normalization 1) 26/83 (33%) 2) 22/27 (17%) p=0.02 Hyper- triglyceridemia normalization 1) 51/63 (81%) 2) 34/124 (27%) p<0.0001 OSA (no CPAP) 1) 10/100 (10%) 2) 4/130 (3%) p=0.04	Perioperative complications (%) 1) 8.0 2) .5 p<0.001 Reoperations (%) 1) 2.1 2) 8.9 p<0.001 LABG: long-term complications were less likely to occur in males than females (male: 2/131 vs. female: 59/555, p<0.001) RYGB: similar rates of long-term complications male: 0/131 vs. female: 4/555) No deaths in either group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Olivan 2009	Prospective cohort	1) T2D RYGB 2) T2D Diet WL 3) Non-T2D obese controls	N=30 1) 11 2) 10 3) 9	Each participant followed until equivalent weight loss of 10 kg	BMI > 35 <60 years old Diagnosed with T2D diagnosis <5 years Not on antidiabetic meds HbA1c <8%	Mean age 1) 44.12 2) 47.9 3) 37.4 Mean weight (kg) 1) 117.6 2) 110.6 3) 121.1 0% male Mean BMI 1) 47.4 2) 42.8 3) 45.5	Mean weight (kg) 1) 106.4 2) 100.7 p=0.429 Mean BMI 1) 41.4 2) 39.0 p=0.233	No severe adverse effects in either group
Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
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Omana 2010	Retro-	1) VSG	N=123	1) 15	Not reported	Mean age	Mean weight (kg)	No mortality or major
	spective	2) LAGB	1) 49	2) 17 months		1) 45	1) 104.6	complications related
	cohort		2) 74			2) 41	2) 101.1 p=NS	to procedures
						Mean BMI		Minor complications
						1) 52	Mean weight loss	(%)
						2) 44	(kg)	1) 12
							1) 39.2	2) 15
						Mean weight (kg)	2) 22.5	
						1) 144.0	p<0.01	
						2) 122.7		
							Mean change in	
						Mean EBW (kg)	BMI	
						1) 81.8	1) -14.2	
						2) 59	2) -8.0	
							p<0.01	
							Mean %EWL (%)	
							1) 50.6	
							2) 40.3	
							p=0.03	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Palikhe 2014	RCT	1) VSG	n=31	12.5 months	20-75 years old;	Mean age	Change in weight	Major complication
		2) IMT	1) 14		BMI≥27.5	1) 47	(kg)	(esophageal
			2) 17		kg/m2; T2D	2) 52	1) -28.0	perforation)
							2) -8.6	1) 2
						Mean BMI	p<0.001	2) 0
						1) 40.5		
						2) 35.8	Change in BMI	No deaths in either
							1) -11.3	group
						26% male	2) -3.3	
							p<0.001	
						Mean weight (kg)		
						1) 99.5	Mean %EWL (%)	
						2) 90.4	1) 61.2	
							2) 27.4	
							p<0.001	
							%EWL	
							1) 27.9	
							2) 9.4	
							p<0.001	
							Resolution of T2D	
							(%)	
							1) 36	
							2) 0	
							p=0.007	
							Resolution of	
							hypertension (%)	
							1) 29	
							2) 0	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Parikh 2014	RCT	1) LAGB 2) LSG 3) RYGB 4) Medical weight management (MWM)	N=56 1) 5 2) 16 3) 7 4) 28	6 months	T2D; BMI 30-35; Meets other NIH criteria for bariatric surgery	Mean age Surgery: 46.8 MWM: 53.9 Mean BMI Surgery: 32.8 MWM: 32.4 % Female Surgery: 79% MWM: 79%	Diabetes Remission (%) 1) 33 2) 91 3) 33 4) 0 P=0.025 No longer requires T2D Medication (%) 1) 33 2) 100 3) 67 4) 12 P=0.016	 ≤30 day complications Surgery: 1 MWM: 0 >30 day complications Surgery: 1 MWM: 0
Pham 2014	Retro- spective cohort	1) LAGB 2) VSG 3) RYGB	N=81 1) 20 2) 24 3) 23	24 months	Patients with T2D diagnosis matched with obese patients without T2D for age, sex, BMI, and surgery type	Mean age 45.7 Mean BMI 48	T2D remission (%) 1) 20.0 2) 62.5 3) 52.0 2 vs. 1, p=0.0026 1 vs. 3, p=NS No difference between groups for resolution of hypertension Weight loss was not significantly between those with and without T2D	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Pihlajamaki 2010	Retro- spective cohort	1) RYGB 2) LAGB	N=55 1) 29 2) 26	12 months	BMI >40 or >35 with significant comorbidity Prior failure of dietary/drug treatments No contra- indications for surgery	Mean weight (kg) 1) 130 2) 145 27% male Mean BMI 1) 46 2) 50.1 T2D 1) 8/29 2) 19/26 Mean age 1) 45.2	Mean weight (kg) 1) 98 2) 123 p<0.001 Mean BMI 1) 34.6 2) 42.6 p<0.001 T2D 1) 2/29 2) 1/26 p=NS	None reported
						2) 45.9		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Roslin 2012	Prospective cohort	1) RYGB 2) VSG 3) DS	N=38 1) 12 2) 13 3) 13	6 months	>18 years 1991 NIH criteria	Mean weight (lb) 1) 281.9 2) 279.8 3) 342.8 Mean BMI 1) 47.3 2) 45.7 3) 54.1 Mean fasting glucose (mg/dL)	Mean weight (lb) 1) 223.3 (b) 2) 214.8 (a) 3) 245 Mean BMI 1) 36.8 2) 35.3 3) 38.2 Mean fasting glucose (mh/dL)	None reported
						1) 105.5 2) 98.2 3) 97.2 Mean HbA1c (%) 1) 6.8 2) 5.8 3) 6.1	1) 86.9 2) 83.0 3) 77.9 HbA1C (%) 1) 5.9 (b,c) 2) 5.4 (a) 3) 5.3 (a) a: p<0.05 compared to (1); b: p<0.05 compared	
							to (2); c: p<0.05 compared to (3)	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Roslin 2014	Prospective cohort	1) RYGB 2) VSG 3) DS	N=38 1) 13 2) 12 3) 13	12 months	Age >18 years 1991 NIH criteria	Mean weight (lb) 1) 281.1 2) 290.3 3) 353.0 Mean BMI 1) 47.7 2) 45.7 3) 55.9 Mean HbA1c (%) 1) 6.6 2) 5.8 3) 6.0	Mean weight (lb) 1) 184.4 2) 202.0 3) 182.2 Mean BMI (kg/m2) 1) 30.7 2) 31.1 3) 27.5 a: p<0.05 compared to (1); b: p<0.05 compared to (2); c: p<0.05 compared to (3)	None reported
Sabbagh 2010	Prospective cohort	1) VSG primary procedure 2) VSG after failed LAGB 3) LAGB	N=111 1) 50 2) 9 3) 52	24 months	Follow-up >24 months	Mean age 1) 39.4 2) 41.2 3) 36 Mean BMI 1) 50.4 2) 50.8 3) 43.8	Mean BMI 1) 33.8 2) 35.3 3) 33.2 p=NS Mean %EWL 1) 67.4 2) 60.3 3) 58.6 p=0.14 Mean %EBMIL 1) 32.77 2) 30.01 3) 24.42	Reoperations (%) 1) 2 2) 11 3) 30.76 p<0.0001 Late complications 1) 0 2) 0 3) 13 p=NR No deaths in any group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Saunders 2007	Retro-	1) Vertical	N=2,823	30 days	Not reported	Median age 42	Readmissions	Overall complications
	spective	banded	1) 776				within 30 days	2) 39
	cohort	gastroplasty-	2) 1,185			25 % male	2) 86	3) 10
		RYGB (results	3) 862				3) 27	
		not reported				Median BMI	p=NR	
		here)				2) 46		
		2) RYGB				3) 44		
Sorrot 2011	Potro	3) LAGB	N-24	12 months		Madian aga (yaar)	Modian RMI	Poodmission rate (%)
Seriot 2011	spective	2) Medical	1) 17	12 monuns	1001 NIH critoria	1) 56 0		1) 10
	cohort	management	2) 17		1551 Nill Citteria	2) 62 0	2) 34 3	2) 0
	conore	for T2D	2,17			2) 02.0	n<0.001	2,0
		101 120				Median BMI (kg/m2)	p 10.001	
						1) 34.6	Median weight (lb)	Mortality
						2) 34.0	1) 157	1) 0
							2) 233	2) 0
						Median weight (lb)	p<0.001	
						1) 214		
						2) 237	Mean %EWL (%)	
							1) 70	
						Female (n)	2) -4	
						1) 13	p<0.001	
						2) 6		
							Resolution of T2D	
							1) 11/17	
							2)0	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Spivak 2012	Retro- spective cohort	1) LAGB 2) RYGB	N=232 1) 127 2) 105	5-10 years	1991 NIH criteria	Mean age 1) 42.1 2) 40.6 14% male Mean weight (kg) 1) 124.4 2) 133.6 Mean BMI 1) 45.9 2) 48.2 EW (kg) 1) 61.8 2) 70 5	Mean %EWL 1) 43 2) 67 p<0.01 Mean change in BMI 1) 10 2) 16 p<0.01	Failure Rate (%) 1) 23.5 2) 7.1 Conversions to open 1) 2 1) 3 Late reoperations (%) 1) 24.1 2) 9.9 Morality 1) 0 2) 1
Stephens 2008	Retro- spective cohort	 1) Vertical banded gastroplasty- RYGB (results not reported here) 2) RYGB 3) LAGB 	N=3,692 1) 1203 2) 1472 3) 1017	Not reported	Not reported	Median age 41 25% male Median BMI 46	Median hospital length of stay BMI<60 kg/m2 (days) 2) 2 3) 1 p=NR Median hospital length of stay BMI_60 kg/m2 (days) 2) 3 3) 1 p=NR	Mortality 2) 2 3) 0

