Controversies in Obesity Management

A Technology Assessment

Final Report Appendices

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Completed by:

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Appendix A: Literature Search Strategy

Ovid

1. Vagus Nerve Stimulation/ or (vag* nerve block/ or gastric electrical stimulation or maestro).ti,ab
2. gastric balloon/ or (intragastric balloon or gastric balloon).ti,ab
3. (gastric sleeve OR bypass liner OR endobarrier OR endoluminal sleeve OR duodenaljejunal bypass OR gastrointestinal liner OR duodenal jejunal bypass).ti,ab
4. (Glucagon-Like Peptide 1/ and (liraglutide or saxenda or victoza)) or (saxenda or victoza or liraglutide).ti,ab
5. (Benzazepines/ and (lorcaserin or belviq)) or (lorcaserin or belviq).ti,ab
6. ((drug combinations/ or fructose/ or phentermine/) and (qsymia or (phentermine and topiramate))) or qsymia.ti,ab. or (phentermine and topiramate).ti,ab.
7. ((drug combinations/ or naltrexone/ or bupropion/) and (contrave or mysimba or (naltrexone and bupropion))) or contrave.ti,ab. or mysimba.ti,ab. or (naltrexone and bupropion).ti,ab.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. (overweight/ or obesity/ or obesity, morbid/) or (overweight or obesity).ti,ab
10. 8 and 9
11. Limit 10 to (English language and humans and year="2000 – 2015")

Embase

1. 'implanted vagus nerve stimulator'/ OR (vag* NEAR/2 stimulat*):ab,ti OR (vag* NEAR/2 block):ab,ti OR 'maestro':ab,ti OR 'gastric electrical stimulation':ab,ti
2. 'gastric balloon' OR 'intragastric balloon':ab,ti OR 'gastric balloon':ab,ti
3. 'gastric sleeve' OR 'bypass liner':ab,ti OR 'endobarrier':ab,ti OR 'endoluminal sleeve':ab,ti OR 'duodenaljejunal bypass':ab,ti OR 'gastrointestinal liner':ab,ti OR 'duodenal jejunal bypass':ab,ti
4. 'liraglutide' OR 'saxenda':ab,ti OR 'victoza': ab,ti
5. 'lorcaserin' OR 'belviq':ab,ti
6. 'phentermine plus topiramate' OR ('phentermine' AND 'topiramate') OR 'qsymia':ab,ti
7. 'amfebutamone plus naltrexone' OR ('naltrexone' AND 'bupropion') OR 'mysimba':ab,ti OR 'contrave':ab,ti
8. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
9. 'obesity'/exp OR obes*:ab,ti OR overweight:ab,ti
10. #8 AND #9 AND [humans]/lim AND [embase]/lim AND [2000-2015]/py

Include:

- **Population:** Adults and adolescents (age 12-17) with BMI>=25 (overweight and/or all categories of obese)
- **Interventions:**
    - Bariatric surgery procedures (RYGB, VSG, LAGB, BPD/DS)
    - Devices
        - Gastric electrical stimulation (primarily Maestro system)
            - Synonyms: vagus nerve block, vbloc, vagal block
        - Duodenal-jejunal bypass sleeve (Endobarrier)
            - Synonyms: endoluminal sleeve, gastric sleeve, gastrointestinal liner
        - Intragastric balloon (e.g. Silimed BIS, ReShape duo, Bioenteric BIB, etc.)
            - Note: should be temporary intervention (i.e. approximately 6 months)
    - Medications
        - Naltrexone/bupropion sustained release (Contrave in US; Mysimba in EU)
        - Phentermine/topiramate extended-release (Qsymia)
        - Lorcaserin (Belviq)
        - Liraglutide (Saxenda)
- **Comparator:** head-to-head with any of listed interventions or active comparator (sham, placebo, usual care, lifestyle intervention)
- **Outcomes:**
    - Mortality
    - Reduction in BMI, %EWL
    - Improvement/resolution of comorbidity
    - Quality of life, pain, function
    - Complications/adverse events
    - Economic outcomes (payer costs, patient productivity, cost-effectiveness, possibly costs to employers)
- **Timing:** >=6 months for comparative studies; >=2 years for case series. EXCEPTION: harms data from comparative studies with less than 6 months follow-up is ok
- **Sources:** Systematic reviews, meta-analyses, RCTs, comparative studies, case series with >50 patients and >=2 years follow-up

Date of search: April 10, 2015

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[1]	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 (T2DM, 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
Aronne 2013[2]	RCT	1) PHEN/TPM 7.5/46 2) PHEN/TPM 15/92 3) Placebo 4) PHEN 7.5 5) PHEN 15 6) TPM 46 7) TPM 92 4), 5), 6), 7) not reported here	n=756 1) 107 2) 108 3) 109 4) 109 5) 108 6) 108 7) 107	28 weeks	Age 18-70; BMI 30-45; no use of PHEN/TPM in past 3 months; no WL or participation in WL in past 3 months or weight gain >5 kg	Mean age 1) 44.6 2) 44.6 3) 45.0 % female 1) 79.4 2) 78.7 3) 78.9 Mean BMI 1) 36.6 2) 35.9 3) 36.2	Mean % WL 1) -8.46 2) -9.21 3) -1.71 p<0.05 for 1) and 2) vs. 3) Participants with >=5% WL 1) 62.1 2) 66.0 3) 15.5 p<0.0001 for 1) and 2) vs. 3)	Mortality: 0 Serious AE 1) 1 2) 2 3) 0 *Not considered related to drugs* Discontinuation (%) 1) 15.1 2) 21.3 3) 7.3
Arterburn 2014[3]	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 AE Hazard ratio LAGB vs. RYGB: 0.46; p=0.006 Subsequent hospitalization Hazard ratio LAGB vs. RYGB: 0.73; p<0.001

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Astrup 2012[4]	RCT extension of Astrup 2009	1) LIRA 1.2 2) LIRA 1.8 3) LIRA 2.4 4) LIRA 3.0 5) Orlistat 6) Placebo Note: All LIRA/placebo switched to LIRA 2.4 at week 52 then to LIRA 3.0 mg between weeks 70-96	n=564 1) 95 2) 90 3) 93 4) 93 5) 95 6) 98	2 years	See Astrup 2009[5]	See Astrup 2009[5]	Yr. 2 mean weight change (kg) Pooled LIRA: -5.3 Orlistat: -2.3 p<0.001 % with >5% WL Pooled LIRA: 52 Orlistat: 29 p<0.001 Prediabetes/ Metabolic syndrome (%) Pooled LIRA: 16/16 Orlistat: 32/20	Patients who reported hypoglycemia (n) LIRA: 8 Placebo: 1 Participants with any SAEs (%) 1) 5.3 2) 4.4 3) 4.3 4) 5.4 5) 4.2 6) 3.1 Withdrawal due to AEs 1) 3.2 2) 6.7 3) 1.1 4) 2.2 5) 0 6) 3.1

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Astrup 2009[5]	RCT	1) LIRA 1.2 2) LIRA 1.8 3) LIRA 2.4 4) LIRA 3.0 5) Orlistat 6) Placebo	n=564 1) 95 2) 90 3) 93 4) 93 5) 95 6) 98	20 weeks	Age 18-65 BMI 30-40 <5% change in weight during previous 3 months Fasting plasma glucose <7mmol/L	Mean age 45.9 % female 76 Mean BMI 34.7 Mean weight (kg) 97.3 % prediabetes/ metabolic syndrome 1) 31/25 2) 36/21 3) 36/22 4) 31/28 5) 29/23 6) 36/34	Mean weight change (kg) 1) -4.8 2) -5.5 3) -6.3 4) -7.2 5) -4.1 6) -2.8 2), 3), 4) vs. 6) p<0.0001 1) vs. 6): p=0.003 3) vs. 5): p=0.003 4) vs. 5): p<0.0001 % with >=5% WL 1) 52.1 2) 53.3 3) 60.8 4) 76.1 5) 44.2 6) 29.6 % prediabetes/ metabolic syndrome 1) 18/17 2) 1.4/14 3) 5.5/5 4) 4.9/11 5) 31/20 6) 35/21 2), 3), 4) vs. 5) and 6): p<0.0001 (prediabetes only)	Withdrawal due to AE (%) 1) 4.2 2) 5.6 3) 9.7 4) 5.4 5) 3.2 6) 3.1 Overall AE (%) 1) 11 2) 18 3) 22 4) 12 5) 17 6) 19 Participants with any SAE (%) 1) 1.0 2) 4.4 3) 2.2 4) 1.0 5) 0 6) 1.0

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Benaiges 2012[6]	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
Bowne 2006[7]	Prospective cohort	1) RYGB 2) LAGB	n=106 1) 46 2) 60	16.2 months	1991 NIH criteria	Mean age 43 20% male Mean BMI 56 Mean weight 153.1kg	Length of stay (days) 1) 3.5 2) 1.8 p<0.002 Mean change in BMI 1) -26.5 2) -9.8 p<0.001 Mean %EWL 1) 52 2) 31 p<0.001 RYGB had more significant resolution of T2DM (p=0.05) and sleep apnea (p=0.01) compared to LAGB	Conversion to open surgery 1) 0 2) 1 Early complications 1) 8 2) 11 p=NS Late complications 1) 11 2) 43 p<0.05 Reoperations 1) 3 2) 15 p=0.04 Mortality 1) 0 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[8]	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 T2DM 1) 17 (50%) 2) 26 (76%) p=0.04 RYGB significantly better measures in components of MA II (p<0.001)	Early/late complications 1) 2/9 2) 11/3 p=0.02/p=NS Reoperations 1) 12 2) 2 p=0.009 No deaths in either group
Carlin 2013[9]	Retro-spective cohort	1) VSG 2) RYGB 3) LAGB	n=8,847 (2,949 in each group)	≤3 years	Not specified	Mean age 46 26% male Mean BMI 47.5	Mean %EWL at 3 years 1) 56 2) 67 3) 44 p<0.0004 Comorbidity remission at 1 year (%) 1) 40-66 2) 45-80 3) 18-37 No differences in QoL; patient satisfaction significantly worse for LAGB at 3 years (p=0.0001)	% overall complications 1) 6.3 2) 10.0 3) 2.4 p<0.0001 % serious complications 1) 2.4 2) 2.5 3) 1.0 p<0.0001 % 30-day reoperations 1) 1.4 2) 1.6 3) 0.4 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[10]	RCT	1) RYGB 2) LAGB 3) intensive lifestyle weight-loss intervention (ILWLI)	n=69 1) 24 2) 22 3) 23	12 months	T2DM diagnosis Age 25-55 BMI 30-40	Mean age 47 19% male Mean BMI 35.5	Mean BMI change 1) -9.7 2) -6.2 3) -3.6 p<0.001 Mean weight change (%) 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 T2DM (%) 1) 50 2) 27 3) 0 p<0.001 Complete remission of T2DM (%) 1) 17 2) 23 3) 0 p=0.047	Serious adverse events: 1) 1 2) 2 3) 0 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
Dixon 2008[11]	RCT	1) LAGB 2) life-style change	n=60 1) 30 2) 30	2 years	BMI 30-40 Age 20-60 T2DM ≥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 T2DM remission (%) 1) 73 2) 13 p<0.001 HbA1c (%) 1) -1.81 2) -0.38 p<0.001	No major complications in either group Reoperations (LAGB) 2 revisions 1 reversal surgery Mortality not reported

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Dixon 2012[12]	RCT	1) LAGB 2) conventional weight loss treatment	n=60 1) 30 2) 30	2 years	Age 18-60 years BMI 33-55 Diagnosed with sleep apnea ≥6 months OR AHI ≥20 events/hour At least 3 prior weight loss attempts	Mean age 1) 47.45 2) 50.0 18% male Mean BMI 1) 46.3 ± 6.0 2) 43.8 ± 4.9 Mean weight 1) 134.9 2) 126.0 AHI (events/hour) 1) 65.0 2) 57.2	Mean weight loss (kg) 1) -27.8 2) -5.1 p<0.001 Mean weight loss (%) 1) 20.6 2) 2.9 p<0.001 Mean BMI at 2 years 1) 36.6 2) 42.3 AHI 1) -25.5 2) -14.0 p=NS QoL (SF 36): Physical role, general health, vitality, physical component summary was significantly better for LAGB (p=0.04)	Complications 1) 1 2) NR 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
Fidler 2011[13]	RCT	1) Lorcaserin 10 BID 2) Lorcaserin 10 QD 3) Placebo	n=4,004 1) 1,602 2) 801 3) 1,601	52 weeks	Age 18-65 BMI 30-45 (or 27-29.9 with comorbidity)	% female: 79.8 Mean age: 43.8 Mean BMI 1) 36.0 2) 36.8 3) 35.9	% with >=5% WL 1) 47.2 2) 40.2 3) 25.0 p<0.001 Mean weight change (%) 1) -5.8 2) -4.7 3) -2.8 p<0.001 Mean BMI change 1) -2.1 2) -1.7 3) -1.0 p<0.001	Overall (%) 1) 82.6 2) 81.5 3) 75.3 Serious AE (%) 1) 3.1 2) 3.4 3) 2.2 Discontinuation due to AE (%) 1) 7.2 2) 6.2 3) 4.6
Fuller 2013[14]	RCT	1) IGB + behavioral modification 2) behavior modification alone ("control group")	n=66 1) 31 2) 35	1) 6 months of balloon with 12 months follow-up 2) 12 months follow-up	Age 18-60 BMI 30-40 for 2 years Failed supervised weight loss program Metabolic syndrome	Age 1) 43.4 2) 48.1 33% male Weight 1) 104.6 2) 103.4 BMI 1) 36 2) 36.7	% WL @ 6 & 12 months 1) -14.2/-9.4 2) -4.8%/5.3 p<0.0001/p=0.008 BMI reduction 1) 3.4 2) 1.9 p=.01 %EWL 1) 32.7 2) 17.8 p=.006	Removal of the balloon in 3 patients (only 1/3 related to excessive nausea and vomiting)

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Gadde 2011[15]	RCT	1) PHEN/TPM 7.5/46 2) PHEN/TPM 15/92 3) Placebo	n=2,487 1) 498 2) 995 3) 994	56 weeks	BMI 27-45 with 2 or more comorbidities age 18-70	Mean age 1) 51.1 2) 51.0 3) 51.2 % female: 70 Mean BMI 1) 36.2 2) 36.6 3) 36.7 % Hypertension 1) 52 2) 52 3) 53 % T2DM/impaired glucose tolerance 1) 69 2) 67 3) 68	Mean weight change (%) 1) -7.8 2) -9.8 3) -1.2 % Participants with >=5% WL 1) 62 2) 70 3) 21 Mean change PHQ-9 Score 1) -1.4 (95% CI: -1.7, -1.1) 2) -1.3 (95% CI: -1.5, -1.1) 3) -1.0 (95% CI: -1.2, -0.8) % with decrease in concomitant antidiabetic med. 1) 3.0 2) 3.7 3) 2.5 p=NR	SAE (%) 1) 3 2) 5 3) 4

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Galvani 2006[16]	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 p=NR NS between groups for resolution of comorbidities	Both groups had similar rates of complications and reoperations Mortality 1) 1 2) 0
Garvey 2012[17]	Extension study for CONQUER (SEQUEL)	1) PHEN/TPM 7.5 2) PHEN/TPM 15 3) placebo	n=676 1) 153 2) 295 3) 227	108 weeks	BMI 27-45 At least 2 comorbidities Completed CONQUER trial and followed study protocol	Age 1) 52.2 2) 51.2 3) 52.7 34% male Weight 1) 102.2 2) 101.9 3) 101.1 BMI 1) 36.1 2) 36.2 3) 36.0	% weight loss (@108 weeks - ITT analysis) 1) 9.3 2) 10.5 3) 1.8 p<.0001 vs. placebo Reduction in antihypertensive medication use (%) 1) 13.1 2) 15.6 3) 7.5 p=NR	SAEs (%) 1) 5.9 2) 8.1 3) 6.2 p=NS Discontinuation due to AEs 1) 4.5 2) 4.4 3) 3.1 p=NS

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Garvey 2014a[18]	Extension study OB-202 and secondary analysis of CONQUER (all patients with T2DM)	1) PHEN/TPM 15mg 2) placebo (OB-202/DM-230)	n=130 (OB-202/DM-230) 1) 75 2) 55	56 weeks (both trials)	T2DM diagnosis	OB-202/DM-230 Study Age 1) 49.7 2) 49.5 31% male BMI 1) 35.5 2) 35.2 HbA1c 1) 8.8 2) 8.5	OB-202/DM-230 Study Mean weight change (%) 1) 9.4 2) 2.6 p<.0001 % with HbA1c <7% 1) 53 2) 40 p<.05 Patients decrease # antidiabetic meds (%) 1) 18.7 2) 5.5	OB-202/DM-230 Study Hypoglycemic events (# of subjects) 1) 12 2) 5 Subjects discontinuing 1) 1 2) 0
Garvey 2014b[19]	Secondary analysis of CONQUER	1) PHEN/TPM 7.5mg 2) PHEN/TPM 15mg 3) placebo	n=475 1) 115 2) 201 3) 159	56 weeks	Subjects with prediabetes and/or metabolic syndrome	Age 1) 52.4 2) 51.3 3) 52.5 35% male BMI 1) 36.2 2) 36.3 3) 36.1	% weight loss 1) 10.9 2) 12.1 3) 2.5 p<.001 Absolute risk reduction of progression to T2DM (%) 1) 3.5 2) 2.5 3) 11.4	Discontinuation of treatment due to TEAEs (%) 1) 6.1 2) 5.5 3) 3.1 p=NR SAEs (%) 1) 7.0 2) 8.5 3) 5.0 p=NR No deaths occurred

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Genco 2006[20]	RCT (crossover)	1) IGB followed by sham 2) sham followed by IGB	n=32 1) 16 2) 16	6 months	NIH criteria	Age: 36.2 25% male BMI: 43.7	<u>1st 3 months</u> Weight loss 1) 15 2) 3 Mean BMI reduction 1) 5.8 2) 0.4 Mean %EWL 1) 34 2) 2.1 <u>3 months following crossover</u> Weight loss 1) 6 2) 13 Mean BMI 1) 1.1 2) 5.1 Mean %EWL 1) 4.6 2) 31 All weight outcomes, p<.001	No mortality or complications Minor AEs (nausea, vomiting, heartburn) controlled with medications