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Strain 2007	Prospective cohort	1) RYGB 2) BPD	N=72 1) 50 2) 22	Mean follow-up (months) 1) 15.5 2) 19.5	Met NIH guidelines for bariatric surgery eligibility	Mean age 1) 46.2 2) 40.6 58% male Mean BMI (kg/m2) 1) 46.2 2) 53.6	Mean BMI 1) 31.5 2) 30.3 p=NS	Postoperative complications (%) 1) 10 2) 9 Reoperations 1) 0 2) 1 (reversal) No death in either group
Tedesco 2013	Retro- spective cohort	 LAGB with history of substance abuse LAGB with no history of substance abuse VSG with history of substance abuse VSG with no history of substance abuse RYGB with history of substance abuse RYGB with no history of substance abuse 	N=205 1) 11 2) 12 3) 22 4) 50 5) 41 6) 69	12 months	Veterans	Mean age 51.5 79.9% male Mean BMI 46.2	Mean %EWL (%) 1) 33.4 2) 34.0 3) 59.6 4) 57.3 5) 75.8 6) 69.5 p=NS	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Toelle 2012	Cross- sectional	1) LAGB 2) VSG 3) RYGB 4) BPD	N=141 1) 39 2) 31 3) 43 4) 28	Time between pre- and post- measurement (months) 1) 49.33 2) 11.10 3) 11.12 4) 21.18	Patients who were taking no calcium and/or vitamin D supplements and had received bariatric procedure ~6 weeks prior	Mean age 1) 43.4 2) 44.0 3) 46.8 4) 46.0 19% male Mean BMI 1) 42.7 2) 45.7 3) 44.3 4) 45.2	Mean BMI 1) 33.1 2) 34.1 3) 33.2 4) 30.5 p=NS Mean change in BMI 1) -22.6 2) -24.9 3) -25.3 4) -32.4 p=0.001 Mean %EBMI 1) 56.2 2) 56.4 3) 60.6 4) 74.1 p=0.011	None reported
Topart 2012	Retro- spective cohort	1) VSG 2) RYGB 3) BPD	N=507 1) 88 2) 360 3) 59	3-4 months	BPD for patients with BMI <u>></u> 50 VSG selectively indicated according to the ASMBS position statement RYGB for patients with BMI <u>></u> 40 but <u><</u> 50	Mean age 1) 47.1 2) 40.9 3) 38.5 24% male Mean BMI 1) 49.2 2) 44.3 3) 54.9	Not reported	Major complications (%) 1) 6.8 2) 4.7 3) 8.4 Reoperations 1) 3 2) 14 3) 2 90-day mortality rate 1) 0 2) 1 3) 0