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Genco 2013[21]	RCT	1) IGB followed by diet 2) IGB followed by another IGB	n=50 1) 25 2) 25	13 months	Age 25-35 BMI 40-49.9 All patients had an eating disorder	Mean age 1) 31 2) 32.9 23% male Mean BMI 1) 41.2 2) 42.8	Mean BMI 1) 35.1 2) 30.9 p<.005	No major complications in any group Mortality not reported
Greenway 2010[22]	RCT	1) NB 16 2) NB 32 3) Placebo 1 & 2 with 360mg bupropion, both administered 2x/day	n=1,742 1) 578 2) 583 3) 581	56 weeks	Age 18-65 BMI 30-45 (with uncomplicated obesity) BMI 27-45 (with dyslipidemia and or hypertension	Age 1) 44.4 2) 44.4 3) 43.7 15% male Weight 1) 99.5 2) 99.7 3) 99.5 BMI 1) 36.2 2) 36.1 3) 36.2	% weight loss 1) 5.0 2) 6.1 3) 1.3 % with >= 5% 1) 39 2) 48 3) 16 1&2 vs. 3 for weight outcomes, p<.0001	Nausea (%) 1) 27.2 2) 29.8 3) 5.3 Other AEs less frequent than placebo No increased depression or suicidal thoughts in NB groups Any AE leading to discontinuation (%) 1) 21.4 2) 19.5 3) 9.8
Hedberg 2012[23]	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
Hollander 2013[24]	RCT	1) NB 32/360 2) Placebo	n=424 1) 265 2) 159	56 weeks	T2DM Age 18-70 BMI 27-45 HbA1c 7-10% Fasting blood glucose <270 mg/dL Not taking T2DM medication or on stable doses of oral antidiabetes drugs for >=3 months prior to randomization Systolic and diastolic blood pressure <145 and <95 mmHg, respectively	Mean age 53.9 % female: 53.6 Mean BMI: 36.5 Mean weight (kg) 1) 105.0 2) 106.3	Mean weight change (%) 1) -5.0 2) -1.8 p<0.001 % with >=5% WL 1) 44.5 2) 18.9 p<0.001 % achieving HbA1c<7.0% 1) 44.1 2) 26.3 p<0.001	Discontinuation due to AE (%) 1) 29.3 2) 15.3 SAE (%) 1) 3.9 2) 4.7 Overall AE (%) 1) 90.4 2) 85.2 Gastrointestinal disorders (nausea/vomiting) (%) 1) 42.3/18.3 2) 7.1/2.6 Change in IDS-SR 1) +0.53 2) -1.41 p=0.001

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Ikramuddin 2013[25]	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
Ikramuddin 2014[26]	RCT	1) VBLOC 2) Sham	n=239 1) 162 2) 77	12 months	BMI 40-45 or 35-40 with 1 or more comorbidities	Mean age 47 % female 1) 87 2) 81 Mean BMI: 41 % T2DM 1) 6 2) 8 % Hypertension 1) 39 2) 42 % Dyslipidemia 1) 56 2) 60 % Obstructive sleep apnea 1) 20 2) 30	% EWL 1) 24.4 2) 15.9 95% CI of difference (3.1, 13.9) Mean weight change (%) 1) 9.2 2) 6.0	Revision/reposition/replace (n,%) 1) 8, 4.9 2) 0 Removal by 12 months (n,%) 1) 5, 3.1 2) 8, 10.4 Serious adverse events directly related to device: 3.7%

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Koehestanie 2014[27]	RCT	1) DJBL + diet 2) Diet	n=77 1) 38 2) 39	12 months (DJBL removed at 6 months)	Age 18-65 BMI 30-50 T2DM<10 years HbA1c 7.5-10.0%	Mean age 1) 49.5 2) 49.0 % male 1) 61.8 2) 64.1 Mean BMI 1) 34.6 2) 36.8 Mean weight (kg) 1) 105.4 2) 110.8 HbA1c (%) 1) 8.3 2) 8.3	Mean weight change (kg) 1) -6.8 2) -4.0 p=0.07 Mean BMI change 1) -2.2 2) -1.3 p=0.06 %EWL 1) 19.8 2) 11.7 p<0.05 HbA1C (%) 1) 7.3 2) 8.0 p=0.95 % who decreased use of metformin/sulfonylurea/insulin 1) 16.7/40.0/36.7 2) 7.9/13.9/20.5 p=NR	Overall AE (%) 1) 76.3 2) 59 Device-related AE requiring hospitalization 1) 5 2) N/A

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Konopko-Zubrzycka 2009[28]	RCT	1) IGB 2) Diet + exercise Both groups began with 1 month of VLCD	n=36 1) 21 2) 15	10 months (balloon removed at 6 months)	Age 20-60; BMI >=40	Mean age 1) 41 2) 42.8 Male/female (n) 1) 11/10 2) 6/9 Mean BMI 1) 47.3 2) 47.1 Mean weight (kg) 1) 138.5 2) 138.9	Weight change at 6 months (%) 1) -12.3 p<0.0001 2) -2.3 p=NS	Serious AE:0
Lean 2014[29] (See Astrup 2009[5] and Astrup 2012[4])	RCT	1) LIRA 3.0 2) LIRA 2.4 3) LIRA 1.8 4) LIRA 1.2 5) Placebo 6) Orlistat 120	n=561 1) 93 2) 93 3) 90 4) 95 5) 98 6) 95	24 weeks + 84-week extension	Age 18-65; stable weight; BMI 30-40; fasting plasma glucose<7 mmol	Mean age 45.9 Mean BMI: 34.8 % female 1) 75 2) 76 3) 76 4) 77 5) 75 6) 77	Mean 2-yr WL for liraglutide 2.4/3 participants who experienced at least one episode of nausea/vomiting: 6.9 kg (vs. 4.1 kg for no nausea/vomiting, p=0.006	Proportion of individuals reporting nausea/vomiting during year 1 1) 38 2) 31 3) 23 4) 17 5) 4 6) 4 % of reports of nausea/vomiting that were severe for pooled liraglutide: 2/9

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Liang 2013[30]	RCT	1) usual care 2) usual care + exanatide 3) RYGB	n=108 1) 36 2) 34 3) 31	1 year	T2DM 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
Martin 2011[31]	RCT	1) Lorcaserin 10 BID 2) Placebo	n=57 1) 29 2) 28	56 days	Age 18-65; BMI 27-45; able to exercise; not actively attempting to become pregnant, impregnate, donate sperm, engage in in vitro fertilization; healthy	Mean age 1) 49.0 2) 48.4 % female 1) 69.0 2) 67.9 Mean BMI 1) 35.9 2) 35.2	Mean weight (kg) 1) -3.8 2) -2.2 p=0.01	Serious AE: 0 Change in depressive symptoms: 0

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Mingrone 2012[32]	RCT	1) conventional medical therapy 2) BPD 3) RYGB	n=60 1) 20 2) 20 3) 20	2 years	BMI ≥35 T2DM duration ≥5 years HbA1c ≥7%	Mean Age 1) 43.5 2) 42.8 3) 43.9 47% male Mean BMI 1) 45.6 2) 45.1 3) 44.9 Mean weight (kg) 1) 136.4 2) 137.9 3) 129.8	Mean change in BMI 1) -2.6 2) -16.0 3) -15.5 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	Late complications 2) 6 3) 3 Reoperations 2) 1 3) 1 No deaths in any group
O'Brien 2006[33]	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 (kg) 1) 74.5 2) 89.5 Mean 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

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
O'Brien 2010[34]	RCT	1) LAGB 2) lifestyle intervention	n=50 1) 25 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 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 p<0.001	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[35]	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 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
O'Neil 2012[36]	RCT	1) Lorcaserin 10 BID 2) Lorcaserin 10 QD 3) Placebo	n=603 (604 randomized) 1) 256 2) 95 3) 252	52 weeks	T2DM treated with metformin and/or sulfonylurea HbA1c at screening of 7-10% Age 18-65 BMI 27-45 able to participate in moderate intensity exercise program	Mean age 1) 53.2 2) 53.1 3) 52.0 % female 1) 53.5 2) 55.8 3) 54.4 Mean BMI 1) 36.1 2) 36.1 3) 35.9	% change weight 1) -4.5 2) -5.0 3) -1.5 % Participants with >=5% WL 1) 37.5 2) 44.7 3) 16.1 BMI change 1) -1.6 2) -1.7 3) -0.6 p<0.001 for all comparisons to 3) Change in IWQOL-LITE score 1) +11.3 2) +12.6 3) +10.2 1) vs. 3) p=NS 2) vs. 3) p=0.042	% at 52 weeks with Echocariographic valvulopathy not present at baseline 1) 2.5 3) 2.9 3) 0.5 % who experienced serious AE 1) 6.3 2) 8.4 3) 6.7 Discontinuation from AE (n) 1) 22 2) 6 3) 11
Peker 2011[37]	Prospective comparative cohort	1) LAGB 2) 2 consecutive IGBs	n=32 1) 16 2) 16	18 months	LAGB: BMI>=40 or >=35 with comorbidities	Median age 1) 36.5 2) 33.5 Female/male (n) 1) 12/4 2) 12/4 Median BMI 1) 40.7 2) 35.9	Res./Improvement/ No change T2DM 1) 0/3/0 2) 2/2/1 Hypertension 1) 1/1/1 2) 1/2/1 %EWL 1) 43.5 2) 43.7	Mortality: 0 Band removal (n): 2 No complications detected in IGB group

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Pi-Sunyer 2015[38]	RCT	1) LIRA 3.0 2) Placebo	n=3,731 1) 2,487 2) 1,244	56 weeks (+12 week crossover)	Age>=18; BMI>=30 or >=27 with dyslipidemia or hypertension; Excluded if had Type I or Type II diabetes	Age 1) 45.2 2) 45.0 % female 1) 78.7 2) 78.1 Mean BMI 1) 38.3 2) 38.3	% weight loss 1) 8.0 2) 2.6 % >=5% weight loss 1) 63.2 2) 27.1 Diabetes diagnosis (n) 1) 4 2) 14 P<0.001 for all comparison	% discontinuation from AE 1) 9.9 2) 3.8 % experienced an AE 1) 80.3 2) 63.3 % experienced nausea 1) 40.2 2) 14.7 p=NR
Ponce 2013[39]	RCT	1) IGB 2) Diet and exercise	n=30 1) 21 2) 9	48 weeks	BMI 30-40	Mean age 1) 38.9 2) 45.3 % female 1) 81 2) 100 Mean BMI 1) 34.7 2) 35.6	%EWL at 48 weeks 1) 30 2) 25 p=NS % achieving EWL>=25% 1) 19 2) 7.7 p=NS Mean % weight loss at 9 months 1) 7.5 2) 4.6 p=NR Change in SF-36 at 36 weeks Physical/Mental component 1) +3.8/-1.3 2) +3.1/-3.4	Readmission for nausea (n) 1) 4 2) NR Mortality: 0 Bowel obstruction/perforation: 0/0 Early removal: 0 Device migration: 0

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Raffaelli 2014[40]	Prospective cohort	1) RYGB 2) Lifestyle intervention and medical therapy for comorbidities	n=40 1) 20 2) 20	12 months	BMI ≥40 or >35 with T2DM 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[41]	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[42]	RCT	1) RYGB 2) BPD/DS	n=60 1) 31 2) 29	5 years	BMI 50-60 Age 20-50 years	Mean age 1) 35 2) 36 30% male Mean BMI 1) 54.8 2) 55.2 Mean weight (kg) 1) 162 2) 162	Mean BMI 1) 41.2 2) 33.1 p<0.001 Weight regain (kg) 1) 9.9 2) 8.7 p=NS Remission of T2DM 1) 4/5 (80%) 2) 6/6 (100%) p=NS Remission of metabolic syndrome 1) 17/20 (85%) 2) 22/23 (96%) p=NS	Patients with adverse events (%) 1) 67.7 2) 79.3 p=NS Patients with hospital readmissions (%) 1) 29 2) 59 p=0.02 Patients with surgery related to procedure (%) 1) 9.7 2) 44.8 p=0.002
Romero 2012[43]	Prospective cohort	1) VSG 2) RYGB 3) T2DM controls 4) Non-T2DM controls	n=22 1) 6 2) 6 3) 5 4) 5	6 weeks (controls evaluated on single occasion)	T2DM diagnosis Severely obesity	Mean age 1) 49.5 2) 49.2 3) 50.0 4) 48.0 41% male Mean BMI 1) 52.8 2) 50.8 3) 46.0 4) 46.4	Mean BMI 1) 47.0 2) 45.1 Mean weight loss (%) 1) 11.3 2) 13.0 Mean HbA1c (%) 1) 5.0 2) 4.5 (within group comparisons p=NS for main outcomes)	None reported

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Sarr 2012[44]	RCT	1) VBLOC (treatment): Complete block of vagal neural impulses 2) VBLOC (control): Very low, clinically unimportant level of charge delivered to vagus nerve	n=294 1) 192 2) 102	12 months	Age 18-65 BMI 40-45 or 35-39.9 with one or more obesity-related comorbidities Failure to achieve weight loss with behavioral intervention or pharmaco-therapy.	Mean age 46 Mean BMI 41 % female 1) 90 2) 86 % with T2DM 1) 3 2) 5	% EWL 1) 17 2) 16 p=NS % of participants achieving >=25% EWL 1) 22 2) 25 p=NS Change in IWQOL-Life Score 1) +13 (p<0.001) 2) +13 (p<0.001) between groups: p=NS SF-36 and BDI-II: no differences between groups in the physical or mental components	Mortality: 0 Revisionary procedure (n): 14 Early device removal (n): 16
Schauer 2012[45]	RCT	1) intensive medical therapy (IMT) 2) RYGB 3) VSG	n=150 1) 50 2) 50 3) 50	12 months	Age 20-60 years T2DM diagnosis BMI 27-43	Mean age 1) 49.7 2) 48.3 3) 47.9 34% male Mean BMI 1) 36.3 2) 37.0 3) 36.1	Mean weight (kg) 1) 99.0 2) 77.3 3) 75.5 Mean BMI 1) 34.4 2) 26.8 3) 27.2 p<0.001 for 2) and 3) vs. 1); p=NR for 2) vs. 3) in both outcomes	Reoperation 1) 0 2) 3 3) 1 Adverse event requiring hospitalization 1) 4 2) 11 3) 4 No deaths

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Schauer 2014[46]	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 T2DM 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 3) 9.5	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 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
Shikora 2015[47]	RCT (18-month results of ReCharge trial. See Ikramuddin 2014)	1) vBloc 2) Sham	n=239 1) 162 2) 77	18 months	BMI 40-45 or 35-40 with 1 or more comorbidities	Mean age: 47 % female 1) 87 2) 81 Mean BMI: 41 T2DM/HTN/DYS/OSA (%) 1) 4/39/56/20 2) 7/42/60/30	% EWL 1) 23.5 2) 10.2 Difference: 13.4 (95% CI: 8.4, 18.4) %TWL 1) 8.8 2) 3.8 Difference: 5.0 (95% CI: 3.1, 6.9)	% heartburn/dyspepsia 1) 25 2) 4 % neuroregulator site pain 1) 38 2) 42 % abdominal pain 1) 14 2) 3

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Smith 2009[48]	RCT	1) Lorcaserin 10 QD 2) Lorcaserin 15 QD 3) Lorcaserin 10 BID 4) Placebo	n=469 1) 117 2) 118 3) 116 4) 118	12 weeks	Age 18-65; BMI 30-45	Mean age 1) 41.5 2) 41.3 3) 41.5 4) 41.6 % female 1) 82.1 2) 93.2 3) 85.3 4) 87.3 Mean BMI 1) 36.2 2) 36.9 3) 36.2 4) 36.4	Mean BMI change 1) -0.7 2) -1.0 3) -1.3 4) -0.1 Change in weight (kg) 1) -1.7 2) -2.2 3) -3.1 4) -0.2 p<0.001 for 1),2),&3) vs. 4)	Nausea/dizziness (%) 1)8.5/6.0 2) 9.3/7.6 3) 11.2/7.8 4) 3.4/0 Headache (%) 1) 29.9 2) 32.2 3) 26.7 4) 17.8 Discontinued from AE (n) 1) 1 2) 9 3) 2 4) 3
Smith 2010[49]	RCT	1) Lorcaserin 10 2) Placebo All patients also received diet/exercise counseling	n=3,182 1) 1,595 2) 1,587	52 weeks	Age 18-65; BMI 30-45 or 27-45 with comorbidities	Mean Age 1) 43.8 2) 44.4 % female 1) 82.9 2) 84.0 Mean BMI 1) 36.2 2) 36.2	Mean BMI change 1) -2.09 2) -0.78 p<0.001 % Participants with >=5% WL 1) 47.5 2) 20.3 p<0.001 Mean WL (%) 1) 5.81 2) 2.16 p<0.001	Upper respiratory infections/headache (%) 1) 14.8/18.0 2) 11.9/11.0 Nausea/dizziness (%) 1)7.5/8.2 2) 5.4/3.8 Incidence of depressive symptoms (%) 1) 2.5 2) 2.2

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Søvik 2010[50]	RCT	1) RYGB 2) BPD	n=60 1) 31 2) 29	12 months	BMI 50-60 Age 20-50 years	Mean age 1) 35 2) 36 30% male Mean BMI 1) 54.8 2) 55.2 Mean weight (kg) 1) 162 2) 162	%EBMIL 1) 54.4 2) 74.8 p<0.001 Mean BMI 1) 38.5 2) 32.5 p<0.001	Early complications 1) 4 2) 7 Late complications 1) 5 2) 9 Reoperations 1) 2 2) 1 All outcomes above p=NS No deaths in either group
Søvik 2011[51]	RCT	1) RYGB 2) BPD	n=60 1) 31 2) 29	24 months	BMI 50–60 Age 20–50 years	Mean age 1) 35 2) 36 30% male Mean BMI 1) 54.8 2) 55.2 Mean weight (kg) 1) 162 2) 162	Mean weight (kg) 1) 111 2) 88.3 Mean BMI 1) 37.5 2) 30.1 p<0.001 Both outcomes p<0.001	Late complications 1) 9 2) 12 Reoperations 1) 3 2) 7

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Wadden 2011[52]	RCT	1) NB 32/360 2) Placebo Note: All participants also received behavior modification	n=793 1) 591 2) 202	56 weeks	Age 18-65; BMI 30-45 or 27-45 with controlled hypertension and/or dyslipidemia	Mean age 1) 45.9 2) 45.6 % female 1) 89.3 2) 91.6 Mean BMI 1) 36.3 2) 37	% with >5% WL 1) 66.4 2) 42.5 p<0.001 % Change weight 1) -7.8 2) -4.9 p<0.001 IWQOL-Lite total score % change 1) +23.9 2) +17.7 p<0.001	% Discontinued from AE 1) 25.4 2) 12.4 Serious AEs related to drug (cholecystitis) (n) 1) 2 2) N/A
Wadden 2013[53]	RCT	1) LIRA 3.0 2) Placebo	n=422 1) 212 2) 210	56 weeks	Age >=18; BMI >=30 or >=27 with comorbidities; lost >=5% weight during VLCD	Mean age 1) 45.9 2) 46.5 %female 1) 84 2) 79 Mean BMI 1) 36 2) 35.2	% Change weight 1) -6.2 2) -0.2 p<0.0001 % Participants with >5% WL 1) 50.5 2) 21.8 p<0.0001 Mean BMI change 1) -2.1 2) 0 p<0.0001	% experiencing adverse events 1) 91.5 2) 88.6 Symptomatic hypoglycemia (n) 1) 11 2) 5 GI-related AE leading to withdrawal (n) 1) 11 2) 0

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Winslow 2012[54]	RCT	1) PHEN/TPM 15/92 2) Placebo	n=45 1) 22 2) 23	28 weeks	Age 30-65; BMI 30-40; OSA; apnea-hypopnea index>=15; unwilling to comply with PAP treatment	Mean age 1) 53.4 2) 51.4 % female 1) 59.1 2) 34.8 Mean BMI 1) 36.0 2) 35.3	% change weight 1) -10.3 2) -4.2 % Participants with >=WL 1) 72.7 2) 47.8 p=0.0846 Mean change in apnea-hypopnea index 1) -31.5 2) -16.6	% with Treatment-emergent AE 1) 90.9 2) 73.9

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[55]	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 T2DM 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
Alfa Wali 2014[56]	Retrospective comparative cohort	1) IGB 2) LAGB 3) RYGB	n=983 1) 88 2) 533 3) 362	1 year	NICE criteria for surgery	Mean age 48.10 % Female 79.3 Mean BMI 47.52	%EWL 1) 14.05 2) 22.95 3) 41.67 3 vs. 1 & 3 vs. 2, p<.0001 At 9 months and 1-year follow up, LAGB and IGB had comparable %EWL while RYGB remained significantly more effective.	Social deprivation does not affect the degree of excess weight loss after bariatric surgery

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Alley 2012[57]	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 %EBMIL 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
Angrisani 2013[58]	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

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Ballantyne 2006[59]	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/ml): 1) 12.3 2) 9.1 p<0.05 p=NS for HbA1c or glucose	None reported
Bayham 2012[60]	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 T2DM on hypoglycemic meds	Mean age 49 30% male Mean BMI 47.5	Discontinued T2DM 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

Author/Year	Study Design	Comparators / Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Benaiges 2011[61]	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
Benaiges 2013[62]	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 T2DM resolution (%) 1) 62.1 2) 60 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
Brunault 2011[63]	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 for VSG, but no other differences	Reoperations 1) 20 2) 5 p=NS Postoperative fistula 1) 0 2) 3 p=0.01 No deaths reported
Busetto 2007[64]	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[65]	Retro-spective cohort	1) VSG 2) LAGB	n=32 (16 in each group	1 year	T2DM diagnosis Age 30-60 BMI 25-35	Mean age 45.3 34% male Mean BMI 30	T2DM remission 1) 1 (50%) 2) 9 (100%) P=0.002 Partial remission 1) 7 2) 7	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[66]	Prospective cohort	1) RYGB 2) LAGB	n=362 (181 in each group)	Up to 3 years	Not reported	Mean age 42.5 16% male Mean BMI 47.2	Mean %EWL at 1 year 1) 76 2) 48 p<0.001 T2DM resolution (%) 1) 78% 2) 50% p=0.010 HLD resolution (%) 1) 61 2) 40 p=0.009 HTN resolution (%) 1) 81 2) 56 p=0.003	Minor reoperation 1) 25 2) 28 p=NS Major reoperation 1) 10 2) 15 p=NS Downward trend over 3 years significant in favor of LAGB 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
Cotugno 2015[67]	Retrospective comp cohort	1) Bariatric surgery (RYGB [15] or VSG [16]) 2) LIRA + ongoing hypoglycemic drugs	n=62 1) 31 2) 31	1 year	Patients with T2DM	Age 1) 47 2) 56 p<.001 Weight (kg) 1) 122 2) 107 p=.004 BMI 1) 44 2) 40 p=.03 Mean HbA1c 1) 7.9 2) 8.4 p<.005	BMI reduction 1) 14 2) 1.4 p<.001 Weight loss (kg) 1) 38 2) 5 (51% achieved at least 5% weight loss) p<.001 HbA1c reduction 1) 2.2 2) 1.3 p=NS Use of meds @ 12 months Hypertension 1) 2/23 2) 19/17 Dyslipidemia 1) 2/10 2) 14/13 No significance testing for meds	AEs 1) 34 2) 7 No significance testing done for AEs

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Coupaye 2013[68]	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 (6 mos) 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[69]	Retro-spective cohort	1) RYGB 2) VSG	n=31 1) 16 2) 15	Up to 24 months	T2DM 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
Davidson 2013[70]	Secondary analysis of CONQUER	1) PHEN/TPM (7.5mg) 2) hypertension (15mg) 3) placebo	hypertension 1) 516 2) 256 3) 514 n=1286 dyslipidemia 1) 526 2) 271 3) 526 n=1323	56 weeks	BMI 27-45 Patients with dyslipidemia and/or hypertension at the start of the trial	Age: 51.1 % male: 30% Weight: 103.1 BMI: 36.6	% weight loss (hyper) 1) 8.5 2) 10.5 3) 2.1 % weight loss (dys) 1) 8.1 2) 10.1 3) 1.9 Both p<.0001 vs. placebo Dose-related weight loss induced by PHEN/TPM ER treatment was accompanied by significant improvements in cardiovascular disease risk factors in participants who had dyslipidemia or hypertension at baseline and were similar to the overall population	AEs (hyper) (%): 1) 85.4 2) 88.8 3) 77.3 (0.4% severe) AEs (dys) (%): 1) 86.5 2) 88.3 3) 75.9 (0.6% severe) Discontinuation due to AEs: (hyper): 1) 9.7 2) 11.9 3) 19.8 (dys): 1) 12.4 2) 18.0 3) 8.8 1 death occurred in the placebo group of the subgroup with dyslipidemia p=NR for all harms

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
del Genio 2007[71]	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 significant in 2) (p=0.002)	None reported
Demaria 2010[72]	Retro-spective cohort	1) RYGB 2) LAGB	n=218 (109 in each group)	90 days	T2DM 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[73]	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 2) 53 ± 11 %EBW at 24 months 1) 67 ± 18 2) 63 ± 21 p=NS for both comparisons Hospital LOS* 1) 5.9d 2) 8.7d p<0.05	Wound infection* 1) 47 2) 25 p=NS Postop anastomotic leak* 1) 8 2) 7 Mortality 1) 2 2) 1 *from full sample only
Dixon 2007[74]	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[75]	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 T2DM 1) 2/2 2) 2/3 Fishers exact 0.65	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

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Dorman 2012[76]	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 T2DM 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 vs. -1.3, p<0.001 Mean change in BMI (RYBG vs. LAGB) -14.8 vs. -6.5, 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 vs. -1.3, p=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[77]	Retro-spective cohort	1) RYGB 2) VSG	n=38699 1) 33867 2) 4832	6 months	>17 years old	Mean age 1) 45.4 2) 46 % male 1) 20.9 2) 26.7 Mean BMI 1) 47.6 2) 47.9 Preoperative GERD 1) 50.4% 2) 44.5%	Resolution of GERD 1) 62.8% 2) 15.9% p0<0.001 The percentage of patients who experienced resolution of comorbidities was decreased in the VSG patients who had preoperative GERD	New onset GERD 1) 2.2% 2) 8.6% p<0.05 Postoperative complications (15.1% vs 10.6%), gastrointestinal adverse events (6.9% vs 3.6%), and increased need for revisional surgery (0.6% vs 0.3%) were higher for VSG (all 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-Sanchez 2012[78]	Prospective cohort	1) BPD/DS 2) VSG	n=31 1) 18 2) 13	90 days	Not reported	Mean age 1) 40.06 2) 43.15 23% males Mean BMI 1) 50.05 2) 48.01 Mean HbA1c 1) 6.75 2) 6.56 Mean Cholesterol 1) 5.06 2) 5.02 Mean Triglycerides 1) 1.63 2) 1.68	BMI 1) -7.98 2) -7.98 p=NS HbA1c 1) -1.81 2) -.81 p<0.01 Mean Cholesterol 1) -1.62 2) -.12 p<0.001 Mean Triglycerides 1) -.22 2) -.37 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
Gehrer 2010[79]	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

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Genco 2008[80]	Retrospective comp cohort	1) IGB 2) structured diet and behavioral modification	n=260 1) 130 2) 130	≥12 months	Consecutive patients undergoing IGB or diet program Age 18-60 BMI >35 or <35 with at least 1 comorbidity	Age 1) 38.0 2) 37.7 23% male Weight 1) 117.1 2) 115.9 BMI 1) 42.1 2) 41.9	After balloon removal Mean BMI 1) 35.4 2) 38.9 %EWL 1) 33.9 2) 24.3 Weight outcomes, p<.01 Weight regain after 24 months in IGB group Resolution T2DM 1) 16/41 2) 11/38 Hypertension 1) 18/39 2) 10/39 Joint disease 1) 7/19 2) 4/16 All comorbidity outcomes, p<.001; resolution of OSA in all patients in both groups Other outcomes reported improvement or no change	No mortality or complications

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Genco 2009[81]	Case-control	1) VSG 2) IGB	n=120 1) 40 2) 80	12 months	Consecutive patients undergoing the interventions of interest	Age 1) 41.2 2) 40.9 30% male Weight 1) 157.2 2) 156.1 BMI 1) 54.8 2) 54.1	6 month follow-up Mean BMI 1) 46.2 2) 47.1 %EWL 1) 33.6 2) 34.7 12 month follow-up Mean BMI 1) 43.1 2) 48.1 %EWL 1) 35.2 2) 35.1 Patients in IGB group gained weight b/w 6-12 months while VSG patients cont'd to lose weight. No significant differences between groups for weight outcomes or for improvement of comorbidities @ any point.	No deaths of complications in either group

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Genco 2010[82]	RCT	1) IGB followed by diet 2) IGB followed by another IGB	n=100 1) 50 2) 50	2 years	Age 25-35 BMI 40-49.9	Age 1) 31.4 2) 32.1 20% male Weight 1) 106.3 2) 107.1 BMI 1) 42.6 2) 42.9	@ study end: %EBL 1) 25.1 2) 51.9 Mean BMI 1) 35.9 2) 30.9 After 24 months: Mean BMI 1) 41.1 2) 36.8 All weight outcomes, p<.05	Complications were comparable b/w groups
Halperin 2014[83]	RCT	1) RYGB 2) T2DM and weight management	n=38 1) 19 2) 19	12 months	T2DM >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[84]	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 Overall morbidity (%) 1) 26.5 2) 13.2 p=0.01 Reoperation (%) 1) 3.4 2) 2.5 p=NS No deaths occurred
Himpens 2006[85]	RCT	1) LAGB 2) VSG	n=80 1) 40 2) 40	3 years	Not reported	Mean Age 38 20% male Median BMI 38	Mean weight loss (kg) 1) 17 2) 29.5 p<0.0001 Mean %EWL 1) 48 2) 66 p=0.0025 Mean change in BMI 1) -18.0 2) -27.5 p=0.0004	GERD occurrence (%) 1) 8.8 2) 21.8 p=NS All reoperations 1) 9 2) 4 Revisions 1) 4 (to RYGB) 2) 2 (to DS) Overall complications 1) 16 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[86]	Prospective cohort	1) VSG 2) LAGB 3) RYGB (lap) 4) RYGB (open)	n=28616 1) 944 2) 12193 3) 14491 4) 988	1 year	Not reported	Mean age 1) 46.52 2) 44.31 3) 44.6 4) 45.52 23% male Mean BMI 1) 46.24 2) 43.91 3) 46.07 4) 48.80	Mean change in BMI 1) -11.87 2) -7.05 3) -15.34 T2DM resolution (%) 1) 55 2) 44 3) 83 Hypertension resolution (%) 1) 68 2) 44 3) 79 OSA resolution (%) 1) 62 2) 38 3) 66 GERD resolution (%) 1) 50 2) 64 3) 70	30-day reoperations 1) 28 (2.97%) 2) 112 (0.92%) 3) 728 (5.02%) 4) 50 (5.06%) 30-day morbidity 1) 53 (5.61%) 2) 175 (1.44%) 3) 857 (5.91%) 4) 148 (14.98%) Mortality 1) 2 (0.21%) 2) 10 (0.08%) 3) 49 (0.34%) 4) 11 (1.11%)

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Iesari 2013[87]	Prospective cohort	1) diet-induced weight loss 2) BPD	n=20 1) 10 2) 6	6 months	No T2DM diagnosis	Mean age 1) 41.2 2) 38 25% male Mean BMI 1) 49 2) 49.7	Mean weight loss 1) 14.7 (p<0.01) 2) 29.9 (p<0.01) Mean change in BMI 1) -5.2 (p<0.05) 2) -10.5 (p<0.05)	None reported
Inabet 2012[88]	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	T2DM remission 28% for LAGB, 62% RYGB, 52% VSG, and 74% BPD/DS	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%)

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Jan 2007[89]	Retro-spective cohort	1) LAGB 2) RYGB	n=898 1) 406 2) 492	5 years	BMI ≥40 or BMI ≥35 with comorbidities	Mean age 1) 47 2) 44 17% male Mean BMI 1) 51 2) 49	Mean %EWL 1) 49 2) 58.6 Mean weight loss (kg) 1) 48.1 2) 47.7 Mean change in BMI 1) 16.2 2) 18 p=NS	Complications (%) 1) 24 2) 32 p=0.002 Adverse events (%) 1) 5 2) 9 p=NS Reoperation rate (%) 1) 17 2) 17 p=NS One RYGB death
Karlsen 2013[90]	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 2) 43 SF 36: Physical 1) 34 2) 39 Mental 1) 41 2) 2 Emotional 1) 32 2) 42	SF 36 change from baseline: Physical 1) 16.8 2) 4.9 p<0.001 Mental 1) 9.6 2) 3.5 p=0.007 Emotional 1) 42.7 2) 15.7 p<0.007 25.2; 95% CI, 15.0-35.4	None reported

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Kashyap 2013[91]	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 T2DM 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[92]	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 2) -15.3 p=NS %EBMIL 1) 61.4 2) 68.2 p=NS Mean %EWL 1) 62.1 2) 68.5 p=NS No significant differences were seen for resolution of comorbidities between groups	Early morbidity (%) 1) 10 2) 13 p=NS Late morbidity (%) 1) 10 2) 10 p=NS Reoperations 1) 1 2) 1 No mortality

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Kim 2006[93]	Retro-spective cohort	1) RYGB 2) LAGB	n=392 1) 232 2) 160	18 months	BMI ≥40 or BMI ≥35 w/comorbidities	Mean Age 1) 38.5 2) 41.7 17% male Mean BMI 1) 47.2 2) 47.1	Mean %EWL 1) 68 2) 47.5 p=NS Mean %EWL for BMI >50 1) 50.5 2) 40.7 p=NS Significant improvement of comorbidities including, hypertension, T2DM, hyperlipidemia, arthritis, GERD, and stress urinary incontinence were not statistically different between groups.	Early complications (%) 1) 5.2 2) 0.6 Late complications (%) 1) 0.4 2) 3.7 Overall complications were not significantly different. 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
Kokkinos 2013[94]	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[95]	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[96]	Prospective cohort	1) RYGB 2) hypocaloric diet	n=19 1) 9 2) 10	1 month	Females with T2DM	Mean Age 45.6 Mean Weight 112kg Mean BMI 43.3 Mean T2DM 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 T2DM medications vs. 2 in the diet group	No serious adverse events in any group.
Leonetti 2012[97]	Prospective cohort	1) VSG 2) conventional therapy	n=60 1) 30 2) 30	18 months	Morbid obesity with T2DM	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 *p<0.001* Mean HbA1c (%) 1) 6.0 2) 7.1 *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
Leyba 2011[98]	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[99]	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[100]	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[101]	Prospective cohort	1) LAGB (non-T2DM) 2) RYGB (non-T2DM) 3) RYGB (T2DM) 4) very low-calorie diet (T2DM)	n=54 1) 11 2) 16 3) 15 4) 12	3 weeks	(1), (2), (3), (4): fulfilled international criteria for bariatric surgery; (4): eligible for dietary treatment and did not wish to undergo surgery	Mean age 1) 46.3 2) 48.6 3) 51.3 4) 50.8 Mean BMI 1) 43.1 2) 44.2 3) 43.5 4) 40.2 Mean weight (kg) 1) 118.6 2) 128.2 3) 121.3 4) 112.0	Mean weight (kg) 1) 113.1 2) 119.4 3) 112.5 4) 105.3 Mean BMI 1) 40.5 2) 40.9 3) 40.4 4) 37.7 3 & 4 vs. 1 & 2, p=NS for both outcomes	None reported
Martins 2011[102]	Prospective cohort	1) RYGB 2) residential intermittent program 3) commercial weight loss camp 4) hospital outpatient program	n=179 1) 50 2) 27 3) 56 4) 46	1 year	Not reported	Mean age 1) 40 2) 40.2 3) 38.4 4) 41.4 29% male Mean BMI 1) 45.2 2) 45.3 3) 48.3 4) 44.3	Weight loss (kg) 1) 40.3 2) 21.7 3) 17.6 4) 6.7 Weight loss (%) 1) 30.5 2) 14.8 3) 13.0 4) 5.3 1 vs. 2, 3 or 4 for both outcomes, p<0.0001	None reported

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Messiah 2013[103]	Prospective cohort	1) RYGB 2) LAGB	n=890 1) 454 2) 436	1 year	Aged 11-19	25% male Mean BMI 1) 53.6 2) 49.14 Mean weight 1) 167.58 2) 155.66	Mean change in BMI 1) -17.1 2) -6.9 p<0.001 Mean weight loss (kg) 1) 48.6 2) 19.8 p<0.001 Hyperlipidemia improved (%) 1) 58.8 2) 23.3 p<0.05 T2DM, hypertension, asthma, and OSA improved in both groups but were not statistically different b/w them	120 total complications 1) 98 2) 22 Readmissions 1) 45 2) 10 Reoperations 1) 29 2) 8 1 death after RYGB (cardiac failure)

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Mingrone 2002[104]	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[105]	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[106]	Prospective cohort	1) RYGB 2) BPD 3) Transoral endoscopic vertical gastroplasty	n=79 1) 20 2) 30 3) 29 (results excluded from table)	24 months	Met 1991 NIH guidelines for bariatric surgery	Mean age 1) 42.1 2) 40.2 14% male Mean BMI 1) 44.8 2) 47.5	Mean BMI 1) 29.2 2) 29.6 Total weight loss (%) 1) 34.7 2) 37.1 EBMIL (%) 1) 81.1 2) 79.1 Mean weight loss (kg) 1) 45 2) 48 p=NR for any outcome	Early complications 1) 2 2) 0 Late complications 1) 0 2) 5 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
Nelson 2012a[107]	Retro-spective cohort	1) BPD 2) RYGB	n=78,951 1) 1,545 2) 77,406	≥2 years	Not reported	Mean age 1) 45.4 2) 45.3 % male 1) 21.6 2) 26 Mean BMI 1) 52 2) 48	Mean change in BMI 1) -36 2) -43 p<0.05 >50 BMI subgroup Mean %EWL 1) 79 2) 67 p<0.01 Comorbidity control of T2DM, hypertension, and sleep apnea were all superior with the DS (all p<0.05)	Early reoperation (%) 1) 1.5 2) 3.3 p<0.001 Late reoperation (%) 1) 1.3 2) 1.1 p=NS Any reoperation (%) 1) 11.5 2) 7.2 p<0.001 Similar rates for >50 BMI. 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[108]	RCT	1) RYGB 2) LAGB	n=197 1) 111 2) 86	4.2 years	BMI 40-60 or 35 with comorbidities Age 18-60	Mean age 1) 41.4 2) 45.8 23% male Mean BMI 1) 47.5 2) 45.5	Mean %EWL 1) 68.4 2) 45.5 p<0.05 Mean change in BMI 1) -17 2) -15 p<0.05 Mean %EWL ≥50 vs. BMI <50 (RYGB) 61.0% vs. 70.9%, p<0.05 Mean %EWL ≥50 vs. BMI <50 (LAGB) 34.3 vs. 49.7, p<0.05 QoL after 1 year (SF-36) scores for all 8 health domains comparable with that of US norms and were not significantly different between groups	Early complications 1) 17 (15.3%) 2) 4 (4.7%) p=0.02 Late complications 1) 15 (13.5%) 2) 0 (0%) p<0.01 Reoperations 1) 14 2) 11 p=NS (LAGB had more late reoperations than RYGB but the difference was not significant) 30- and 90-day and mortality was zero for both groups 1 year mortality 1) 1 (0.9%) (unrelated to surgery) 2) 0 (0.0%)