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Topart 2013	Retro-	1) RYGB	N=180	Mean (months)	BMI <u>></u> 50	Mean age	Mean %EWL	Revisions
	spective	2) BPD	1) 97	1) 46		1) 41.0	1) 63.7	1) 13
	cohort		2) 83	2) 44.3		2) 38.3	2) 84.0	2) 5
							p<0.00001	
				Results reported		23% male		Reoperation
				for 3 years			Mean BMI	1) 2
						Mean BMI	1) 35.9	2) 7
						1) 54.6	2) 29.8	(all due to leaks)
						2) 55.5		
							Remission of OSA	Complications
						Prevalence of	(%)	1) 12
						comorbidities	1) 89	2) 23
							2) 90	p=0.0095
						OSA	p=NS	
						1) 41		Mortality
						2) 11	Remission of T2D	1) 1
							(%)	2) 1
						T2D	1) 92.3	
						1) 16	2) 86.6	
						2) 16	p=NS	
						Hypertension	Hypertension	
						1) 30	suspension of	
						2) 17	medication (%)	
							1) 66.6	
							2) 77.7	
							p=0.0039	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Tsoli 2013	Prospective cohort	1) BPD (open) 2) VSG	N=24 1) 12 2) 12	12 months	T2D diagnosis Morbidly obese classification	Mean age 1) 42.3 2) 40.3 38% male Mean BMI 1) 57.6 2) 43.7	Mean BMI 1) 32.4 2) 27.9 p=0.014 Mean %EWL 1) 73.4 2) 75 p=NS	None reported
Vidal 2007	Prospective cohort	1) VSG 2) RYGB	N=85 1) 35 2) 50	4 months	T2D diagnosis Caucasian	Mean age 1) 49.4 2) 49.4 38% male Mean BMI 1) 52.0 2) 47.6 Metabolic syndrome (%) 1) 91.4 2) 94.0	Mean EBMIL (%) 1) 41.4 2) 45.3 p=NS Mean weight loss (% from B/L) 1) 20.6 2) 21.0 p=NS T2D resolution 1) 18 2) 31 p=NS Resolution of metabolic syndrome (%) 1) 18 2) 31 p=NS	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Vidal 2008	Prospective cohort	1) VSG 2) RYGB	N=91 1) 39 2) 52	12 months	T2D diagnosis Metabolic syndrome diagnosis Caucasian T2D treatment prior to surgery	Mean age (year) 1) 49.9 2) 49.3 37% male Mean BMI (kg/m2) 1) 51.9 2) 47.7	Mean EBMIL (%) 1) 63.00 2) 66.06 T2D resolution 1) 33 2) 44 Metabolic syndrome resolution (%) 1) 62.2 2) 67.3 p=NS for all	None reported
Von Mach 2004	Prospective cohort	1) RYGB 2) LAGB 3) Controls	N=19 1)4 2)9 3)6	24 months	BMI >37	Mean age 1) 44.5 2) 41.1 3) 49.0 47% male Mean BMI 1) 42.7 2) 41.0 3) 41.2 Mean weight (kg) 1) 113.3 2) 117.2 3) 113.5	outcomes Mean BMI 1) 30.5 (c) 2) 34.0 (c) 3) 41.4 (a, b) Mean weight loss (%) 1) -28.6 (p<0.01)	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Wahlroos 2007	Prospective cohort	1) very low- calorie diet 2) LAGB	N=39 1) 14 2) 25	1) 6 weeks 2) 3 months	Weight ≤150 kg LAGB patients not prescribed pre-operative VLCD No diagnosis of T2D or hepatic steatosis	Age range 1) 17-64 2) 20-62 0% male Mean weight (kg) 1) 118.8 2) 104.5 Mean waist circumference (cm) 1) 118.7 2) 110.7 Mean BMI 1) 45	Mean weight (kg) 1) 110.0 (p<0.001) 2) 94.9 (p<0.001) Mean waist circumference (cm) 1) 111.1 (p<0.001) 2) 101.5 (p<0.001) Mean BMI 1) 42 (p<0.001) 2) 35 (p<0.001)	None reported
						2) 38		

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Weiner 2013	Retro- spective cohort	1) RYGB 2) VSG	N=2,031 1) 1,345 2) 686	5 days	1991 NIH criteria and German guidelines for bariatric surgery	Median age 1) 43 2) 39 44% male Mean BMI 1) 46.3 2) 57.8	None reported	Patients with complications on 5th day of hospital stay, prolonging stay 1) 66 2) 49 Leakage requiring reoperation (n) 1) 22 2) 12 p<0.05 Bleeding (n) 1) 10 2) 19 Early complications 1) 66 (4.9%) 2) 49 (7.14%) p=0.039 Mortality 1) 1 2) 1

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Widhalm 2011	Prospective cohort	1) LAGB 2) RYGB	N=18 1) 8 2) 9 1 patient received VSG; results not reported here	42 months	Met the criteria for bariatric surgery in adolescents according to the interdisciplinary European guidelines	Mean age 17.7 33% male Mean BMI 1) 49.6 2) 52.0 Mean weight (kg) 1) 159 2) 154	Mean weight loss (kg) 1) -20 2) 36 Mean weight (kg) 1) 150 2) 118 Mean BMI 1) 49.1 2) 32.5	Revision to RYGB 1) 4 2) 0 No adverse effects Mortality reported
Woel- nerhanssen 2011	RCT	1) RYGB 2) VSG	N=23 1) 12 2) 11	12 months	No diagnosis of T2D BMI >40 with at least 1 comorbidity Age <60 years 2 years of unsuccessful conservative treatment Approval for surgery by patient's health insurance	Mean age (year) 1) 41.4 2) 35.2 Mean BMI (kg/m2) 1) 47.6 2) 44.7 Mean weight (kg) 1) 133.3 2) 120.2	p=NR Mean weight (kg) 1) 87.3 2) 86.3 Mean weight loss (%) 1) 34.5 2) 27.9 p=NS for all between- group comparisons	None reported
Wong 2009	Retro- spective cohort	1) LAGB 2) VSG 3) RYGB 4) Intragastric balloon	N=225 1) 57 2) 71 3) 7 4) 120 (results not shown)	1) 24 months 2) 8 months 3) 24 months	Asian patients in Hong Kong with BMI >37 or >32 with T2D or 2 other obesity- related comorbidities	Mean age 39.6 35% male Mean BMI 36.3	Mean %EWL 1) 34 2) 51 3) 61 Mean change in BMI (%) 1) 13 2) 22 3) 26	Overall complications 1) 5 2) 6 3) 3 No deaths in any group