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Nocca 2011[109]	Retro-spective cohort	1) VSG 2) RYGB	n=68 1) 35 2) 33	1 year	>35 BMI All patients undergoing T2DM therapy	Mean age 1) 46.5 2) 47.5 Mean weight (kg) 1) 139.4 2) 131.40 Mean duration T2DM (years) 1) 6.7 2) 7.8 Mean HbA1c 1) 7.9 2) 8.2	Mean %EWL 1) 60.12 2) 56.35 Mean change in BMI (%) 1) -29.80 2) -29.75 T2DM remission 1) 35/35 (100%) 2) 31/33 (91.4%) p=NS for all outcomes	Perioperative morbidity 1) 1 (2.9%) 2) 2 (5.8%) No deaths in either group
Norstrand 2012[110]	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 Nocturnal HTN 1) 42 (86%) 2) 29 (71%) Daytime HTN 1) 37 (76%) 2) 27 (66%)	Mean weight loss (kg) 1) -41 (p≤0.001) 2) -10 (p≤0.001) Nocturnal hypertension change 1) -28 (67%) (p≤0.001) 2) -2 (7%) (p=NS) Daytime hypertension change 1) -24 (65%) (p≤0.001) 2) -3 (11%) (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
Olsen 2012[111]	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
Ortega 2012[112]	Retro-spective cohort	1) RYGB 2) VSG	n=407 1) 307 2) 100	12.5 months	BMI >40 or 35-40 with major obesity-associated comorbidities 2 or more physician-supervised weight loss attempts within preceding 3 years No previous weight loss surgery	Mean age 1) 43 2) 46 24% male Mean BMI 1) 46 2) 53 Mean weight (kg) 1) 122 2) 138	Mean %EWL 1) 76 2) 68 p<0.0001	None reported

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Padwal 2014[113]	Prospective cohort	1) RYGB 2) intensive medical management 3) wait-listed controls	n=500 1) 150 2) 200 3) 150	2 years Subjects progressed from wait list to IMT to surgery and didn't remain in original study groups for duration of study	BM ≥40 or ≥35 with at least 1 comorbidity	Mean age 1) 43.5 2) 43.9 3) 43.6 12% male Mean BMI 1) 46.2 2) 48 3) 49.4 Mean weight (kg) 1) 128 2) 132 3) 134 Mean HbA1c (%) 1) 5.9 2) 6.3 3) 6.2	Mean weight loss (kg) 1) -22.0 2) -4.1 3) -1.5 p<0.0001 Mean weight loss (%) 1) -16.3 2) -2.8 3) -0.9 p<0.0001 Mean change in BMI 1) -7.8 2) -1.5 3) -0.6 p<0.0001	None reported

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Paluszkiewics 2012[114]	RCT	1) VSG 2) RYGB (open)	n=72 1) 36 2) 36	12 months	BMI ≥40 or ≥35 with at least 1 comorbidity Age 18-60 years	Mean age 1) 43.9 2) 44.9 32% male Mean BMI 1) 46.1 2) 48.6 Mean weight (kg) 1) 130.7 2) 137.7	Mean %EWL 1) 67.6 2) 64.2 Mean change in BMI 1) 32.8 2) 33.8 Mean weight (kg) 1) 91.7 2) 96.8 Hypertension remission 1) 17 (47.2%) 2) 19 (52.7%) T2DM remission 1) 6 (16.7%) 2) 5 (13.9%) Dyslipidemia remission 1) 26 (72.2%) 2) 18 (50.0%) p=NS for all comparisons	Major/minor complications (%) 1) 8.3/10.1 2) 0.0/16.6 p=NS for both Reoperations 1) 0 (0.0%) 2) 1 (5.5%) 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
Parikh 2005[115]	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[116]	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[117]	RCT	1) RYGB 2) VSG	n= 23 1) 12 2) 11	12 months	Non-diabetic patients from study center (subgroup of ongoing "Swiss Multicenter Bypass or Sleeve Study")	Mean age 41.4 35.2 26% male Mean weight (kg) 1) 133.3 2) 120.2 Mean BMI 1) 47.6 2) 44.7	Mean weight (kg) 1) 87.3 2) 86.3 Mean BMI 1) 31.1 2) 32.0 Mean %EBMIL 1) 77.0 2) 65.6 p=NS for all outcomes	None reported

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Peterli 2013[118]	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 *Resolution or improvement of comorbidities (%)* Hypertension 1) 32/94 2) 32/89 Dyslipidemia 1) 45/95 2) 25/84 T2DM 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 2011[119]	Retro-spective cohort	1) RYGB 2) LAGB	n=294 1) 215 2) 79	42 months	Not reported	Mean age 1) 44.7 2) 48.1 17% male Mean BMI 1) 48.7 2) 45.3	Mean %EWL 1) 46 2) 65 p=NS Mean BMI 1) 32.1 2) 35.7 p=NS	None reported
Prachand 2006[120]	Retro-spective cohort	1) BPD 2) RYGB	n=350 1) 198 2) 152	36 months	BMI >50	Mean age 1) 40.4 2) 40.5 17% male Mean weight (lb) 1) 368.2 2) 346.3 Mean BMI 1) 58.8 2) 56.4	Mean BMI 1) 33.6 2) 37.2 p=0.05 Mean %EWL 1) 68.9 2) 54.9 p<0.05 Mean weight loss (lb) 1) 173.5 2) 118.0 p<0.01	60-day reoperation rate (%) 1) 4.0 2) 5.3 p=NS Other complications not reported 30 day mortality 1) 1 2) 0

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Puzziferri 2008[121]	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 excess weight (lb) 1) 168.0 2) 152.7	Mean %EWL 1) 75.06 2) 43.53 p<0.001	None reported
Romy 2012[122]	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
Schouten 2010[123]	RCT	1) DJBL 2) VLCD	n=41 1) 30 (26 successfully implanted) 2) 11	12 weeks	Age 18-55; BMI 40-60 kg/m2 or >35 with comorbidities; on waiting list for RYGB	Mean age 1) 40.9 2) 41.2 Male:Female 1) 8:22 2) 2:9 Mean BMI 1) 48.9 2) 49.2	%EWL at 12 weeks 1) 19.0 2) 6.9 p=0.00 Mean BMI at 12 weeks 1) 43.4 2) 47.3 p=0.23 Continuous lowering of diabetes medication (n) 1) 5 2) NR p=NR	Overall adverse events (%) 1) 100 2) 27.3 Early explant (%) 1) 15.4 2) N/A
Scopinaro 2011[124]	Prospective cohort	1) BPD 2) medical management of T2DM	n=68 1) 30 2) 38	12 months	T2DM diagnosis for at least 3 years Age 35-70 years BMI 25-34.9 HbA1c $\geq$7.5%	Mean age 1) 56.4 2) 59 71% male Mean BMI 1) 30.6 2) 30.2 Mean HbA1c (%) 1) 9.3 2) 8.3	Mean BMI 1) 25.3 (p<0.05) 2) 30.2 (p=NS) Resolution of T2DM 1) 9 (30%) 2) NR Improvement of T2DM (%) 1) 17 2) NR Control of T2DM (n %) 1) 25, 83 2) NR	Conversions 1) 0 2) N/A Early postoperative complications 1) 5 2) N/A Major late postoperative complications 1) 0 2) N/A 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
Skroubis 2011[125]	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 T2DM (%) 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 T2DM (%) 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[126]	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[127]	Prospective cohort	1) RYGB 2) BPD 3) LAGB 4) VSG	n=221 1) 101 2) 49 3) 41 4) 30	1) 19.1 months 2) 27.5 months 3) 21.4 months 4) 16.7 months	1991 NIH criteria	Mean age 1) 44.3 2) 43.9 3) 39.8 4) 41.9 31% male Mean BMI 1) 46.7 2) 53.2 3) 44.3 4) 61.4	Mean BMI 1) 32.5 2) 27.8 3) 39.5 4) 37.2 p<0.001 Mean %EWL 1) 70 2) 84 3) 38 4) 49 p<0.0001	None reported
Takihata 2014[128]	Prospective comparative cohort	1) Intensive lifestyle modification 2) IGB	n=16 1) 8 2) 8	6 months	BMI>35 kg/m2	Mean age 1) 47.4 2) 40.9 Male/female (n) 1) 2/6 2) 5/3 Mean BMI 1) 48.5 2) 45.2	Mean BMI 1) 42.2 2) 41.0 p=0.401 %EWL 1) 25.4 2) 54.2 p=0.248	Nausea/vomiting (n) 1) NR 2) 4

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Tayyem 2011[129]	Prospective comparative cohort	1) IGB 2) LAGB	n=47 1) 17 2) 30	14 months	Adults who fulfilled NICE guidelines for bariatric surgery (BMI>=40 or>=35 with comorbidities; failed weight loss through non-surgical measures)	Mean age 1) 40.9 2) 39.9 %female 1) 65 2) 80 Mean BMI 1) 61.4 2) 50.9	%EWL 1) 26.2 2) 44.0 p=0.004 Decrease in BMI 1) 9.4 2) 11.2 p=0.012 cure or improvement (%) T2DM 1) 67 2) 80 HTN 1) 83 2) 81 p=0.92 Hyperlipidemia 1) 67 2) 82 p=0.61 OSA 1) 50 2) 100 Similar % improvement in QOL across all domains of SF-36 for both groups	Mortality: 0 Nausea/vomiting (n) 1) 4 2) 0

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
te Riele 2008[130]	Retro-spective cohort	1) LAGB 2) RYGB	n=106 1) 53 2) 53	1) 23 months 2) 18 months	1991 NIH criteria	Median age 1) 40.3 2) 38.0 17% male Median BMI 1) 50.9 2) 51.3 Median weight (kg) 1) 147.0 2) 151.0	Median Mean %EWL 1) 43.4 2) 59.9 p<0.001 Median BMI 1) 38.3 2) 34.0 p=NR	Minor complications 1) 5 2) 3 Severe complications 1) 1 2) 9 Reoperations 1) 2 2) 10 No deaths in either group
Viana 2013[131]	Prospective cohort	1) RYGB 2) VSG	n=48 1) 24 2) 24	12 months	21- 59 years old; BMI between 40 and 45 ; history of multiple unsuccessful attempts to reduce weight; female	Mean age 1) 33.8 2) 37.2 Mean weight (kg) 1) 115.1 2) 106. 8 Mean BMI 1) 42.0 2) 42.7	Mean weight (kg) 1) 74.3 2) 74.6 Mean BMI 1) 27.2 2) 69.6 p=NS for all outcomes	None reported

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Vidal 2013[132]	Retro-spective cohort	1) RYGB 2) VSG	n=249 1) 135 2) 114	24 months	1991 NIH criteria Age 18-60 years	Mean age 1) 44.5 2) 44.8 17% male Mean BMI 1) 45.4 2) 44.8 *Major comorbidities (n, %)* Dyslipidemia 1) 79, 58.5 2. 57, 50 Hypertension 1) 50, 37 2) 38, 33.3 Sleep apnea 1) 27, 20 2) 42, 36.8 T2DM 1) 39, 28.8 2) 24, 21	Mean %EWL 1) 66 2) 65 p=NS Mean BMI 1) 30.8 2) 29.2 p=NS *Resolution/ improvement of comorbidities 1 year after surgery (%)* Hypertension 1) 72 2) 71 T2DM 1) 92 2) 95 Dyslipidemia 1) 68 2) 58 OSA 1) 95 2) 90	Reoperations 1) 6 2) 4 p<0.001 Conversions to open 1) 3 2) 2 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
Vilarrasa 2013[133]	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 0% male Mean BMI 1) 46.87 2) 49.06	Mean BMI 1) 30.94 2) 31.46 Mean %EWL 1) 67.51 2) 67.01 p=NS for all between-group comparisons	None reported
Vix 2013[134]	RCT	1) VSG 2) RYGB	n=100 1) 55 2) 45	12 months	BMI ≥40 and ≤60 Age 18-60 years	Mean age 1) 35.13 2) 35.23 18% male Mean BMI 1) 45.57 2) 47.09	Mean %EWL 1) 82.97 2) 80.38 p=NR	None reported

Author/Year	Study Design	Comparators /Intervention	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Weber 2004[135]	Prospective cohort	1) RYGB 2) LAGB	n=206 1) 103 2) 103	24 months	BM I>40 or >35 with comorbidities History of obesity >5 years Failed conservative treatment >2 years Age 18-60 years old	Mean age 1) 40.1 2) 39.6 18% male Mean BMI 1) 47.8 2) 48.0 Excess weight (kg) 1) 72.3 2) 73.0 Hypertension 1) 54 2) 62 T2DM 1) 38 2) 45 Dyslipidemia 1) 75 2) 64	Mean BMI 1) 31.9 2) 36.8 p<0.02 Mean %EWL 1) 54 2) 42 p<0.05 Hypertension 1) 12 2) 18 p=NS T2DM 1) 6 2) 18 p=0.007 Dyslipidemia 1) 35 2) 64 p=0.001	Conversion to open 1) 1 2) 0 Early reoperations 1) 11 2) 1 p=0.003 Late reoperations 1) 4 2) 26 p<0.001 Conversion to RYGB 1) N/A 2) 17 No deaths in either group
Zerrweck 2014[136]	Retro-spective cohort	1) RYGB 2) VSG	n=77 1) 32 2) 45	12 months	BMI 50–59.9	Mean BMI 1) 52.7 2) 53.87 72% male Mean age 1) 35.4 2) 37.5	Mean %EWL 1) 63.9 2) 43.9 p<0.05 Mean BMI 1) 34.8 2) 40.9 p<0.05	Major complications 1) 2 2) 2 Reoperations 1) 0 2) 1 (trocar-site bleeding) 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[137]	Retro-spective cohort	1) LAGB 2) RYGB	n=620 1) 204 2) 416	>5	Not reported	Mean age 1) 36 2) 37 22% male Mean BMI 1) 46 2) 46	Mean %EWL 1) 52.6 2) 79.9 p<0.0001 Mean BAROS 1) 3.71 2) 4.04 p=0.02	Conversion to RYGB 1) 37 2) N/A Mortality 1) 0 2) 2

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[138]	Retro-spective cohort	1) RYGB 2) VSG	n=70 1) 36 2) 34	18 months	BMI>40 or BMI>35 with significant comorbidities Age 18-60 years Supervised and failed diet & exercise program	Mean Age 1) 39.7 2) 38.3 61% male Mean BMI 1) 46.31 2) 50.39	Mean %EWL 1) 77.6 2) 57.1 p=0.003 BMI 1) -16.31 2) -10.21 p<0.05 Resolution of T2DM (%) 1) 85.7 2) 100 Resolution of hypertension (%) 1) 46.7 2) 53.8 Differences in resolution of comorbidities were not significant	Early complications 1) 9 (25%) 2) 3 (8.8%) Late complications 1) 13 (36.1%) 2) 7 (20.6%) Complications were not significantly between groups. Reoperations 1) 3 2) 1 No deaths in either group after 1 year

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Angrisani 2006[139]	Retrospective comparative cohort	1) IGB then LAGB/RYGB/DS 2) IGB alone	n=168 1) 86 2) 82	12 months	Patients intended for bariatric surgery; Retrospectively allocated to 2 groups based on refusal/acceptance of surgery after removal of IGB	Mean age 37.1 % female 59.4 Mean BMI 54.4 kg/m2	Mean BMI after IGB removal 1) 47.6 2) 48.1 p=NS Mean BMI after 1 year 1) 31.8 2) 32.9 p=NS %EWL after IGB removal 1) 35.1 2) 51.7 p=0.001 %EWL after 1 year 1) 69.6 2) 27.1 p=0.001	Not reported

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Batsis 2009[140]	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 T2DM 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 All outcomes p<0.001	Not reported

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Bekheit 2014[141]	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[142]	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[143]	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 T2DM, 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[144]	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 T2DM, 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
Busetto 2004[145]	Case-control	1) IGB (followed by LAGB) 2) LAGB alone (historical cohort)	n=86 1) 43 2) 43	1) 1.1 years 2) 4.4 years p<.001	1) patients who had LAGB following IBG 2) NIH criteria	Age 1) 43.3 2) 42.8 61% male Weight (kg) 1) 171.0 2) 163.4 BMI 1) 58.4 2) 56.9	During IBG: BMI reduction: 9.1 Weight loss (kg): 26.4 %EWL: 26.1 %EWL 6 months after surgery: 1) 33.6 2) 26.1 p<.01 No significant differences in %EWL at any time point thereafter	Intraoperative complications (n, %): 1) 0, 0.0 2) 3, 7.0 p=NS Conversion to open (n, %): 1) 0, 0.0 2) 7, 16.3 p<.05

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Chen 2013[146]	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[147]	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
Christou 2009[148]	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/late complications 1) 74/61 2) 11/24 p=0.86/ p=0.002 Early/late reoperations 1) 32/27 2) 0/23 p=NR/p=NR 3 RYGB deaths
Conason 2013[149]	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[150]	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. Mortality reported
Cozacov 2014[151]	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[152]	Retro-spective cohort	1) RYGB 2) VSG	n=90 1) 60 2) 30	Up to 2 years	T2DM 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 p=NS	None reported
DiGiorgi 2008[153]	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	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[154]	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
Doldi 2002[155]	Prospective cohort	1) IGB + VLCD 2) VLCD	n=73 1) 31 2) 42 (plus a series of 281 patients undergoing IGB	18 months	>40 BMI in preparation for surgery to reduce risk OR 35-40 BMI with comorbidity OR BMI<35 in patients with failed attempts at weight loss OR BMI <30 with a psychological indication in a multidisciplinary treatment program	Age 41.6 (for series of 281 patients) % male 23.5 Weight 1) 128 2) 111.7 BMI 1) 43.9 2) 41	Weight loss after 12 months (IGB removal after 4 months) 1) M: -24kg, F: +4.3 2) M -18.7, F-15.1kg At the 18th month, all patients regained weight and this trend was more evident in group B patients. 1) M: +10kg, F: +1.3kg 2) M: +0.8, F: +3.0 In patients receiving 2 balloons (n=39), weight loss of <7kg was observed after the first balloon in 16.2% of patients and after the second balloon in 46.1%.	Balloon intolerance: 7.7% Gastric ulcer: 0.6% Gastric erosions: 0.3% IGB deflation: 2.4%
Ducarme 2013[156]	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

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Eldar 2012[157]	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%) 3) 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 2012[158]	Retro-spective cohort	1) LAGB 2) RYGB	n=36 (42) 1) 19 (22) 2) 17 (20) Patients (preg-nancies)	18 months	Women who became pregnant after surgery	Mean age 1) 30.4 2) 31.2 Mean BMI (before surgery) 1) 42.7 2) 50.5 BMI at conception 1) 33.9 2) 32.9 BMI after pregnancy 1) 36.9 2) 35.1 Weight at conception 1) 92.7 2) 87.5 Weight after pregnancy 1) 101.2 2) 93.7	Gestational age (weeks) 1) 38.7 2) 38.9 Birth weight (g, total) 1) 3224.8 2) 2983.5 Pregnancy-induced hypertension 1) 1 2) 0 Preterm labor 1) 3 2) 1 No differences in pregnancy outcomes were statistically significant.	Complications 1) 2 2) 4 No reoperations No deaths reported

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Fenske 2013[159]	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 p=NS	None reported
Fredheim 2013[160]	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[161]	Retro-spective cohort	1) RYGB 2) VSG 3) LAGB	n=2199 1) 1327 2) 619 3) 253	17 months	None reported	Mean age 1) 46.3 2) 46.1 3) 48.1 47% male Mean BMI 1) 48.1 2) 44.2 3) 42.2	Mean change in BMI 1) -14.8 2) -11.2 3) -5.6 1 vs. 2 OR 1 & 2 vs. 3, p<0.01	Reoperations 1) 88 (0 conversions) 2) 11 (5 conversions) 3) 26 (10 conversions)
Friedrich 2013[162]	Prospective cohort	1) VSG 2) multi-disciplinary intervention program (MIP)	n=54 1) 27 2) 27	12 months	Aged 18-65 BMI >30	Mean Age 1) 45.4 2) 45.3 Mean weight (kg) 1) 149.2 2) 132.9 26% male Mean BMI 1) 51.7 2) 44.8 Hypertension 1) 67% 2) 63% T2DM 1) 41% 2) 7%	Mean %EWL 1) 64.5% 2) 38.3% p<0.001 Mean weight loss (kg) 1) 48.8 2) 21.7 p=NS BMI 1) -16.6 2) -7.2 p=NS Prevalence HTN 1) 38% 2) 44% p=NS Prevalence T2DM 1) 4% 2) 7% 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
Gan 2007[163]	Prospective cohort	1) LAGB 2) VSG 3) RYGB	n=72 1) 9 2) 11 3) 20	13 months	HbA1c >6%	Mean BMI 1) 45.6 2) 52.8 3) 43.5 43% male Mean HbA1c 1) 8.9 2) 8.0 3) 8.0	% patients not taking T2DM medications 1) 17% 2) 33% 3) 69% 2 & 3 vs. 1, p<0.0001 Mean %EWL 1) 34.2 2) 35.9 3) 66.2 1 vs. 2, p=NS 3 vs. 1 & 2, p<0.001	Major complications 1) 0 2) 1 3) 2 No deaths in any group
Gersin 2010[164]	RCT	1) DJBL 2) sham procedure	n=47 1) 21 2) 26	12 weeks	Age 18-55 BMI 40-60 OR <35 with 1 or more comorbidities Patients failing on nonsurgical weight loss	Age 44 19% male BMI 46 Weight 131	Results presented for completers %EWL 1) 11.9 2) 2.7 p<.001 At least 10% %EWL 1) 62 2) 17 p=.01 % weight loss 1) 5.8 2) 1.5 p=.002	Early removal of DJBL: 7 (3 due to GI bleeding, 2/3 were SAEs)

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Gothberg 2014[165]	Prospective cohort	1) adolescent RYGB 2) conventional care 3) adult RYGB	n=243 1) 81 2) 81 3) 81	2 years	Aged 13-18 years BMI >40 or >35 with comorbidities	Mean age 1) 15.6 2) 15.8 3) 39.7 35% male Mean BMI 1) 45.5 2) 42.0 3) 42	Mean weight loss (%) 1) 32 2) -3 3) 31 p=NR No significant differences in weight loss between genders.	Surgical complications were comparable to the adult group, but only reported in detail for adolescents. No postoperative mortality
Gracia-Solanas 2011[166]	Retro-spective cohort	1) BPD- S (Scopinaro) 2) BPD - M (modified) 3) RYGB	n=437 1) 150 2) 115 3) 152	7 years	Not reported	Mean age 1) 39.9 2) 44.8 3) 42.2 24% male Mean BMI 1) 52.7 2) 52.8 3) 44.7	Mean BMI @ 5 years 1) 26.9 2) 28.9 3) 31.5 Mean %EWL @ 5 years 1) 85% 2) 76% 3) 68% Hypertension resolution @ midpoint 1&2) 87% 3) 70% Dyslipidemia resolution @ midpoint 1&2) 100% 3) 70%	Mortality (<30 days) 1&2) 3/265 (1.1%) 3) 1/152 (0.7%) Early complications (<30 days) 1&2) 75/265 (28.3%) 3) 45/152 (29.6%) p=NS Iron deficiency (>30 days) 1) 62% 2) 40% 3) 32.9% p=0.05 Reoperations 1) 8 (3.2%) 2) 0 (0.0%) 3) 1 (0.8%)

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Hofso 2010[167]	Prospective cohort	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. T2DM 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[168]	Prospective cohort	1) RYGB 2) VSG	n=153 1) 98 3) 55	35.4 months	T2DM ≥6 months Patients were considered for surgery based on current guidelines	Mean age 50.6 38% male Mean BMI 46.5 Mean T2DM duration (years) 5.9 HbA1c 7.5% Mean waist circumference 133.5	No T2DM resolution (%) 1) 31.4 2) 20.4 p=NS T2DM reoccurrence (%) 1) 10.31 2) 16.2 p=NS Mean %EWL 1) 65.4 2) 61.2 p=NS	None reported
Jimenez 2015[169]	Retro-spective cohort	1) RYGB 2) VSG	n=232 1) 121 2) 111	48.7 months	T2DM 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 T2DM remission (%) 1) 80.2 2) 65.8 p=0.013 T2DM 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[170]	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[171]	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[172]	RCT	1) RYGB 2) VSG	n=37 1) 19 2) 18	12 months	BMI ≥35 w/T2DM 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 BMI change 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
Khoo 2014[173]	Prospective cohort	1) T2DM support and education (DSE) 2) RYGB	n=61 1) 31 2) 30	12 months	T2DM diagnosis BMI ≥40 or BMI ≥35 w/comorbidities 18-60 years	Mean age 1) 47.4 2) 49.6 33% male Mean weight 1) 114.3 2) 120.1 Mean BMI 1) 40.1 2) 43.4 Mean HbA1c (%) 1) 7.51 2) 7.53 Mean waist circumference 1) 122.7 2) 130.3	Mean weight loss (kg) 1) 0.6 2) 33.6 BMI 1) 0.3 2) -12.2 Waist circumference 1) -1.0 2) -26.6 HbA1c 1) 0.4 2) -1.2 All p<0.001	No postoperative complications in surgery group Mortality not reported

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Korner 2009[174]	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[175]	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: 0

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Lee 2012a[176]	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 T2DM 1) 3/3 2) 0/0 p=NR Resolution of dyslipidemia 1) 2/2 2) 1/2 p=NR	Revisions 1) 0 2) 2
Lee 2012b[177]	RCT	1) IGB 2) Sham Both groups also received step 1 American Heart Association diet plus exercise	n=18 1) 8 2) 10	6 months	Age 21-65; histologic evidence of NASH; BMI≥27; failed at least 6 months of medical therapy for weight loss	Median age 1) 43 2) 47 % male 1) 37.5 2) 80.0 Median BMI 1) 30.3 2) 32.4	Mean BMI 1) 28.7 (p=0.12) 2) 31.6 (p=0.022) Change in median BMI 1) -1.52 2) -0.8 p=0.0008 NAFD activity score 1) 2 2) 4 p=0.03	NR

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Leeman 2013[178]	Prospective comparative cohort	1) IGB 2) Weight management program After 6 months, members of both groups received LAGB, VSG, or RYGB	n=28 1) 15 2) 13	2 years	eligible for bariatric surgery; BMI>55 or weight>200 kg; part of preoperative structured weight management program	Median age 1) 48 2) 40 % female 1) 67 2) 69	Mean %EWL at 2 years 1) 33.6 2) 52.5 p=0.11 Median %EWL at 6 months 1) 17.1 2) 16.1 p=0.295	Early balloon removal (n) 1) 3 2) N/A
Lennerz 2014[179]	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[180]	Retro-spective cohort	1) RYGB 2) routine medical management (RMM)	n=267 1) 152 2) 115	2 years	Complete follow-up at 2 annual visits BMI ≥35 and T2DM	Mean age 1) 51.4 2) 53.1 37% male Mean BMI 1) 47.4 2) 40.7 LDL 1) 93.1 2) 97.4 SBP 1) 138 2) 132	Mean %EWL 1) 61.6 2) -1.6 p<0.01 Mean weight loss (%) 1) 31.4 2) +.7 p<0.01 Mean change in LDL (mm/dl) 1) -10.2 (p<0.05) 2) -6.9 (p=NS) Mean change in SBP 1) -14.1 (p<0.01) 2) -2.5 (p=NS)	Adverse events/Re-admissions/ED visits (related to surgery) 21/82/36 No mortality within 90 days
Li 2009[181]	Retro-spective cohort	1) RYGB 2) VSG	n=548 1) 496 2) 52	1) 27 months 2) 17 months	Not reported	Mean age 1) 42.9 2) 40.5 25% male Mean BMI 1) 48.5 2) 43.0	Weight loss >24% 1) 79.4 2) 13 p=NS	Incidence of complicated gallstones (%) 1) 1.8 2) 1.9 p=NS Symptomatic gallstones (%) 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
Mathus-Vliegen 2014[182]	RCT	1) IGB then IGB 2) Sham then IGB All patients who achieved weight loss goal after initial 3 months proceeded with study	n=40 1) 19 2) 21	26 weeks	Age >=18; 3-month stable BMI of at least 32; failure to lose weight within a supervised WL program; absence of gastrointestinal lesions; large hiatal hernia and previous bariatric surgery	Mean age 41.5 % female 90 Mean BMI 43.1	Mean weight change (%) 1) -14.2 2) -15.8 p=NR Mean BMI change 1) -6.1 2) -6.5 p=NR	NR
Mathus-Vliegen 2002[183]	RCT	1) IGB then IGB 2) Sham then IGB All patients who achieved weight loss goal after initial 3 months proceeded with study	n=43 1) 23 2) 20	2 years	At least age 18 and BMI of at least 32	Age 41.1 16% male Weight 1) 125.9 2) 124.0 BMI 1) 43.0 2) 43.6	Weight after 13 weeks 1) 111.0 2) 114.7 p=NS BMI after 13 weeks 1) 38.4 2) 39.8 p=NS 52-week % WL 1) 21.7 (95% CI, 16.24-27.16) 2) 19.61 (95% CI, 6.21-22.94) 65-week % WL 1) 17.5 (95% CI, 11.63-23.43) 2) 17.5 (95% CI, 13.93-21.14)	There was a significant negative influence of the balloon on total reflux time at week 52 (r=0.78, p=0.000, adjusted r2=0.58).

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Matsuo 2013[184]	Prospective cohort	1) RYGB 2) LI 3) Healthy normal weight control	n=29 1) 5 2) 10 3) 14	1) 12 months 2) 6 months	Age 12-19	Mean age (year) 1) 16.5 2) 13.2 3) 14.3 38% male Mean BMI (kg/m2) 1) 59.2 2) 34.9 3) 19.1 Mean weight (kg) 1) 180.3 2) 92.7 3) 53.5	Mean weight (kg) 1) 105.6 (p<0.05) 2) 79.8 (p<0.05) Mean BMI (kg/m2) 1) 34.8 (p<0.05) 2) 29.4 (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
Miranda 2013[185]	Retro-spective cohort	1) RYGB 2) nutrition clinic management	n=19 1) 13 2) 6	1) 4.2 years 2) 2.4 years	Patients with heart failure BMI >35 Age >18 years	Mean age 1) 62 2) 69 31% male Mean BMI 1) 55 2) 42 Mean weight (kg) 1) 146 2) 132 Hypertension 1) 12 2) 6 Dyslipidemia 1) 11 2) 5 T2DM 1) 10 2) 2 Smoker 1) 4 2) 2 QoL scores 1) 3 2) 4.5	Mean weight loss (kg) 1) 47 (p<0.001) 2) -8 (p<0.001) Mean change in BMI 1) -15 (p<0.001) 2) +5 (p<0.001) Hypertension 1) 13 2) 6 Dyslipidemia 1) 8 2) 6 T2DM 1) 6 2) 3 p=0.049 Smoker 1) 1 2) 0 QoL scores 1) 7 (p=0.001) 2) 6 (p=NS) p=0.06	None reported

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Mognol 2005[186]	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-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Mohos 2011[187]	Retro-spective cohort	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 T2DM 1) 9/10 (90%) 2) 7/13 (55%) Resolution of hypertension 1) 14/19 (73%) 2) 10/23 (43%) Resolution of GERD 1) 22/24 (92%) 2) 6/24 (25%) 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[188]	Retro-spective cohort	1) RYBG 2) VSG 3) LAGB	n=586 1) 367 2) 115 3) 104	1) 15 months 2) 11.6 months 3) 18.6 months	NIH 1991 criteria	Mean age 1) 42.6 2) 43.7 3) 45.8 24% male Mean BMI 1) 47.1 2) 46.0 3) 41.5	Mean %EWL 1) 67.3% 2) 59.9% 3) 31.2% p<0.01	Symptomatic cholelithiasis 1) 21 (5.7%) 2) 7 (6.1%) 3) 0.0 (0.0%) 1 vs. 2, p=NS 3 vs. 1 and 2, p=0.02 Cholecystectomy in first year after surgery 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[189]	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 both 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[190]	Retro-spective cohort	1) BPD/DS 2) VSG 3) RYGB	n=130 1) 42 2) 40 3) 48	2 years	Not reported	Mean age 1) 38 2) 46 3) 45 12% male Mean BMI 1) 52 2) 43 3) 44 ReynoBPD Risk Score (for cardiovascular risk) 1) 4.7 2) 3.9 3) 3.8	Weight loss (kg) 1) 21 2) 12 3) 16 BMI (%) 1) -42 2) -27 3) -35 1 vs. 2 and 3, p<0.01 BPD had a significantly greater reduction in cardiovascular risk scores compared to VSG or RYGB (p=0.005)	RR score 1) -2.7 2) -1.9 3) -1.4 1 vs. 2 and 3, 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[191]	Retro-spective cohort	1) RYGB 2) LAGB	n=1295 1) 609 2) 686	1) 2 years 2) 1.6 years	Per recommendations 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) T2DM 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[192]	Prospective cohort	1) T2DM RYGB 2) T2DM Diet WL 3) Non-T2DM 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 T2DM 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
Omana 2010[193]	Retro-spective cohort	1) VSG 2) LAGB	n=123 1) 49 2) 74	1) 15 2) 17 months	Not reported	Mean age 1) 45 2) 41 Mean BMI 1) 52 2) 44 Mean weight (kg) 1) 144.0 2) 122.7 Mean EBW (kg) 1) 81.8 2) 59	Mean weight (kg) 1) 104.6 2) 101.1 p=NS Mean weight loss (kg) 1) 39.2 2) 22.5 p<0.01 Mean change in BMI 1) -14.2 2) -8.0 p<0.01 Mean %EWL (%) 1) 50.6 2) 40.3 p=0.03	No mortality or major complications related to procedures Minor complications (%) 1) 12 2) 15

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Palikhe 2014[194]	RCT	1) VSG 2) IMT	n=31 1) 14 2) 17	12.5 months	20-75 years old; BMI≥27.5 kg/m2; T2DM	Mean age 1) 47 2) 52 Mean BMI 1) 40.5 2) 35.8 26% male Mean weight (kg) 1) 99.5 2) 90.4	Change in weight (kg) 1) -28.0 2) -8.6 p<0.001 Change in BMI 1) -11.3 2) -3.3 p<0.001 Mean %EWL (%) 1) 61.2 2) 27.4 p<0.001 %EWL 1) 27.9 2) 9.4 p<0.001 Resolution of T2DM (%) 1) 36 2) 0 p=0.007 Resolution of hypertension (%) 1) 29 2) 0	Major complication (esophageal perforation) 1) 2 2) 0 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
Parikh 2014[195]	RCT	1) LAGB 2) LSG 3) RYGB 4) Medical weight management (MWM)	n=56 1) 5 2) 16 3) 7 4) 28	6 months	T2DM; 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 T2DM 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[196]	Retro-spective cohort	1) LAGB 2) VSG 3) RYGB	n=81 1) 20 2) 24 3) 23	24 months	Patients with T2DM diagnosis matched with obese patients without T2DM for age, sex, BMI, and surgery type	Mean age 45.7 Mean BMI 48	T2DM 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 T2DM	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[197]	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 T2DM 1) 8/29 2) 19/26 Mean age 1) 45.2 2) 45.9	Mean weight (kg) 1) 98 2) 123 p<0.001 Mean BMI 1) 34.6 2) 42.6 p<0.001 T2DM 1) 2/29 2) 1/26 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
Roslin 2012[198]	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) 1) 105.5 2) 98.2 3) 97.2 Mean HbA1c (%) 1) 6.8 2) 5.8 3) 6.1	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) 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)	None reported
Rodriguez 2009[199]	RCT	1) DJBL 2) Sham	n=18 1) 12 2) 6	24 weeks	Age 18-55 BMI 30-50 T2DM<10 years; HbA1c 7-10%	Mean age 47 % female 61 Mean BMI 38.9	Mean weight change at week 20 (kg) 1) -10.2 2) -7.1 p=NR	Device-related AE (n) 1) 12 2) N/A Device explant from AE (n) 1) 3 2) N/A

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Roslin 2014[200]	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[201]	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[202]	Retro-spective cohort	1) Vertical banded gastroplasty-RYGB (results not reported here) 2) RYGB 3) LAGB	n=2,823 1) 776 2) 1,185 3) 862	30 days	Not reported	Median age 42 25 % male Median BMI 2) 46 3) 44	Readmissions within 30 days 2) 86 3) 27 p=NR	Overall complications 2) 39 3) 10
Serrot 2011[203]	Retro-spective cohort	1) RYGB 2) Medical management for T2DM	n=34 1) 17 2) 17	12 months	BMI <35 1991 NIH criteria	Median age (year) 1) 56.0 2) 62.0 Median BMI (kg/m2) 1) 34.6 2) 34.0 Median weight (lb) 1) 214 2) 237 Female (n) 1) 13 2) 6	Median BMI 1) 25.8 2) 34.3 p<0.001 Median weight (lb) 1) 157 2) 233 p<0.001 Mean %EWL (%) 1) 70 2) -4 p<0.001 Resolution of T2DM 1) 11/17 2) 0	Readmission rate (%) 1) 18 2) 0 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
Spivak 2012[204]	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[205]	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[206]	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
Tarnoff 2009[207]	RCT	1) DJBL 2) VLCD	n=39 1) 25 2) 14	12 weeks	Age 18-55; BMI 40-60 or >=35 with comorbidities; history of failure with nonsurgical WL; candidate for RYGB	Mean age 1) 38 2) 43 Male/female (n) 1) 10/15 2) 6/8 Mean BMI 1) 42 2) 40	%EWL at 12 weeks 1) 22.1 2) 5.3 p=0.02 % Participants with >=10%WL 1) 92 2) 21 p=0.0001 Improvement in diabetes (reduction in medication n/total) 1) 3/4 2) 1/1	Early removal of device (n) 1) 5 2) N/A Multiple implantation attempts (n) 1) 5 2) N/A Overall participants with >=1 AE (n) 1) 16 2) 0 Severe events (n) 1) 5 2) 0