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Woodard	Prospective	1) RYGB	N=838	12 months	None reported	Mean age	Mean %EWL	None reported
2010	cohort	2) LAGB	1) 765			1) 43.8	1) 78	
			2) 73			2) 46.6	2) 47.6	
							p<0.05	
						37% male		
							Mean BMI	
						Mean BMI	1) 31.4	
						1) 47.4	2) 35.3	
						2) 44.4	p<0.05	
Yong 2012	Prospective	1) RYGB	N=23	6 months	BMI >32	Median age	Mean %EWL	None reported
	cohort	2) exenatide	1) 13		T2D diagnosis for	1) 42.2	1) 57.3	
		therapy	2) 10		less than 10 years	2) 45.9	2) 23.8	
							p<0.01	
						30% male		
							Abdominal girth loss	
							(cm)	
							1) 15.3	
							2) 10.1	
							p<0.05	
							Mean BMI	
							1) 32	
							2) 36	
							p<0.05	
							Moon EDMIL (%)	
							1) 57	
							1) J/	
							2/24 n<0.01	

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Yousseif 2014	Prospective cohort	1) RYGB 2) VSG	N=18 1) 10 2) 8	12 weeks	Female BMI 40–50 Age 60 years No prior bariatric procedure	Mean age (year) 1) 46.8 2) 41.4 0% male Mean BMI (kg/m2) 1) 45 2) 44	Mean BMI 1) 37.9 2) 37.4 p=NS Mean weight loss (kg) 1) 18.7 2) 19.9 p=NS Mean %EWL (%) 1) 39.4 2) 37.8 p=NS	None reported

Author/Year	Study Design	Comparators/ Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Zhang 2013	Prospective	1) VSG	N=558	12 months	1991 NIH criteria	Mean age	Mean %EWL (%)	None reported
	cohort	2) RYGB	1) 200			1) 44.2	1) 30.7	
			2) 358			2) 47.5	2) 33.4	
							P=NS	
						24% male		
							OSA (%)	
						Mean BMI	1) 3.26	
						1) 47.9	2) 4.15	
						2) 46.1	p=0.338	
						OSA (%)	GERD (%)	
						1) 34	1) 13.2	
						2) 25.1	2) 7.3	
							p<0.001	
						GERD (%)	Live and incidencial (0/)	
						1) 13	Hyperlipidemia (%)	
						2) 13.7	1) 11.1	
						Uunarlinidamia (9/)	2) 12 n=NS	
						пурепірійенна (%)	p=ins	
						1) 25.5	Illumentancian (9/)	
						2) 27.1		
						Hyportonsion (%)	1) 57.0	
							2) 23.0 n=NS	
						2) 52 5	p=145	
						2, 52.5	T2D (%)	
						T2D (%)	1) 13 5	
						1) 28	2) 10 4	
						2) 31 8	n=NS	
						2, 31.0		
						Musculoskeletal	Musculoskeletal	
						disease (%)	disease (%)	
						1) 20	1) 5.62	
						2) 18.7	2) 3.7	
							p=NS	

Appendix C

Evidence Summary Key Question 2

Author, Year	Procedure	No. Patients	Duration follow-up		Factors Associated with Success	Statistical Technique
Alami, 2007	RYGB	61	12 months	•	Pre-operative weight loss decreases operating time and short term EWL	Chi-square; Multiple linear regression
Becouarn, 2010	RYGB or LAGB or VSG	539	4 years	•	Pre-operative weight loss not associated with post-operative weight loss	Logistic regression
Birkmeyer, 2010	LAGB vs. VSG vs. RYGB	15,275	30 days	•	High surgeon High hospital volume	Logistic regression
Bueter, 2007	LAGB 1) Successful 2) Unsuccessful	71	27 months	• • •	Baseline BMI Female Post-operative vomiting Eating behavior Physical activity	Pearson chi- square; Logistic regression
Carlin, 2013	RYGB 1) Single surgeon, cases 1-50 2) Single surgeon, cases 51-100 3)Multi- disciplinary team, cases 101- 200	200	12 months	•	Team approach Female Learning curve	Logistic regression
Chen, 2012	RYGB	200	12 months	•	Female Surgeon experience Team approach	Logistic regression
Chevallier, 2007	LAGB	1,238	2 years	• • •	Younger age Lower baseline BMI Physical activity Eating habits High surgeon volume	Logistic regression
Compher, 2012	RYGB	60	2 years	•	Male Attend post-operative office visits Younger age Lower baseline BMI	Mixed effects model

Author, Year	Procedure	No. Patients	Duration follow-up		Factors Associated with Success	Statistical Technique
Courcoulas, 2003	RYGB	4,685	3 years	•	High surgeon High hospital volume	MIXED procedure; linear model with binary outcomes
Dallal, 2009	RYGB	1,168	3 years	•	Higher initial weight Male	Student's t- test; mixed- effects
Elakkary, 2006	LAGB	38	12 months	•	Post-operative support groups	T-test
Gould, 2011	RYGB or LAGB	32,509	3 years	•	High hospital volume	Random/fixed effects
Harnisch, 2008	RYGB	1,629	2 years	•	Pre-operative weight gain/loss not differentially associated with perioperative complications or EWL	Not specified
Huerta, 2008	RYGB	40	2 years	•	Pre-operative weight loss associated with shorter operative time but not EWL or perioperative complications	Student's t- test; chi- square; Fisher's exact test; Multivariate regression
Jamal, 2006	RYGB	324	12 months	•	No pre-operative dietary counseling	ANOVA; Fisher's exact test; chi- square
Leahey, 2009	RYGB or LAGB	32	10 weeks	•	Post-operative patients more likely than pre- operative patients to complete interventions designed to reduce eating behaviors associated with weight gain	Chi-square; t- test

Author, Year	Procedure	No. Patients	Duration follow-up	Factors Associated with Success	Statistical Technique
Lier, 2011	Not specified	141	2 years	Unwillingness to participate in counselling groups predictors: • Social phobia • Avoidant personality disorder	Pearson chi- square; Student's t- test
Lier, 2012	RYGB	141	12 months	 Pre-surgical counselling not associated with treatment adherence to lifestyle changes 	ANOVA; Contingency table analysis
Lutfi, 2006	RYGB	180	12 months	Baseline BMI<50Single marital status	Logistic regression
Ma, 2006	RYGB	494	12 months	 Younger age Lower baseline weight Male Non-T2DM 	Linear regression
Masoomi, 2011	RYGB	226,452	Not reported	 GI tract leaks: Congestive heart failure Chronic renal failure Age>50 years Medicare Male Chronic lung disease 	Logistic regression
Melton, 2008	RYGB	495	12 months	Predictors of suboptimal weight loss: Greater BMI T2DM Male	Logistic regression
Murr, 2007	RYGB	19,174	5 years	 Younger age Female Low surgeon/hospital volume 	Logistic regression
Nguyen, 2004	RYGB	24,166	3 years	High volume hospitals	Pearson chi- square; ANOVA