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Tedesco 2013[208]	Retro-spective cohort	1) LAGB with history of substance abuse 2) LAGB with no history of substance abuse 3) VSG with history of substance abuse 4) VSG with no history of substance abuse 5) RYGB with history of substance abuse 6) 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[209]	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[210]	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 ≥50 VSG selectively indicated according to the ASMBS position statement RYGB for patients with BMI ≥40 but ≤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[211]	Retro-spective cohort	1) RYGB 2) BPD	n=180 1) 97 2) 83	Mean (months) 1) 46 2) 44.3 Results reported for 3 years	BMI ≥50	Mean age 1) 41.0 2) 38.3 23% male Mean BMI 1) 54.6 2) 55.5 Prevalence of comorbidities OSA 1) 41 2) 11 T2DM 1) 16 2) 16 Hypertension 1) 30 2) 17	Mean %EWL 1) 63.7 2) 84.0 p<0.00001 Mean BMI 1) 35.9 2) 29.8 Remission of OSA (%) 1) 89 2) 90 p=NS Remission of T2DM (%) 1) 92.3 2) 86.6 p=NS Hypertension suspension of medication (%) 1) 66.6 2) 77.7 p=0.0039	Revisions 1) 13 2) 5 Reoperation 1) 2 2) 7 (all due to leaks) Complications 1) 12 2) 23 p=0.0095 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
Tsoli 2013[212]	Prospective cohort	1) BPD (open) 2) VSG	n=24 1) 12 2) 12	12 months	T2DM 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[213]	Prospective cohort	1) VSG 2) RYGB	n=85 1) 35 2) 50	4 months	T2DM 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 T2DM 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[214]	Prospective cohort	1) VSG 2) RYGB	n=91 1) 39 2) 52	12 months	T2DM diagnosis Metabolic syndrome diagnosis Caucasian T2DM 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 T2DM resolution 1) 33 2) 44 Metabolic syndrome resolution (%) 1) 62.2 2) 67.3 p=NS for all outcomes	None reported
Von Mach 2004[215]	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	Mean BMI 1) 30.5 (c) 2) 34.0 (c) 3) 41.4 (a, b) Mean weight loss (%) 1) -28.6 (p<0.01) 2) -16.0 (p<0.01) 3) 0.5 (p=NS) a: p<0.05 compared to (1); b: p<0.05 compared to (2); c: p<0.05 compared to (3)	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[216]	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 T2DM 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 2) 38	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

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Weiner 2013[217]	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
Widhalm 2011[218]	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 p=NR	Revision to RYGB 1) 4 2) 0 No adverse effects Mortality reported

Author/Year	Study Design	Comparators /Interventions	# of Patients	Mean/Median Time to Follow-up	Entry Criteria	Baseline Characteristics	Main Outcomes	Harms
Woel-nerhanssen 2011[219]	RCT	1) RYGB 2) VSG	n=23 1) 12 2) 11	12 months	No diagnosis of T2DM 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	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[220]	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 T2DM 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
Woodard 2010[221]	Prospective cohort	1) RYGB 2) LAGB	n=838 1) 765 2) 73	12 months	None reported	Mean age 1) 43.8 2) 46.6 37% male Mean BMI 1) 47.4 2) 44.4	Mean %EWL 1) 78 2) 47.6 p<0.05 Mean BMI 1) 31.4 2) 35.3 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
Yong 2012[222]	Prospective cohort	1) RYGB 2) exenatide therapy	n=23 1) 13 2) 10	6 months	BMI >32 T2DM diagnosis for less than 10 years	Median age 1) 42.2 2) 45.9 30% male	Mean %EWL 1) 57.3 2) 23.8 p<0.01 Abdominal girth loss (cm) 1) 15.3 2) 10.1 p<0.05 Mean BMI 1) 32 2) 36 p<0.05 Mean EBMIL (%) 1) 57 2) 24 p<0.01	None reported
Yousseif 2014[223]	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[224]	Prospective cohort	1) VSG 2) RYGB	n=558 1) 200 2) 358	12 months	1991 NIH criteria	Mean age 1) 44.2 2) 47.5 24% male Mean BMI 1) 47.9 2) 46.1 OSA (%) 1) 34 2) 25.1 GERD (%) 1) 13 2) 13.7 Hyperlipidemia (%) 1) 25.5 2) 27.1 Hypertension (%) 1) 52 2) 52.5 T2DM (%) 1) 28 2) 31.8 Musculoskeletal disease (%) 1) 20 2) 18.7	Mean %EWL (%) 1) 30.7 2) 33.4 P=NS OSA (%) 1) 3.26 2) 4.15 p=0.338 GERD (%) 1) 13.2 2) 7.3 p<0.001 Hyperlipidemia (%) 1) 11.1 2) 12 p=NS Hypertension (%) 1) 37.8 2) 25.8 p=NS T2DM (%) 1) 13.5 2) 10.4 p=NS Musculoskeletal disease (%) 1) 5.62 2) 3.7 p=NS	None reported

Appendix C: Patient and Programmatic Factors Associated with the Effectiveness and Safety of Bariatric Surgery

Table C1: Patient and Programmatic Factors Associated with Success

Author, Year	Procedure	No. Patients	Duration follow-up	Factors Associated with Success	Statistical Technique
Alami, 2007[225]	RYGB	61	12 months	• Pre-operative weight loss decreases operating time and short term EWL	Chi-square; Multiple linear regression
Becouarn, 2010[226]	RYGB or LAGB or VSG	539	4 years	• Pre-operative weight loss not associated with post-operative weight loss	Logistic regression
Birkmeyer, 2010[227]	LAGB vs. VSG vs. RYGB	15,275	30 days	• High surgeon • High hospital volume	Logistic regression
Bueter, 2007[228]	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[9]	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[229]	RYGB	200	12 months	• Female • Surgeon experience • Team approach	Logistic regression
Chevallier, 2007[230]	LAGB	1,238	2 years	• Younger age • Lower baseline BMI • Physical activity • Eating habits • High surgeon volume	Logistic regression
Compher, 2012[231]	RYGB	60	2 years	• Male • Attend post-operative office visits • Younger age • Lower baseline BMI	Mixed effects model
Courcoulas, 2003[232]	RYGB	4,685	3 years	• High surgeon • High hospital volume	MIXED procedure; linear

					model with binary outcomes
Dallal, 2009[233]	RYGB	1,168	3 years	• Higher initial weight • Male	Student's t-test; mixed-effects
Elakkary, 2006[234]	LAGB	38	12 months	• Post-operative support groups	T-test
Gould, 2011[235]	RYGB or LAGB	32,509	3 years	• High hospital volume	Random/fixed effects
Harnisch, 2008[236]	RYGB	1,629	2 years	• Pre-operative weight gain/loss not differentially associated with perioperative complications or EWL	Not specified
Huerta, 2008[237]	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[238]	RYGB	324	12 months	• No pre-operative dietary counseling	ANOVA; Fisher's exact test; chi-square
Leahey, 2009[239]	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
Lier, 2011[240]	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[241]	RYGB	141	12 months	• Pre-surgical counselling not associated with treatment adherence to lifestyle changes	ANOVA; Contingency table analysis
Lutfi, 2006[242]	RYGB	180	12 months	• Baseline BMI<50 • Single marital status	Logistic regression
Ma, 2006[243]	RYGB	494	12 months	• Younger age • Lower baseline weight • Male • Non-T2DM	Linear regression
Masoomi, 2011[244]	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[245]	RYGB	495	12 months	Predictors of suboptimal weight loss:	Logistic regression

				• Greater BMI • T2DM • Male	
Murr, 2007[246]	RYGB	19,174	5 years	• Younger age • Female • Low surgeon/hospital volume	Logistic regression
Nguyen, 2004[247]	RYGB	24,166	3 years	• High volume hospitals	Pearson chi-square; ANOVA
Nguyen, 2011[248]	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[249]	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[250]	RYGB or LAGB or gastroplasty	105,287	8 years	*In-hospital mortality:* • Male • RYGB • Medicare insurance • T2DM • Age>60 years	Logistic regression
Nijamkin, 2012[251]	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[252]	RYGB	144	12 months	• Post-operative behavior change education • Post-operative nutrition counselling	T-tests; regression; intention to treat
Ortega, 2012[112]	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[253]	RYGB or LAGB or vertical banded gastroplasty	46	25 months	• Attended post-operative support group	Mann-Whitney; Fisher's exact test
Padwal, 2013[254]	Not specified	15,394	10 years	*All-cause mortality predictors:* • T2DM • Current smoker • Male	Logistic regression
Parikh, 2012[255]	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[256]	RYGB	188	12 months	*EWL:* • Non-T2DM *Complication predictors:* • Less surgeon experience • Sleep apnea • Hypertension	Logistic regression
Pontiroli, 2007[257]	LAGB	172	4 years	• BMI • Compliance • Attendance post-op appointments	Stepwise regression
Ray, 2003[258]	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[259]	RYGB	200	92 weeks	• Male • Baseline cognitive restraint • Dietary adherence	Mixed model
Sarwer, 2012[260]	RYGB or LAGB	84	2 years	• Post-operative dietary counseling/Change in eating behavior	Repeated measures mixed effects
Shen, 2004[261]	LAGB vs. RYGB	301	12 months	• Attendance to follow-up visits after LAGB	Student's t-test; Pearson's correlation
Smith, 2013[262]	RYGB	3,410	30 days	• High-volume surgeons	Kruskal-Wallis test; Jonckheere-Terpstra trend test; relative risk; log linear regression
Sockalingam, 2013[263]	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[264]	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[265]	RYGB or VSG	39	6 weeks	• Post-operative acceptance and commitment therapy	ANOVA
Weller, 2007[266]	RYGB or gastroplasty	7,868	30 days	• High surgeon volume • High hospital volume	Logistic regression

Wittgrove, 2000[267]	RYGB	500	5 years	• Non-T2DM	None

Table C2: Summary of Studies that Assess Bariatric Surgery Center Accreditation

Author Year	Description of Study	Results
Birkmeyer 2010[227]	Retrospective analysis of 15,275 patients using data from the Michigan Bariatric Surgery Collaborative's prospective clinical registry from 2006-2009. Multilevel regression models were used to assess variation in risk-adjusted complication rates across hospitals and the effects of procedure volume and accreditation status.	Serious complications: • Accredited: 2.7% (95% CI: 2.5%-3.1%) • Non-accredited: 2.0% (95% CI: 1.5%-2.4%); p=0.41

Dimick 2013[268]	Retrospective analysis of 273,252 Medicare and non-Medicare patients using hospital discharge data from 2004-2009.
	
	A difference-in-differences approach was used to evaluate whether the 2006 CMS decision restricting bariatric surgery to accredited hospitals was associated with improved outcomes in Medicare patients above and beyond existing time trends.
		Overall complications:
		• After vs. before NCD: 8.0% vs. 7.0%
		  ○ RR: 1.14 (95% CI: 0.95-1.33)
		• Accredited vs. non-accredited: 5.5% vs. 6.0%
		  ○ RR: 0.98 (95% CI: 0.90-1.06)
		Serious complications:
		• After vs. before NCD: 3.3% vs 3.6%
		  ○ RR: 0.92 (95% CI: 0.62-1.22)
		• Accredited vs. non-accredited: 2.2% vs 2.5%
		  ○ RR: 0.92 (95% CI: 0.84-1.00)

Flum 2011[269]	A cohort study of 47,030 patients using CMS data from 2004-2008 to determine the impact of the 2006 NCD. Logistic regression models were used with interrupted time-series to account for changes independent of other temporal trends.	Impact of NCD on 90-day mortality: • 0.21% (p=0.18)
Jafari 2013[270]	Retrospective analysis of the 2006-2010 Nationwide Inpatient Sample (n=277,766). Multivariate analysis was performed to examine risk-adjusted serious morbidity and in-hospital mortality between the low- and high-volume centers.	In-hospital mortality for unaccredited centers: • OR: 3.57 (95% CI: 1.49-8.33) Mortality of accredited centers alone (high volume vs. low volume): • 0.22% vs. 0.17% Serious morbidity for unaccredited centers: • OR: 0.84 (95% CI: 0.71-0.98)
Kohn 2010[271]	Analysis of 102,069 bariatric operations using the 1998-2006 Nationwide Inpatient Sample. Logistic regression was employed using generalized estimating equations and assuming a binomial distribution of the data.	(ORs relative to non-accredited facilities) Any complication: • ASMBS-accredited OR: 0.93 (95% CI: 0.81-1.08; p=0.36) • ACS-accredited OR: 0.85 (95% CI: 0.70-1.03; p=0.09) Mortality: • ASMBS-accredited: OR: 0.77 (95% CI: 0.53-1.12; p=0.18) • ACS-accredited: OR: 0.93 (95% CI: 0.59-1.46; p=0.75)

Author Year	Description of Study	Results
Kwon 2013[272]	Retrospective cohort study of 30,755 non-Medicare patients between 2003-2009 using the MarketScan Commercial Claims and Encounter Database. A difference-in-differences approach was used to determine the impact of the 2006 NCD.	Impact of NCD on inpatient mortality: • -0.04% (p=0.1) Impact of NCD on 90-day complication rates: • -2.7% (p=0.01)
Livingston 2009[273]	Analysis of the 2005 National Inpatient Survey to compare outcomes at accredited and non-accredited programs (n=253).	In-hospital mortality: • Accredited OR: 1.76 (95% CI: 0.73-4.26); p=0.21 Morbidity: • Accredited OR: 1.00 (95% CI: 0.87-1.15); p=0.97
Morton 2014[274]	Analysis of the 2010 Nationwide Inpatient Sample to compare accredited with non-accredited hospitals (n=145). Multivariate, multilevel, mixed-effects logistic regression analyses with hospital clustering adjustment to control for potential confounders.	Any in-hospital complication: • Unaccredited OR: 1.09 (95% CI: 1.03-1.16); p=0.005 Incidence of any complication: • 12.3% in unaccredited vs. 11.3% in accredited hospitals; p=0.001 Mortality: • 0.13% in unaccredited vs. 0.07% in accredited hospitals; p=0.019

Nguyen 2010[275]	Analysis of 6,264 Medicare and Medicaid patients using the University Health System Consortium database from October 1, 2004, through September 31, 2007.
	
	Differences in patient characteristics, complications, 30-day readmission rates, and observed in-hospital mortality between groups were analyzed with Pearson χ^2 tests.
		Overall complications:
		• 12.2% before NCD vs. 10.0% after NCD; p<0.05
		  ○ OR: 1.24 (95% CI: 1.06-1.45)
		In-hospital mortality:
		• 0.3% before NCD vs. 0.2% after NCD; p=NS
		  ○ OR: 1.44 (95% CI: 0.57-4.05)

Nguyen 2012[276]	Analysis of 35,284 patients using the 2007-2009 University Health System Consortium database.
	
	Mortality and overall complications were compared at the patient level by relative risks using binomial regression with a log link function and robust standard errors.
		In-hospital mortality:
		• 0.06% in accredited vs. 0.21% in unaccredited hospitals; p=0.003
		  ○ RR: 3.5 (95% CI: 1.5-8.0)
		Overall complications:
		• 2.3% in accredited vs. 2.2% in unaccredited hospitals; p=0.75
		  ○ RR 0.96 (95% CI: 0.77-1.20)

Telem 2015[277]	Retrospective analysis using data from the 2004-2010 New York Statewide Planning and Research Cooperative longitudinal administrative database (n=47,342). Outcomes were analyzed with and without temporal correlation to accreditation year using multivariable logistic regression analysis. Mortality was analyzed using a multiple cox proportional hazard model.	Major complications: • Accredited OR: 0.72 (range 0.63-0.83); p<0.001 Mortality (>30 days): • HR: 0.93 (range 0.76-1.13); p=0.45

Appendix D: Treatment Success with Medication or Lifestyle Management

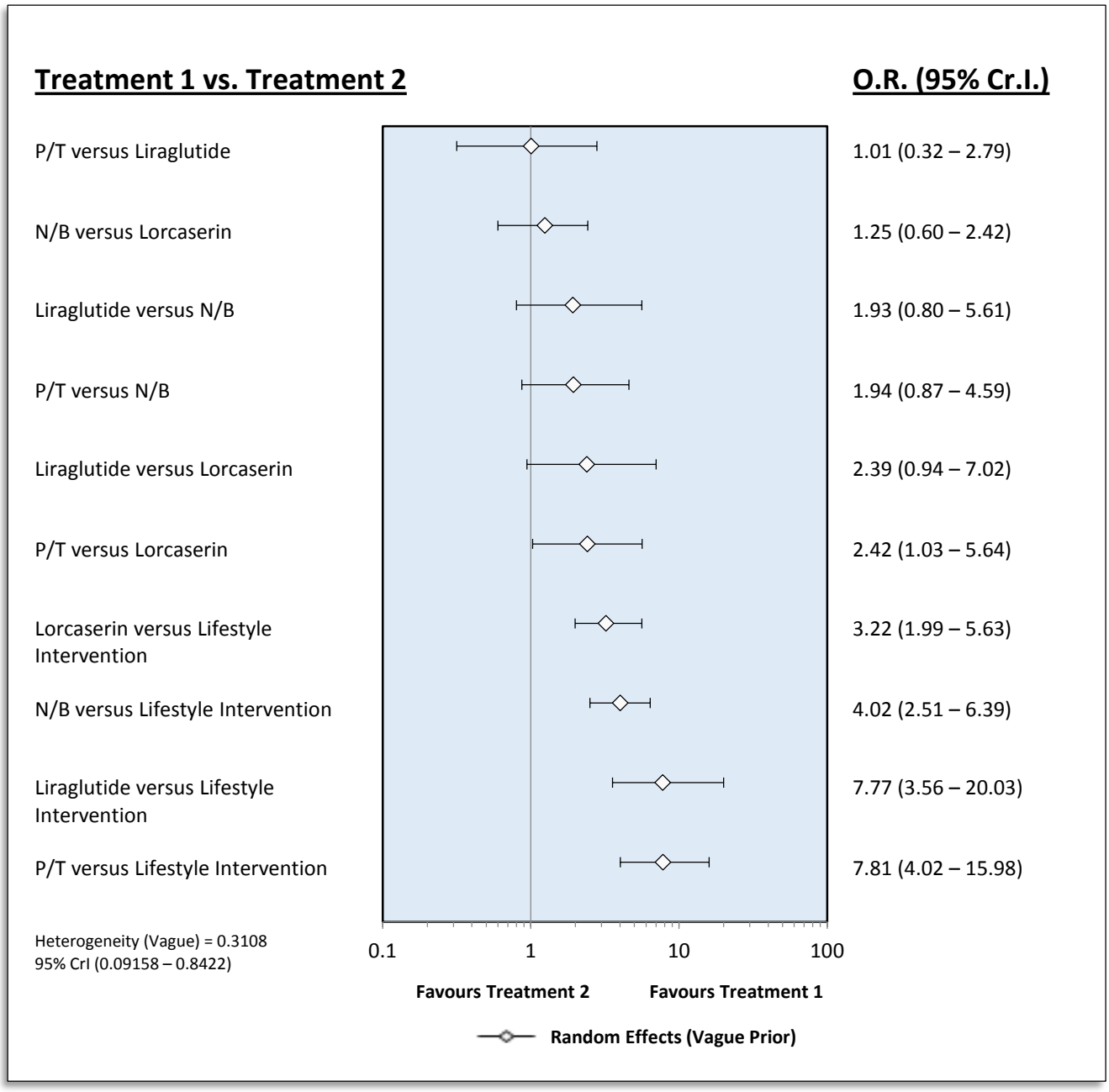
Methods

We conducted a Bayesian network meta-analysis to compare weight loss success with each drug of interest (defined as the proportion of patients achieving 10% or more total weight loss). Data were extracted from the peer-reviewed studies included in our sample and analyzed using WinBUGS software (MRC Biostatistics Unit, Cambridge, UK) via an Excel-based interface (NetMetaXL, Ottawa, Canada).[27]>

We used a random-effects model with vague priors, as this approach is commonly understood to be appropriate when generalizations are to be made from larger and more diverse groups of studies and patients, or when there is heterogeneity across studies' methods and researchers; such models incorporate the most conservative assumptions around study characteristics.[279,280] Our decision to report results based on the random-effects model is supported by comparison of diagnostic statistics, which suggest a slightly better goodness-of-fit than that of a fixed effect model.

Results

Figure D1. Network Meta-Analysis of Achievement of 10% Total Weight Loss



Appendix E: Evidence Tables for Harms of Bariatric Surgery & Medication

Table E1. Study details of good- and fair-quality RCTs and prospective comparative cohorts evaluating harms of bariatric surgery.

Study	Procedure	# of Patients	# of Complications	Median Complication Rate	# of Reoperations	Median Reoperation Rate	Total # of Deaths
Hedberg 2012[23]	BPD	23	4	17.39%	3	13.04%	0
Mingrone 2012[32]	BPD	19	6	31.58%	1	5.26%	0
Nanni 2012[106]	BPD	30	5	16.67%	NR	NR	0
Risstad 2015*[42]	BPD	29	43	148.28%	7	24.14%	0
Scopinaro 2011[124]	BPD	30	5	16.67%	NR	NR	0
Søvik 2010[50]	BPD	29	23	79.31%	1	3.45%	0
Søvik 2011*[51]	BPD	29	10	34.48%	6	20.69%	0
TOTAL	**BPD**	**29**	**6**	**31.58%**	**3**	**13.04**	**0**
Angrisani 2007[1]	LAGB	27	4	14.81%	4	14.81%	0
Angrisani 2013*[58]	LAGB	22	3	13.64%	5	22.73%	0
Bowne 2006[7]	LAGB	46	54	117.39%	15	32.61%	1
Brunault 2011[63]	LAGB	102	NR	NR	20	19.61%	NR
Cottam 2006[66]	LAGB	181	NR	NR	43	23.76%	0
Courcoulas 2014[10]	LAGB	24	6	25.00%	1	4.17%	0
Dixon 2008[11]	LAGB	30	6	20.00%	3	10.00%	NR
Dixon 2012[12]	LAGB	30	1	3.33%	1	3.33%	0
Himpens 2006[85]	LAGB	40	16	40.00%	9	22.50%	NR
Hutter 2011[86]	LAGB	12193	175	1.44%	112	0.92%	10
Nguyen 2009[108]	LAGB	111	15	13.51%	11	9.91%	0
O'Brien 2006[33]	LAGB	39	7	17.95%	5	12.82%	NR
O'Brien 2013[35]	LAGB	57	31	54.39%	17	29.82%	0
Weber 2004[135]	LAGB	103	63	61.17%	27	26.21%	0
TOTAL	**LAGB**	**43**	**6.5**	**17.95%**	**7**	**14.81%**	**11**

Study	Procedure	Total # of Patients	# of Complications	Median Complication Rate	# of Reoperations	Median Reoperation Rate	Total # of Deaths
Angrisani 2007[58]	RYGB	24	4	16.67%	3	12.50%	0
Angrisani 2013*[58]	RYGB	21	3	14.29%	3	14.29%	0
Benaiges 2011[61]	RYGB	95	16	16.84%	NR	NR	0
Bowne 2006[7]	RYGB	40	19	47.50%	13	32.50%	0
Cottam 2006[66]	RYGB	181	NR	NR	25	13.81%	0
Courcoulas 2014[10]	RYGB	22	1	4.55%	0	0.00%	0
Hedberg 2012[23]	RYGB	24	3	12.50%	2	8.33%	1
Helmio 2012[84]	RYGB	117	31	26.50%	4	3.42%	0
Hutter 2011[86]	RYGB	14491	1005	6.94%	778	5.37%	59
Ikramuddin 2013[25]	RYGB	60	22	36.67%	6	10.00%	0
Kashyap 2013[91]	RYGB	20	NR	NR	NR	NR	0
Kehagias 2011[92]	RYGB	30	20	66.67%	1	3.33%	0
Laferrere 2008[96]	RYGB	9	0	0.00%	NR	NR	NR
Leyba 2011[98]	RYGB	75	0	0.00%	NR	NR	0
Liang 2013[30]	RYGB	31	6	19.35%	0	0.00%	0
Mingrone 2012[104]	RYGB	19	3	15.79%	1	5.26%	0
Nanni 2012[106]	RYGB	20	1	5.00%	NR	NR	0
Nguyen 2009[108]	RYGB	111	50	45.05%	14	12.61%	0
Paluszkiewics 2012[114]	RYGB	36	28	77.78%	1	2.78%	0
Peterli 2013[118]	RYGB	110	19	17.27%	0	0.00%	1
Risstad 2015*[42]	RYGB	31	10	32.26%	1	3.23%	1
Schauer 2012[45]	RYGB	50	11	22.00%	3	6.00%	0
Schauer 2014*[46]	RYGB	48	16	33.33%	0	0.00%	0
Søvik 2010[50]	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*[51]	RYGB	31	6	19.35%	1	3.23%	0
Weber 2004[135]	RYGB	103	35	33.98%	11	10.68%	0
TOTAL	**RYGB**	**34**	**13**	**19.35%**	**3**	**6.00%**	**62**
Benaiges 2011[61]	VSG	45	4	8.89%	NR	NR	0
Brunault 2011[63]	VSG	29	8	27.59%	5	17.24%	NR
Helmio 2012[84]	VSG	1221	16	1.31%	3	0.25%	0
Himpens 2006[85]	VSG	40	9	22.50%	4	10.00%	NR
Hutter 2011[86]	VSG	944	53	5.61%	28	2.97%	2
Kashyap 2013[91]	VSG	20	NR	NR	NR	NR	0
Kehagias 2011[92]	VSG	30	23	76.67%	1	3.33%	0
Leyba 2012[98]	VSG	42	4	9.52%	NR	NR	0
Paluszkiewics 2012[114]	VSG	36	29	80.56%	0	0.00%	0
Peterli 2013[118]	VSG	107	9	8.41%	0	0.00%	0
Schauer 2012[45]	VSG	50	4	8.00%	1	2.00%	0
Schauer 2014*[46]	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 E2. Study details of case series evaluating harms of bariatric surgery.

Author/Year	Intervention	# of Patients	Study Follow-up (years)	Patient Characteristics	Complications	Reoperations	Mortality
Cossu 2007[281]	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[282]	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

Author/Year	Intervention	# of Patients	Study Follow-up (years)	Patient Characteristics	Complications	Reoperations	Mortality
Busetto 2014[283]	LAGB	318	Mean: 12.7	Mean age 38.6 18% male Mean BMI 46.7	148 total 12 conversions to open surgery 136 band-related complications 136	116 total (patients) - some patients required more than 1 redo surgery - primarily due to band-related complications	Overall: 15/318
Chevallier 2004[284]	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 total 78 related to band slippage 22 related to port problems	Overall: 0
Jenkins 2006[285]	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[286]	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 7 re-bandings)	Overall: 0
Owers 2013[287]	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

Author/Year	Intervention	# of Patients	Study Follow-up (years)	Patient Characteristics	Complications	Reoperations	Mortality
Phillips 2009[288]	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[289]	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
Edholm 2013[290]	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[291]	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[292]	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

Methods

We conducted a Bayesian network meta-analysis to compare discontinuation from adverse events with each drug of interest. Data were extracted from the peer-reviewed studies included in our sample and analyzed using WinBUGS software (MRC Biostatistics Unit, Cambridge, UK) via an Excel-based interface (NetMetaXL, Ottawa, Canada).[278]

We used a random-effects model with vague priors, as this approach is commonly understood to be appropriate when generalizations are to be made from larger and more diverse groups of studies and patients, or when there is heterogeneity across studies' methods and researchers; such models incorporate the most conservative assumptions around study characteristics.[279,280] Our decision to report results based on the random-effects model is supported by comparison of diagnostic statistics, which suggest a slightly better goodness-of-fit than that of a fixed effect model.

Results

Figure E1. Network Meta-Analysis of Discontinuation from Adverse Events: Medications and Lifestyle Management

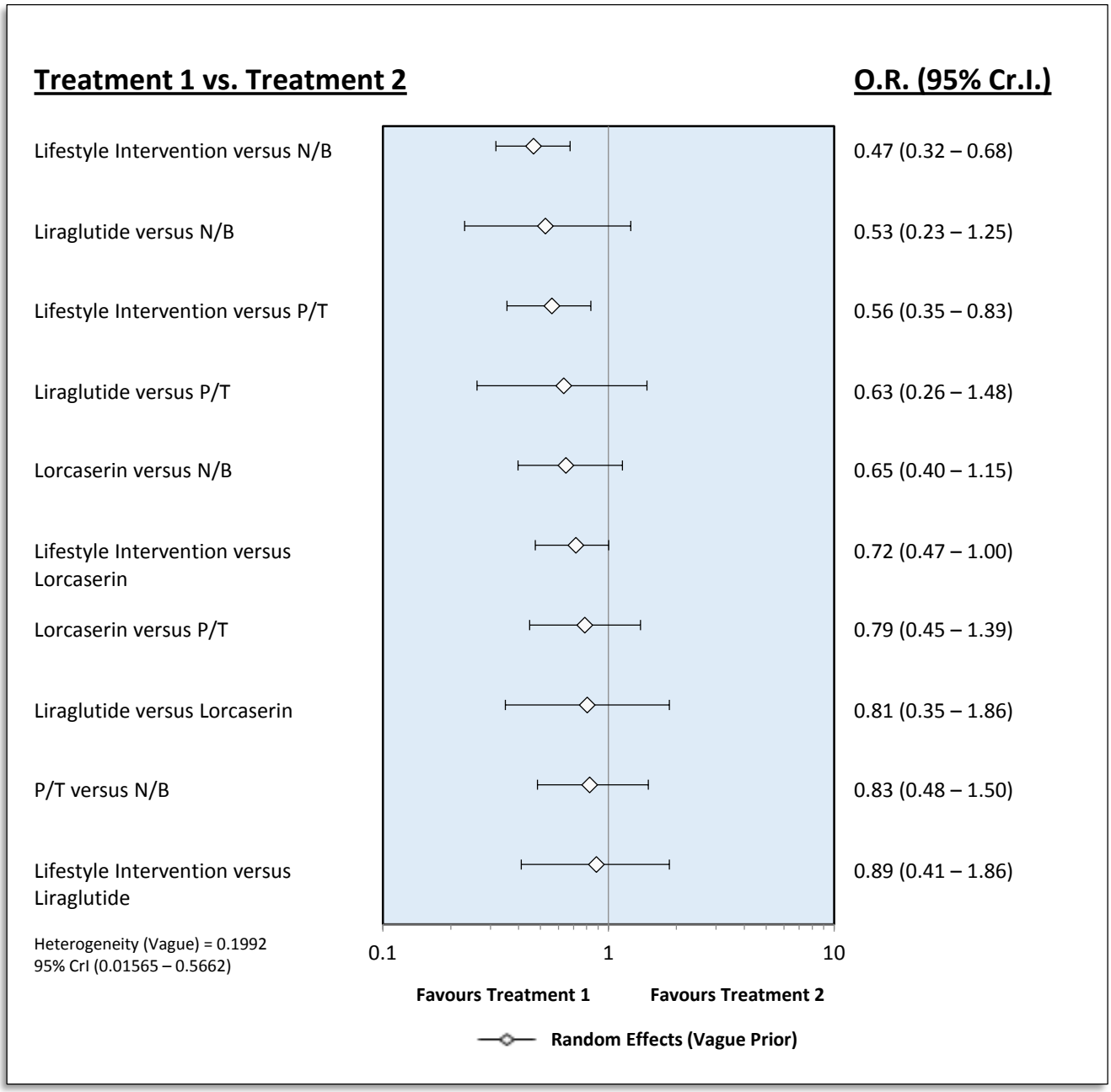


Table E3. Harms associated with liraglutide.

Study	No. liraglutide / total sample	% female; mean age; mean BMI	Follow-up	Overall Adverse Events	Discontinuation from Adverse Events
Astrup 2012[4]	93/564	76.0; 45.9; 34.7	20 weeks (+84 week extension with crossover)	95.7%	7.5%
Pi-Sunyer 2015[38]	2,487/3,731	78.5; 45.1; 38.3	56 weeks (+12 week partial crossover)	80.3%	9.9%
Wadden 2013[53]	212/422	81.5; 46.2; 35.6	56 weeks	91.5%	8.5%

Table E4. Harms associated with Lorcaserin.

Study	No. lorcaserin (10 mg BID)/total sample	% female; mean age; mean BMI	Follow-up	Overall Adverse Events	Discontinuation from Adverse Events
Fidler 2011[13]	1,602/4,004	79.8; 43.8; 36.2	52 weeks	82.6%	7.2%
Martin 2011 [31]	29/57	68.5; 48.7; 35.6	56 days	NR	0
O'Neil 2012[36]	256/603	54.6; 52.7; 36.0	52 weeks	NR	8.6%
Smith 2010[49]	1,595/3,182	84.5; 44.1; 36.2	52 weeks	NR	7.1%
Smith 2009[48]	116/469	87%; 41.5; 36.4	12 weeks	NR	4.3%
NR=not reported					

Table E5. Harms associated with Naltrexone/Bupropion.

Study	No. NB/total sample	% female; mean age; mean BMI	Follow-up	Overall Adverse Events	Discontinuation from Adverse Events
Apovian 2013[293]	1,001/1,496	84.6; 44.4; 36.2	56 weeks	85.9%	24.3%
Greenway 2010[22]	583/1,742	85; 44.2; 36.2	56 weeks	83.1%	19.5%
Hollander 2013[24]	265/424	53.6; 53.9; 36.5	56 weeks	90.4%	29.3%
Wadden 2011[52]	591/793	90.5; 45.8; 36.7	56 weeks	NR	25.4%
NR=not reported					

Table E6. Harms associated with Phentermine/Topiramate.

Study	No. P/T / total sample	% female; mean age; mean BMI	Follow-up	Dose	Overall Adverse Events	Discontinuation from Adverse Event
Allison 2012[294]	512/1,267	83.0; 42.6; 42.2	56 weeks	15/92	NR	16.0%
Aronne 2013[2]	107/567	79.0; 44.7; 36.2	28 weeks	7.5/46	NR	15.1%
Gadde 2011[15]	498/2,487	70.0; 51.1; 36.5	56 weeks	7.5/46	NR	12.0%
Garvey 2014a[294]	75/130	69.0; 49.6; 35.4	28 weeks	15/92	94.7%	1.3%
Winslow 2012[54]	22/45	47.0; 52.4; 35.7	28 weeks	15/92	90.9	9.1%
NR=not reported						

Appendix F: Economic Modeling

Table F1. Relative risk of mortality by age and BMI.

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 F2. Change in health related quality of life as assessed by EQ-5D for each BMI assuming a 30% reduction in BMI.

BMI (kg/m^2)				
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 F3. Cost-effectiveness of bariatric procedures by procedure and 5 year time horizon for BMI≥30.

BMI Level/ Procedure	Cost ($)	Effectiveness (QALYs)	Cost-effectiveness	
			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.

Table F4. Cost-effectiveness of bariatric procedures by procedure and 25 year time horizon for BMI≥30.

BMI Level/ Procedure	Cost ($)	Effectiveness (QALYs)	Cost-effectiveness	
			Vs. 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

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

Table F5. Proportion of patients in alive state with co-morbidities: diabetes, hyperlipidemia, and hypertension [295].

BMI (kg/m^2)				
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%

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

Table F6. 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.

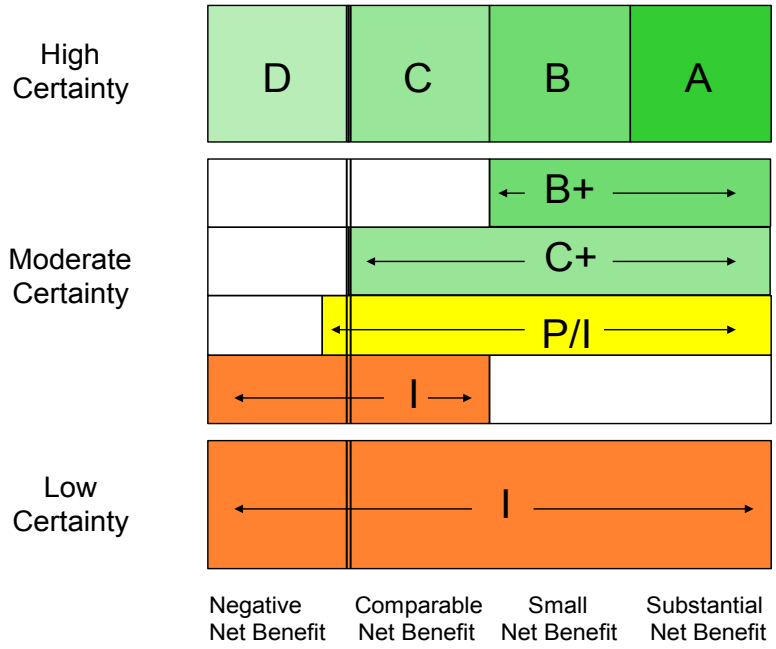
Appendix G: ICER Evidence Matrix

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 (http://www.npcnow.org/issue/cer-collaborative-initiative). 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

1. **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, **I**ntervention, **C**omparator(s), and **O**utcomes of interest. Depending on the comparison, it is often helpful to also define the specific **T**ime Horizon and **S**etting 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.

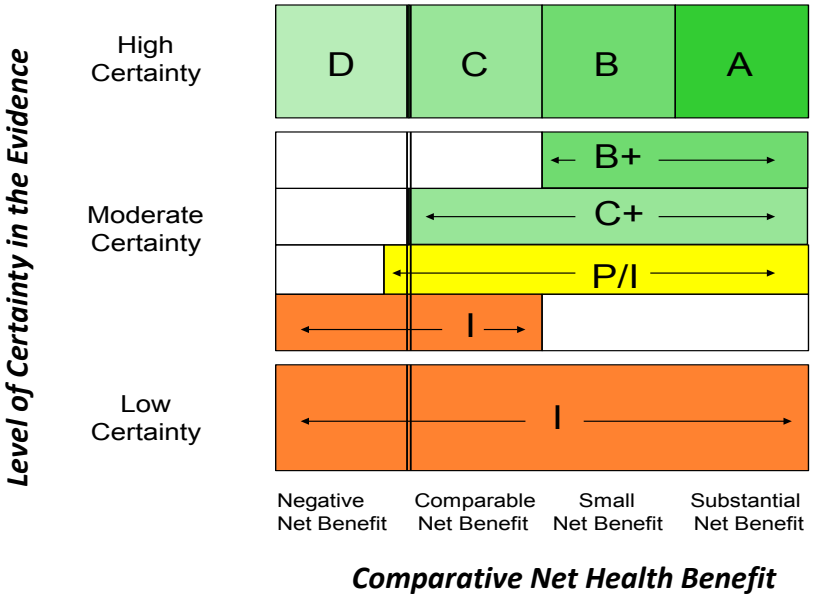
4. **Assign a joint rating in the Evidence Rating Matrix.** The final step is the assignment of the joint rating of magnitude of comparative net health benefit and level of certainty. As shown again in the figure on the following page, when your certainty is **"high,"** the estimate of net benefit is 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 *or* 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, *or* 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) *any* 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



Appendix H: Head-to-Head Comparisons of Surgical Procedures

Gastric Bypass vs. Sleeve Gastrectomy

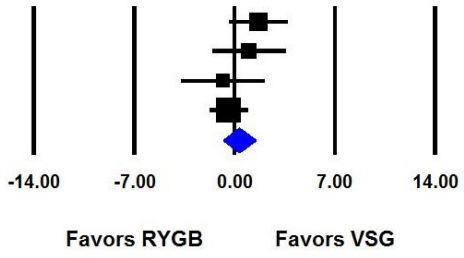
We identified a total of six RCTs and six prospective comparative cohort studies that met our criteria for good or fair quality, involved comparisons of RYGB to VSG, and had at least 12 months of follow-up. An additional RCT described previously compared both RYGB and VSG to nonsurgical management.[45] Characteristics of these studies and main results can be found in Appendix B.