Author, Year	Procedure	No. Patients	Duration follow-up	Factors Associated with Success	Statistical Technique
Nguyen, 2011	RYGB vs. LAGB	304,515	Length of hospital stay	 Mortality predictors: Male Age >50 years Congestive heart failure Peripheral vascular disease Chronic renal failure 	Multivariate regression
Nguyen GC 2013	RYGB	115,507	8 years	 In-hospital mortality/Length of Stay: Non-Hispanic black Male Low hospital volume Medicare/Medicaid insurance 	Chi-square; Fisher's exact test; t-tests; logistic regression
Nguyen, 2013	RYGB or LAGB or gastroplasty	105,287	8 years	 In-hospital mortality: Male RYGB Medicare insurance T2DM Age>60 years 	Logistic regression
Nijamkin, 2012	RYGB	144	12 months	 Post-operative comprehensive nutrition and lifestyle educational intervention 	T-test; chi- square; Wilcoxon signed rank; Mann- Whitney U test
Nijamkin, 2013	RYGB	144	12 months	 Post-operative behavior change education Post-operative nutrition counselling 	T-tests; regression; intention to treat
Ortega, 2012	RYGB vs. VSG	407	12.5 months	 Younger age Lower baseline BMI Higher waist circumference Lower HbA1c Lower triglycerides 	Multiple regression; logistic regression
Orth, 2008a	RYGB or LAGB or vertical banded gastroplasty	46	25 months	 Attended post- operative support group 	Mann- Whitney; Fisher's exact test

Author, Year	Procedure	No. Patients	Duration follow-up	Factors Associated with Success	Statistical Technique
Padwal, 2013	Not specified	15,394	10 years	All-cause mortality predictors: • T2DM • Current smoker • Male	Logistic regression
Parikh, 2012	LAGB	55	6 months	 Pre-operative medically supervised weight management not associated with post- operative weight loss or physical activity 	Intention to treat; completers' analysis
Perugini, 2003	RYGB	188	12 months	EWL: Non-T2DM Complication predictors: Less surgeon experience Sleep apnea Hypertension	Logistic regression
Pontiroli, 2007	LAGB	172	4 years	 BMI Compliance Attendance post-op appointments 	Stepwise regression
Ray, 2003	RYGB	149	2 years	 No. confidants Previous dieting Anticipated postoperative diet- related stress Perceived obesity health problems Motivation unrelated to social distress about obesity 	Student t-test
Sarwer, 2008	RYGB	200	92 weeks	 Male Baseline cognitive restraint Dietary adherence 	Mixed model
Sarwer, 2012	RYGB or LAGB	84	2 years	 Post-operative dietary counseling/Change in eating behavior 	Repeated measures mixed effects
Shen, 2004	LAGB vs. RYGB	301	12 months	 Attendance to follow- up visits after LAGB 	Student's t- test; Pearson's correlation

Author, Year	Procedure	No. Patients	Duration follow-up	Factors Associated with Success	Statistical Technique
Smith, 2013	RYGB	3,410	30 days	 High-volume surgeons 	Kruskal-Wallis test; Jonckheere- Terpstra trend test; relative risk; log linear regression
Sockalingam, 2013	RYGB or VSG	363	2-4 months	 Associated with non- completion of surgery: Past Axis I psychiatric disorders Past anxiety disorders Past substance use disorders 	Chi-square; Fisher's exact; t-tests
Van Nieuwenhove, 2011	RYGB	298	30 days	 Pre-operative diet not associated with differences in operating time or intraoperative complications Pre-operative diet group experienced fewer 30-day complications 	T-test; Mann- Whitney test; chi-square test
Weineland, 2012	RYGB or VSG	39	6 weeks	 Post-operative acceptance and commitment therapy 	ANOVA
Weller, 2007	RYGB or gastroplasty	7,868	30 days	High surgeon volumeHigh hospital volume	Logistic regression
Wittgrove, 2000	RYGB	500	5 years	Non-T2DM	None

Appendix D

Evidence Tables for Harms of Bariatric Surgery

Study	Procedure	# of Patients	# of Complications	Median Complication Rate	# of Reoperations	Median Reoperation Rate	Total # of Deaths
Hedberg 2012	BPD	23	4	17.39%	3	13.04%	0
Mingrone 2012	BPD	19	6	31.58%	1	5.26%	0
Nanni 2013	BPD	30	5	16.67%	NR	NR	0
Risstad 2015*	BPD	29	43	148.28%	7	24.14%	0
Scopinaro 2011	BPD	30	5	16.67%	NR	NR	0
Søvik 2010	BPD	29	23	79.31%	1	3.45%	0
Søvik 2011*	BPD	29	10	34.48%	6	20.69%	0
TOTAL	BPD	29	6	31.58%	3	13.04	0
Angrisani 2007	LAGB	27	4	14.81%	4	14.81%	0
Angrisani 2013*	LAGB	22	3	13.64%	5	22.73%	0
Bowne 2006	LAGB	46	54	117.39%	15	32.61%	1
Brunault 2011	LAGB	102	NR	NR	20	19.61%	NR
Cottam 2006	LAGB	181	NR	NR	43	23.76%	0
Courcoulas 2014	LAGB	24	6	25.00%	1	4.17%	0
Dixon 2008	LAGB	30	6	20.00%	3	10.00%	NR
Dixon 2012	LAGB	30	1	3.33%	1	3.33%	0
Himpens 2006	LAGB	40	16	40.00%	9	22.50%	NR
Hutter 2011	LAGB	12193	175	1.44%	112	0.92%	10
Nguyen 2009	LAGB	111	15	13.51%	11	9.91%	0
O'Brien 2006	LAGB	39	7	17.95%	5	12.82%	NR
O'Brien 2013	LAGB	57	31	54.39%	17	29.82%	0
Weber 2004	LAGB	103	63	61.17%	27	26.21%	0
TOTAL	LAGB	43	6.5	17.95%	7	14.81%	11

Table D1. Study details of good- and fair-quality RCTs and prospective comparative cohorts evaluating harms of bariatric surgery.

Study	Procedure	Total # of Patients	# of Complications	Median Complication Rate	# of Reoperations	Median Reoperation Rate	Total # of Deaths
Angrisani 2007	RYGB	24	4	16.67%	3	12.50%	0
Angrisani 2013*	RYGB	21	3	14.29%	3	14.29%	0
Benaiges 2011	RYGB	95	16	16.84%	NR	NR	0
Bowne 2006	RYGB	40	19	47.50%	13	32.50%	0
Cottam 2006	RYGB	181	NR	NR	25	13.81%	0
Courcoulas 2014	RYGB	22	1	4.55%	0	0.00%	0
Hedberg 2012	RYGB	24	3	12.50%	2	8.33%	1
Helmio 2012	RYGB	117	31	26.50%	4	3.42%	0
Hutter 2011	RYGB	14491	1005	6.94%	778	5.37%	59
Ikramuddin 2013	RYGB	60	22	36.67%	6	10.00%	0
Kashyap 2013	RYGB	20	NR	NR	NR	NR	0
Kehagias 2011	RYGB	30	20	66.67%	1	3.33%	0
Laferrere 2008	RYGB	9	0	0.00%	NR	NR	NR
Leyba 2011	RYGB	75	0	0.00%	NR	NR	0
Liang 2013	RYGB	31	6	19.35%	0	0.00%	0
Mingrone 2012	RYGB	19	3	15.79%	1	5.26%	0
Nanni 2012	RYGB	20	1	5.00%	NR	NR	0
Nguyen 2009	RYGB	111	50	45.05%	14	12.61%	0
Paluszkiewics 2012	RYGB	36	28	77.78%	1	2.78%	0
Peterli 2013	RYGB	110	19	17.27%	0	0.00%	1
Risstad 2015*	RYGB	31	10	32.26%	1	3.23%	1
Schauer 2012	RYGB	50	11	22.00%	3	6.00%	0
Schauer 2014*	RYGB	48	16	33.33%	0	0.00%	0
Søvik 2010	RYGB	31	15	48.39%	2	6.45%	0

Study	Procedure	Total # of Patients	# of Complications	Median Complication Rate	# of Reoperations	Median Reoperation Rate	Total # of Deaths
Søvik 2011*	RYGB	31	6	19.35%	1	3.23%	0
Weber 2004	RYGB	103	35	33.98%	11	10.68%	0
TOTAL	RYGB	34	13	19.35%	3	6.00%	62
Benaiges 2011	VSG	45	4	8.89%	NR	NR	0
Brunault 2011	VSG	29	8	27.59%	5	17.24%	NR
Helmio 2012	VSG	1221	16	1.31%	3	0.25%	0
Himpens 2006	VSG	40	9	22.50%	4	10.00%	NR
Hutter 2011	VSG	944	53	5.61%	28	2.97%	2
Kashyap 2013	VSG	20	NR	NR	NR	NR	0
Kehagias 2011	VSG	30	23	76.67%	1	3.33%	0
Leyba 2012	VSG	42	4	9.52%	NR	NR	0
Paluszkiewics 2012	VSG	36	29	80.56%	0	0.00%	0
Peterli 2013	VSG	107	9	8.41%	0	0.00%	0
Schauer 2012	VSG	50	4	8.00%	1	2.00%	0
Schauer 2014*	VSG	49	7	14.29%	0	0.00%	0
TOTAL	VSG	44	9	9.52%	1	2.00%	2

*Harms from studies with cumulative follow-up are subtracted from the previous report's data.

Table D2.	Study details of	case series evaluating	harms of bariatric surgery.
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Author/Year	Intervention	# of Patients	Study Follow-up (years)	Patient Characteristics	Complications	Reoperations	Mortality
Cossu 2007	BPD	138	Mean: 5 Range: 2-8	40% male Mean BMI 51.2	25 total 14 post- anastomotic stomal ulcers	 11 total 7 for intestinal obstruction 2 for anastomotic ulcers 2 for post-anastomotic stomal ulcer 	Early (<30 days): 3/141
Marceau 2007	BPD	1423	Mean: 7.3 Range: 2-15	Mean age 40.1 28% male Mean BMI 51.5	Kidney stones: 14.8% Malnutrition: 5.0% Anemia: 14%	259 total 83 for intestinal obstruction 176 for incisional hernia	Overall: 67/1423 Early (<30 days): 16/1423
Busetto 2014	LAGB	318	Mean: 12.7	Mean age 38.6 18% male Mean BMI 46.7	148 total12 conversions to open surgery136 band-related complications 136	 116 total (patients) - some patients required more than 1 redo surgery - primarily due to band- related complications 	Overall: 15/318

Author/Year	Intervention	# of Patients	Study Follow-up (years)	Patient Characteristics	Complications	Reoperations	Mortality
Chevallier 2004	LAGB	1000	7	Mean age 40.4 10% male Mean BMI 44.3	192 total 12 were life- threatening 12 conversions to open surgery	111 total78 related to bandslippage22 related to portproblems	Overall: 0
Jenkins 2006	LAGB	125	Mean: 2.8 Range: 0.9- 7.6	Median age 44 14% male Mean BMI 49	18 total 4 open conversions 1 failed band insertion 13 reoperations	13 total 8 for port problems 5 for band removal	Overall: 0
Naef 2007	LAGB	128	Mean: 5 Range: 4.3- 6.3	Mean age 40.2 32% male Mean BMI 44.5	22 total Early complications (<30 days): 8/128 -5 minor, 2 major Late complications (>30 days): 14/128 -2 minor, 12 major	15 total (including 2 band- removals and and 7 re- bandings)	Overall: 0

Author/Year	Intervention	# of Patients	Study Follow-up (years)	Patient Characteristics	Complications	Reoperations	Mortality
Owers 2013	LAGB	932	10	Mean age 43 14% male Mean BMI 43.3	347 total 133 for band- slippage 136 for port- related issues	98 total 82 for band removal related to: - 60 band-slippage - 17 for erosion - 5 band intolerance 16 for port issues (removal or replacement)	Overall: 1 death due to biliary peritonitis in a patient who had undergone simultaneous cholecystectomy
Phillips 2009	LAGB	276	3	Mean age 38.6 22% male Mean BMI 44.5	164 total 53 for gastroesophageal reflux 36 for dysphagia 18 for port-site pain	42 total 2 for band replacements 9 band revisions 5 port replacements 22 port revisions 4 explants	Early (<30 days): 0 Overall: 1/276 related to port replacement surgery
Silecchia 2008	LAGB	448	Mean: 3.2	Mean age 39.4 17% male Mean BMI 43.1	Overall complications not reported	88 total 29 were minor 59 were major Most common reasons: 22 for pouch dilation 12 for band erosion	None reported

Author/Year	Intervention	# of Patients	Study Follow-up (years)	Patient Characteristics	Complications	Reoperations	Mortality
Edholm 2013	RYGB	539	Mean: 11.4 Range: 7-11	Mean age 37.9 17% male Mean BMI 44.5	Overall complications not reported	136 reoperations (including revisions, cholecystectomy, incisional hernias, and bowel obstruction)	None reported
Obeid 2012	RYGB	172	Range: 2-5	Mean age 41 24% male Mean BMI 46	81 total 33 symptomatic internal hernias 22 marginal ulcers 19 gastro- jejunostomy strictures 7 other complications	34 reoperations 33 for internal hernia 1 for small bowel resection	None reported
Suter 2011	RYGB	379	5	Mean age 39.4 26% male Mean BMI 46.3	136 total Majority of complications (43) were symptomatic internal hernia, followed by anastomotic stricture (25)	46 reoperations (all for obstruction and/or internal hernia)	Late deaths (≥2 years following surgery): 9 None were related to surgery

Appendix E Evidence Summary Key Question 6

Mortality Relative Risk Multipliers						
Age	All (≥ 30)	30-34.9	35 - 39.9	40+		
18-59	1.37	1.1	1.01	1.03		
60-69	1.22	1.44	1.31	1.1		
70+	1.09	2.05	1.69	1.29		

Table E1. Relative risk of mortality by age and BMI.

Table E2. Change in health related quality of life as assessed by EQ-5D for each BMI assuming a 30% reduction in BMI.

BMI (kg/m²)								
Diabetes	Diabetes							
Age	All (≥ 30)	30-34.9	35-39.9	40+				
Baseline EQ-5D	0.85	0.91	0.86	0.81				
Baseline BMI	40.0	32.5	27.5	45.0				
Baseline co-morbidities	1.7	1.4	1.2	1.9				
Change in BMI – assume								
30% reduction throughout	12.0	9.8	8.3	13.5				
Change in HRQoL as assessed by EQ-5D	0.0969	0.0639	0.1034	0.1214				
QALY gained (assumed gains Over year)	0.0969	0.0639	0.1034	0.1214				

BMI = Body mass index; kg = kilogram; m = meter

Table E3. Cost-effectiveness of bariatric procedures by procedure and 5 year time horizon for BMI≥30.

BMI Level/	Cost (\$)	Effectiveness	Cost-effectiveness			
Procedure	Cost (\$)	(QALYs)	Vs. SC	Vs. RYGB		
Standard Care	\$18,611	4.0632	NA	NA		
RYGB	\$41,532	4.3330	\$84,971	NA		
VSG	\$35,861	4.3116	\$69,464	Less expensive & less effective (ICER RYGB vs VSG =\$264,759)		
LAGB	\$34,147	4.2499	\$83,217	Less expensive & less effective (ICER RYGB vs LAGB =\$88,912)		
BPD/DS	\$53,846	4.4011	\$104,274	\$180,686		

BPD = biliopancreatic diversion; ICER = incremental cost-effectiveness ratio; LAGB = laparoscopic adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; VSG = vertical sleeve gastrectomy.

NOTE: Because of rounding, performing calculations may not produce the exact results shown.
BMI Level/	Cost (\$)	Effectiveness (QALYs)	Cost-effectiveness		
Procedure				/s. SC Vs. RYGB	
Standard care	\$71,602	15.4488	NA	NA	
RYGB	\$83,245	16.4441	\$5,444	NA	
VSG	\$78,151	16.3695	\$4,911	Less expensive & less effective (ICER RYGB vs VSG =\$68,351)	
LAGB	\$78,455	16.1419	\$5,077	Less expensive & less effective (ICER RYGB vs VSG =\$15,854)	
BPD/DS	\$92,489	16.8416	\$6,207	\$23,252	

Table E4. Cost-effectiveness of bariatric procedures by procedure and 25 year time horizon for BMI≥30.

BPD = biliopancreatic diversion; ICER = incremental cost-effectiveness ratio; LAGB = laparoscopic adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; VSG = vertical sleeve gastrectomy.

NOTE: Because of rounding, performing calculations may not produce the exact results shown

BMI (kg/m²)								
Diabetes								
Age	All (≥ 30)	30-34.9	35 - 39.9	40+				
0-19	1.3%	0.7%	1.4%	2.9%				
20-39	4.9%	2.9%	5.3%	10.2%				
40-59	17.2%	12.1%	19.2%	29.0%				
60+	32.9%	27.0%	36.1%	45.0%				
Hyperlipidemia								
0-19	2.9%	2.2%	3.3%	4.1%				
20-39	11.7%	10.9%	12.2%	13.4%				
40-59	37.7%	37.1%	38.6%	38.0%				
60+	56.7%	56.6%	57.6%	55.6%				
Hypertension								
0-19	2.8%	1.4%	3.2%	6.2%				
20-39	12.4%	9.0%	13.3%	20.8%				
40-59	39.2%	33.6%	42.1%	51.0%				
60+	64.5%	61.1%	66.9%	70.8%				

Table E5. Proportion of patients in alive state with co-morbidities: diabetes, hyperlipidemia, and hypertension (Crawford et al., 2010).

BMI = Body mass index; kg = kilogram; m = meter

Table E6. Results from probabilistic sensitivity analysis – Cost-effectiveness of bariatric procedures over a 10-year time horizon by procedure for BMI≥30.

BMI Level/ Procedure	Cost (\$)	Effectiveness (QALYs)	Cost-effectiveness (\$/QALY gained)					
			Vs. SC	Vs. RYGB				
BMI≥30								
Standard care	\$34,923	7.5680	NA	NA				
RYGB	\$54,089	8.0804	\$37,267	NA				
VSG	\$48,692	8.0427	\$29,145	Less expensive & less effective				
LAGB	\$47,582	7.9247	\$35,520	Less expensive & less effective				
BPD/DS	\$65,875	8.2312	\$46,414	\$77,934				

BPD = biliopancreatic diversion; ICER = incremental cost-effectiveness ratio; LAGB = laparoscopic adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; VSG = vertical sleeve gastrectomy.

NOTE: Because of rounding, performing calculations may not produce the exact results shown.

Appendix F

ICER Evidence Matrix

Formulary decisions require a rigorous evaluation of available evidence, a process that entails judgments regarding the quality of individual clinical studies and, ultimately, an assessment of the entire body of evidence regarding a therapeutic agent. To support this latter step, the Institute for Clinical and Economic Review (ICER) has developed the ICER Evidence Rating Matrix[™]. This user's guide to the ICER Matrix was developed with funding provided by the Comparative Effectiveness Research Collaborative Initiative (CER-CI), a joint initiative of the Academy of Managed Care Pharmacy, the International Society of Pharmacoeconomics and Outcomes Research, and the National Pharmaceutical Council (<u>http://www.npcnow.org/issue/cer-collaborative-initiative</u>). The ICER Matrix presents a framework for evaluating the comparative benefits and risks of therapies in a consistent, transparent system leading to an evidence rating that can guide coverage and formulary placement decisions. The purpose of this user's guide is to help members of Pharmacy and Therapeutics Committees and other decision-makers understand the approach embodied in the matrix, and to help them apply it in a reliable, consistent fashion.

The updated ICER Evidence Rating Matrix is shown below, with a key to the single letter ratings on the following page. Fundamentally, the evidence rating reflects a joint judgment of two critical components:

- a) The **magnitude** of the difference between a therapeutic agent and its comparator in "net health benefit" – the balance between clinical benefits and risks and/or adverse effects (horizontal axis); AND
- b) The level of **certainty** that you have in your best point estimate of net health benefit (vertical axis).



The letter ratings are listed below, according to the level of certainty in the best estimate of net health benefit.

High Certainty

- A = Superior
- B = Incremental
- C = Comparable
- D = Inferior

Moderate Certainty

B+=Incremental or Better C+=Comparable or Better P/I = Promising but Inconclusive I = Insufficient

Low Certainty

I = Insufficient

Steps in Applying the ICER Evidence Rating Matrix

- Establish the specific focus of the comparison to be made and the scope of evidence you will be considering. This process is sometimes referred to as determining the "PICO" – the Population, Intervention, Comparator(s), and Outcomes of interest. Depending on the comparison, it is often helpful to also define the specific Time Horizon and Setting that will be considered relevant.
- 2. Estimate the magnitude of the comparative net health benefit. Working from the scope of evidence established, it is important to quantify findings from the body of evidence on specific clinical benefits, risks, and other potentially important outcomes, such as adherence, so you can compare these side-by-side for the therapeutic agent and comparator. Some organizations compare each outcome, risk, etc. separately without using a quantitative measure to try to sum the overall comparative balance of benefits and risks between the therapeutic agent and the comparator. For these organizations the estimate of comparative net health benefit must be made qualitatively. Other organizations summarize the balance of benefits and risks using formal mathematical approaches such as health utility analysis, which generates a quantitative summary measure known as the quality-adjusted life year (QALY). What is most important, however, is full and transparent documentation of your rationale for assigning the magnitude of comparative net health benefit into one of four possible categories:
 - *Negative:* the drug produces a net health benefit inferior to that of the comparator
 - **Comparable:** the drug produces a net health benefit comparable to that of the comparator
 - Small: the drug produces a small positive net health benefit relative to the comparator
 - **Substantial:** the drug produces a substantial (moderate-large) positive net health benefit relative to the comparator

3. Assign a level of certainty to the estimate of comparative net health benefit. Given the strength of the evidence on comparative benefits and risks, a "conceptual confidence interval" around the original estimate of comparative net health benefit can be made, leading you to an assignment of the overall level of certainty in that estimate. Rather than assigning certainty by using a fixed equation weighting different attributes of the body of evidence, we recommend formal documentation of the consideration of 5 major domains related to strength of evidence: (1) Level of Bias—how much risk of bias is there in the study designs that comprise the entire evidence base? (2) Applicability—how generalizable are the results to real-world populations and conditions? (3) Consistency—do the studies produce similar treatment effects, or do they conflict in some ways? (4) Directness—are direct or indirect comparisons of therapies available, and/or are direct patient outcomes measured or only surrogate outcomes, and if surrogate outcomes only, how validated are these measures? (5) Precision—does the overall database include enough robust data to provide precise estimates of benefits and harms, or are estimates/confidence intervals quite broad?

If you believe that your "conceptual confidence interval" around the point estimate of comparative net health benefit is limited to the boundaries of one of the four categories of comparative net health benefit above, your level of certainty is "high". "Moderate" certainty reflects conceptual confidence interval s extending across two or three categories, and may include drugs for which your conceptual confidence interval includes a small likelihood of a negative comparative net health benefit. When the evidence cannot provide enough certainty to limit your conceptual confidence interval within two to three categories of comparative net health benefit, then you have "low" certainty.

4. Assign a joint rating in the Evidence Rating Matrix. The final step is the assignment of the joint rating of magnitude of comparative net health benefit and level of certainty. As shown again in the figure on the following page, when your certainty is "high," the estimate of net benefit is relatively assured, and so there are distinct labels available: an A rating indicates a high certainty of a substantial comparative net benefit. As the magnitude of comparative net health benefit decreases, the rating moves accordingly, to B (incremental), C (comparable), and finally D, indicating an inferior or negative comparative net health benefit for the therapeutic agent relative to the comparator.

When the level of certainty in the point estimate is only **"moderate,"** the summary ratings differ based on the location of the point estimate and the ends of the boundaries of the conceptual confidence interval for comparative net health benefit. The ratings associated with moderate certainty include **B**+ (incremental or better), which indicates a point estimate of small <u>or</u> substantial net health benefit and a conceptual confidence interval whose lower end does not extend into the comparable range. The rating **C**+ (comparable or better) reflects a point estimate of either comparable, small, <u>or</u> substantial net health benefit and a lower bound of the conceptual confidence interval that does not extend into the inferior range. These ratings may be particularly useful for new drugs that have been tested using noninferiority trial designs, or those involving modifications to an existing agent to provide adherence or safety advantages.

Another summary rating reflecting moderate certainty is **P/I** (promising but inconclusive). This rating is used to describe an agent with evidence suggesting that it provides a comparable, small, or substantial net benefit over the comparator. However, in contrast to ratings **B+** and **C+**, **P/I** is the rating given when the conceptual confidence interval includes a small likelihood that the comparative net health benefit might actually be negative. In our experience the **P/I** rating is a common rating when assessing the evidence on novel agents that have received regulatory approval

with evidence of some benefit over placebo or the standard of care, but without robust evidence regarding safety profiles when used in community practice.

The final rating category is I (insufficient). This is used in two situations: (a) when there is moderate certainty that the best point estimate of a drug's comparative net health benefit is comparable, but there is judged to be a moderate-high likelihood that further evidence could reveal that the comparative net health benefit is actually negative; and (b) <u>any</u> situation in which the level of certainty in the evidence is **"low,"** indicating that limitations in the body of evidence are so serious that no firm point estimate can be given and/or the conceptual confidence interval for comparative net health benefit extends across all 4 categories. This rating would be a common outcome for assessments of the comparative effectiveness of two active drugs, when there are rarely good head-to-head data available; this rating might also commonly reflect the evidence available to judge the comparative effectiveness of a drug being used for an off-label indication.



Comparative Clinical Effectiveness

Comparative Net Health Benefit