Impact on Measures of Body Weight

Across all seven RCTs of interest,[41,45,92,114,117,118,134] reductions in BMI (11-15 points on average, irrespective of baseline values) and other measures of body weight change from baseline were substantial for both RYGB and VSG, but did not differ statistically in *any* of these studies. We conducted a meta-analysis of mean BMI at study end among those RCTs reporting these values along with appropriate measures of variance and drew similar conclusions (mean difference 0.30, 95% CI -0.83, 1.42) (see Figure G1 below). Similarly, no statistical differences were observed in any of the prospective cohort studies. One cohort of 136 patients (mean age 42, 72% female, mean BMI 45) reported a percentage of excess BMI loss of 76% for RYGB at 2 years vs. 63% for VSG, but this difference was not tested statistically.[79]

Figure H1. Meta-analysis of mean BMI at study end: RYGB vs. VSG

Study name	Difference in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Kehegias 2011	1.700	1.033	1.067	-0.325	3.725	1.646	0.100
Paluszkiewicz 2012	1.000	1.297	1.681	-1.541	3.541	0.771	0.441
Peterli 2012	-0.800	1.470	2.160	-3.681	2.081	-0.544	0.586
Schauer 2012	-0.400	0.674	0.454	-1.721	0.921	-0.594	0.553
	0.296	0.574	0.329	-0.828	1.421	0.517	0.605



Heterogeneity: Tau^2= 0.28; Q=3.7; df=3; I^2=20%

Test for overall effect: Z=0.52 (p=0.605)

Impact on Resolution of Comorbidities

Resolution of comorbidities was assessed as a binary variable in a total of four studies comparing RYGB to VSG.[61,62,114,118] Heterogeneity in study designs and patient populations precluded meta-analysis of these studies. As with body weight measures, comorbidity resolution was substantial for both types of surgery and did not statistically differ between groups for nearly all comparisons. In a cohort comparison of 140 patients (mean age 45, 82% female, mean BMI 46) who were followed for 12 months,[61] resolution of hypertension did not differ between groups, but resolution of hyperlipidemia did (100% vs. 75% for RYGB and VSG respectively, p=0.014). An RCT of 217 patients (mean age 43, 72% female, mean BMI 44)[118] found no statistical differences in one-year resolution of hypertension, dyslipidemia, diabetes, sleep apnea, back or joint pain, hyperuricemia (excess uric acid in blood), or depression between groups. A statistical difference was noted for resolution of gastroesophageal reflux disease (GERD), however (23% vs. 14% for RYGB vs. VSG, p=0.008).

Impact on Other Outcomes

Limited data were available from RCTs and prospective cohort studies on the comparative impact of RYGB vs. VSG on other key outcomes. In the Benaiges study of 140 patients,[61] a 40-50% reduction in cardiovascular risk was observed using two scoring mechanisms with both procedures, but no significant differences were found between groups. In the previously-mentioned cohort study of 136 patients,[79] a specific focus was placed on nutritional deficiencies following surgery. At a mean of two years of follow-up, significantly fewer patients undergoing VSG developed incident deficiencies in vitamin B_{12} (18% vs. 58% for RYGB, p<0.0001), and vitamin D (32% vs. 52%, p=0.02) as well as secondary hyperparathyroidism (14% vs. 33%, p=0.02).

Retrospective Cohort Studies

We identified 11 retrospective cohort studies of good- or fair-quality that compared outcomes for RYGB and VSG patients and had at least 12 months of follow-up.[9,69,95,99,109,112,125,132,133,136,296] No statistically-significant differences were found in any key measure of clinical benefit in nine of the 11 studies. One of these studies involved a matched comparison of nearly 9,000 patients receiving VSG, RYGB, or LAGB in a voluntary state registry in Michigan (mean age 46, 74% female, mean BMI 48).[9] In the pairwise comparison of RYGB to VSG, the former was found to result in statistically-significantly greater excess weight loss, greater resolution of type 2 diabetes and dyslipidemia, and improved quality of life and patient satisfaction at three years versus VSG. The other study was a single-center evaluation of 77 "super-obese" (BMI 50-59.9 kg/m^2) patients who were followed for one year.[136] The percentage of excess weight lost at one year was significantly higher in the RYGB group (64% vs. 44% for VSG, p<0.05).

Gastric Bypass vs. Gastric Banding

We identified three RCT reports and four prospective comparative cohort studies of good- or fair-quality that evaluated outcomes for RYGB and LAGB over a minimum of 12 months of follow-up. Details of each study and main results can be found in Appendix B. Of note, two of the RCT reports related to five- and 10-year follow-up from a single RCT (Angrisani 2007; Angrisani 2013).[1,58] Differences in study design and the outcomes measured precluded formal meta-analysis of outcomes in this comparison set; study findings are nonetheless summarized descriptively below.

Impact on Measures of Body Weight

Angrisani and colleagues randomized 51 patients (mean age 34, 82% female, mean BMI 44) to receive RYGB or LAGB in a single-center evaluation in which patients were followed for five years;[58] one of the 27 LAGB patients was lost to follow-up during this period. At five years, mean BMI was statistically-significantly lower for RYGB relative to LAGB (29.8 vs. 34.9, p<0.001), while the percentage of excess weight loss was significantly greater for RYGB (67% vs. 48%, p<0.001). At 10 years, a total of 5/27 LAGB (19%) and 3/24 (13%) RYGB patients were lost to follow-up. Among remaining patients, BMI was essentially unchanged in the RYGB group (30.0 vs. 29.8 at five years), while BMI increased somewhat in the LAGB group (36.0 vs. 34.9 at five years). Excess weight loss remained in favor of RYGB (69% vs. 46% for LAGB, p=0.03).

The other RCT was a fair-quality evaluation of 111 RYGB and 86 LAGB patients (mean age 43, 77% female, mean BMI 47) who were followed for a mean of 4.2 years at a single bariatric surgical clinic.[108] Treatment groups were imbalanced because a greater number of LAGB patients could not obtain insurance approval for surgery. Excess weight loss was statistically-significantly higher in the RYGB group (68.4% vs. 45.4%, p<0.05). In addition, treatment failure, defined as conversion to another procedure because of failure to lose weight or <20% excess weight loss, occurred in 17% of LAGB patients and zero RYGB patients (not statistically tested).

Similar findings were observed in the five prospective cohort comparisons.[7,66,121,135] The largest of these examined 1,733 individuals (1,102 and 631 for RYGB and LAGB respectively) (mean age 44, 85% female, mean BMI 50) at a single large institution, and followed patients for two years.[121] Excess weight loss was statistically-significantly greater for RYGB at two years (75% vs. 44% for LAGB, p<0.0001), and RYGB patients achieved >40% excess weight loss more quickly than their LAGB counterparts.

Impact on Resolution of Comorbidities

Resolution of comorbidities was assessed in binary fashion in one of the RCTs and three cohort studies. Five-year data from the Angrisani RCT[58] indicated that diabetes, hyperlipidemia, and sleep

apnea had resolved in the four patients with these conditions at baseline, regardless of surgical assignment. The only measured comorbidity that remained unresolved was hypertension in three LAGB patients at baseline.

Results were somewhat mixed in the cohort studies. In an evaluation of 106 individuals (mean age 43, 80% female, mean BMI 56) followed for a median of 16 months,[7] RYGB was associated with significantly greater resolution of sleep apnea (88% vs. 39%, p=0.01), but no statistical differences in resolution of diabetes, hypertension, dyslipidemia, asthma, or arthritis. In contrast, a matched evaluation of 362 patients (mean age 43, 84% female, mean BMI 47) followed for up to three years found statistically greater levels of resolution of diabetes, hyperlipidemia, and hypertension among those receiving RYGB.[66] Finally, another matched comparison of 206 patients (mean age 40, 79% female, mean BMI 48) showed statistically greater resolution of type 2 diabetes and dyslipidemia among RYGB patients, but no statistical difference in hypertension.

Impact on Other Outcomes

Limited data were available on the comparative impact of RYGB vs. LAGB with regard to other outcomes. The previously-mentioned Bowne cohort study of 106 patients[7] measured patient satisfaction using a 4-point rating system, and found that 80% of RYGB patients reported that they were very satisfied with the procedure vs. 45% receiving LAGB (p=0.006). The Nguyen RCT evaluated the impact of surgery on health-related quality of life using the SF-36;[108] while some differences in certain domains were noted at earlier timepoints, no statistically-significant differences were noted in individual domains or summary scores by 12 months of follow-up.

Retrospective Cohort Studies

Comparisons of RYGB to LAGB were performed in 13 retrospective cohort studies following patients for at least one year.[3,8,9,16,89,93,95,105,115,116,119,122,130,137] Details of these studies can be found in Appendix B. Findings mirrored those of available RCTs and prospective cohort studies in all but one of these retrospective evaluations. In an evaluation of 590 patients treated at a single center (mean age 41, 80% female, mean BMI 47), differences in excess weight loss at 12 months were similar to that reported in other studies (65% vs. 39%, p<0.001).[16] By 18 months, however, differences had narrowed (63% vs. 55%) and were no longer statistically significant. No data were provided on attrition of the study sample from 12 to 18 months.

Gastric Bypass vs. Biliopancreatic Diversion (With or Without Duodenal Switch)

We identified five reports on three RCTs[23,42,50,51,111] and one prospective cohort study[106] directly comparing RYGB with BPD, with or without DS, of good- or fair-quality, and with follow-up of at least 12 months. Details of each study and major findings are provided in Appendix B.

Impact on Measures of Body Weight

In the three available RCTs, there was consistent and statistically-significantly greater reductions in measures of body weight with BPD/DS relative to RYGB, with mean reductions of 6-8.5 BMI points in all three studies. Unfortunately, appropriate measures of variance were available in only two of these RCTs, so meta-analyses were not conducted. Findings were similar for the prospective cohort study,[106] but could not be included in a meta-analysis because of a lack of hypothesis testing of body-weight measures.

The durability of procedure performance was examined in the three reports of the Søvik RCT. In the 2010 Søvik study, 60 super-obese patients (mean age 35, 70% female, mean BMI 55) were randomized to RYGB or BPD/DS and followed for two years. Mean BMI at 12 months was statistically-significantly lower in the BPD/DS group (32.5 vs. 38.5 for RYGB, $p<0.001$). At 24 months of follow-up, BMI continued to decline in both groups but the magnitude of differences was similar (30.1 vs. 37.5, $p<0.001$).[51] Significant differences in body weight and excess BMI lost were noted in both reports. After five years of follow-up, with a 92% retention rate, the mean BMI for the BPD/DS group remained significantly lower than for the RYGB group (33.1 vs. 41.2 respectively, $p<0.001$), but weight regain (9-10 kg) was comparable for the two groups.[42]

Impact on Resolution of Comorbidities

Information on resolution of comorbidities in this comparison set was extremely limited. In an RCT of 47 super-obese patients (mean age 39, 47% female, mean BMI 54) who were followed for up to four years,[23] the percentage of patients achieving an HbA1c level <5% was reported to be 100% in the BPD/DS group vs. 82% in the RYGB group, although this was not statistically tested. In another small RCT of 30 super-obese patients (mean age 35, 67% female, mean BMI 55) who were followed for two years,[111] the presence of sleep apnea was self-reported by one patient in the BPD/DS group, but this was not tested statistically, nor was it compared to baseline prevalence. Long-term follow-up of the Søvik study in the super-obese (see above) yielded no statistically-significant differences in remission of type 2 diabetes or metabolic syndrome.[42]

Impact on Other Outcomes

Limited data were available from RCTs and prospective cohort studies on the comparative impact of RYGB versus BPD/DS on other outcomes. A single report of an RCT[42] included outcomes on health-related quality of life and nutritional deficiencies after five years of follow-up. Although there were statistically-significant improvements from baseline in domain-specific scores of the SF-36 as well as in the Obesity-related Problems Scale, there were no statistical differences between surgery groups. The rate of newly-diagnosed nutritional deficiencies also did not statistically differ.

Retrospective Cohort Studies

We identified five retrospective cohort studies that met our quality criteria and followed patients for at least 12 months.[73,107,116,120,125] Findings with respect to weight-loss measures were similar to those seen in the prospective evaluations. One evaluation provided more detailed information on comorbidity resolution than presented in prospective studies. This was an analysis of data from a large multicenter registry database, comparing 1,545 BPD/DS patients with a control group of 77,406 undergoing RYGB.[107] Demographics were similar between the two groups (mean age 45, 78% female), but mean BMI was significantly higher in the BPD/DS group (52 vs. 48, p<0.001). Nonetheless, the pre-operative prevalence of hypertension and dyslipidemia was similar in the two groups, and these were resolved to a significantly greater extent by BPD/DS (58% vs. 47% for hypertension and 68% vs. 44% for dyslipidemia, p<0.001 for both comparisons).

Other Surgical Comparisons

Data were limited for other surgical comparisons. We identified a single RCT and single prospective cohort study that met quality and follow-up criteria and involved comparisons other than those described above.[63,85] Both were comparisons of LAGB to VSG. In the RCT, 80 patients (mean age 38, 80% female, mean BMI 38) were randomized to LAGB or VSG and followed for three years.[85] VSG was associated with a statistically-significantly greater percentage of excess weight lost (66% vs. 48% for LAGB, p=0.0025), as well as statistically-significantly greater changes in BMI (median of -27.5 vs. -18, p=0.0004) and body weight (-29.5 vs. -17, p<0.0001). Findings were less dramatic after one year of follow-up in a prospective cohort of 131 patients (mean age 40, 82% female, mean BMI 50),[63] but still favored VSG for excess weight loss (44% vs. 35%, p=0.02) as well as significant improvement on the psychosocial domain of the Quality of Life, Obesity, and Dietetics (QOLOD) rating scale.

Surgical comparisons were varied and heterogeneous in retrospective cohort comparisons. They are available for review in Appendix B.

Appendix I. Public and Representative Private Insurer Coverage Policies

Medicare and Medicaid

Centers for Medicare & Medicaid Services (CMS)

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=5&DocID=100.1&SearchType=Advanced&bc=IAAAAAgAAAAAAA%3d%3d&
http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=38&ncdver=3&DocID=40.5&SearchType=Advanced&bc=IAAAAAgAAAAAAA%3d%3d&
http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33362&ContrId=360&ver=13&ContrVer=1&Date=01%2f01%2f2015&DocID=L33362&SearchType=Advanced&bc=KAAAAAgAAAAAAA%3d%3d&

CMS covers open and laparoscopic RYGB, open and laparoscopic BPD with DS, and LAGB for Medicare beneficiaries who have a BMI ≥ 35 kg/m^2, one or more obesity-related comorbidities (including T2DM), and who have failed prior medical treatment for obesity. Medicare does not cover open AGB, open VSG, or gastric balloon. CMS permits regional Medicare Administrative Contractors (MACs) to determine coverage for laparoscopic VSG based on a determination that "the available evidence does not broadly or clearly distinguish" the patients who may benefit. The MAC with jurisdiction over California, Noridian Healthcare Solutions, permits coverage for laparoscopic VSG if the above three criteria are met but notes that the failure of medication management alone is insufficient to fulfill the prior treatment failure requirement.

In a separate national coverage determination or NCD (40.5), CMS specifies that non-surgical interventions to treat obesity are not covered unless they are essential to the treatment of another medical condition such as hypothyroidism, Cushing's disease, and hypothalamic lesions. Medicare allows Part D plans to determine coverage for weight-loss drugs.

Medi-Cal, California Department of Health Care Services (DHCS)

http://files.medi-cal.ca.gov/pubsdoco/manuals_menu.asp Choose "General Medicine", then "Surgery: Digestive System"
http://www.dhcs.ca.gov/services/Pages/FormularyFile.aspx

Medi-Cal covers RYGB, LAGB, BPD with DS, and VSG for patients with a BMI >40 kg/m^2 or a BMI >35 kg/m^2 and severe comorbidity including life-threatening cardiovascular or pulmonary disease, sleep apnea, uncontrolled diabetes mellitus, or neurological or musculoskeletal problems likely to improve following surgical treatment. All patients must have failed prior attempts to lose weight through conservative methods (i.e., severe obesity for five or more years despite six months of participation in a diet and/or exercise program).

The Medi-Cal formulary does not include liraglutide, lorcaserin, N/B, and P/T.

Representative National Private Insurer Policies

Aetna

http://www.aetna.com/cpb/medical/data/100_199/0157.html
http://www.aetna.com/cpb/medical/data/1_99/0039.html

Aetna covers open and laparoscopic RYGB, VSG, BPD with or without DS, and LAGB for adults with a BMI >40 kg/m^2 or a BMI >35 kg/m^2 with a severe comorbidity such as clinically significant obstructive sleep apnea, coronary heart disease, medically refractory hypertension, or T2DM. The same procedures are covered for adolescents who have completed bone growth and have a BMI >40 kg/m^2 with severe comorbidities or a BMI >50 kg/m^2 with less serious comorbidities (e.g., impairment in completing daily life activities). All beneficiaries must have failed in prior attempts to lose weight, and they must complete either a physician-supervised nutrition and exercise program or a multi-disciplinary surgery preparatory regimen for at least six out of the past 24 months prior to the surgery.

Aetna considers the following procedures to be investigational and experimental: LAGB revision of RYGB or VSG, bariatric surgery to treat idiopathic intracranial hypertension or infertility, gastric bypass to treat gastroparesis, and RYGB to treat gastroesophageal reflux in non-obese patients. Intragastric balloons, gastrointestinal liners, and vagus nerve blockers are also considered experimental and investigational. Bariatric surgery is not considered a medically necessary treatment for T2DM in patients with a BMI <35 kg/m^2.

FDA-approved weight reduction medications (including liraglutide, lorcaserin, N/B, and P/T) are covered for patients who do not lose at least one pound per week after 6 months of a weight-loss regimen that includes diet, increased physical activity, and behavioral therapy. Additionally, patients must either have a BMI ≥30 kg/m^2 or a BMI ≥27 kg/m^2 and serious risk factors that include coronary heart disease, dyslipidemia, hypertension, obstructive sleep apnea, or T2DM.

Anthem

http://www.anthem.com

Anthem covers RYGB, BPD with DS, open and laparoscopic VSG, and LAGB for adults with a BMI ≥40 kg/m^2 or a BMI ≥35 kg/m^2 with an obesity-related comorbid condition. All candidates for surgery must participate in a documented non-surgical weight loss regimen for six consecutive months within the two years prior to surgery.

BPD *without* DS is considered investigational and not medically necessary, as are LAGB for patients with a BMI between 30 and 35 kg/m^2 and vagus nerve stimulation for all levels of obesity. Liraglutide, lorcaserin, N/B and P/T are not listed in the Anthem formulary.

CIGNA

https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0051_coveragepositioncriteria_bariatric_surgery.pdf

CIGNA covers open and laparoscopic RYGB, AGB, and VSG for adults and adolescents who have completed bone growth with a BMI ≥40 kg/m^2 or with a BMI ≥35 kg/m^2 and clinically significant comorbidities related to obesity. BPD with DS is covered only for patients with a BMI >50 kg/m^2. All potential surgery candidates must participate in a medical weight-management program supervised by a physician or registered dietician for at least three consecutive months of the past year; pharmaceutical management alone does not satisfy this requirement.

Gastric banding adjustments are covered when performed to control the rate of weight loss and/or to treat other symptoms resulting from gastric banding. CIGNA does not cover RYGB with simultaneous gastric banding, BPD without DS, surgery to treat T2DM alone, intragastric balloon, duodenal-jejunal bypass liners, and vagus nerve blocking or stimulation. Liraglutide, lorcaserin, N/B and P/T are not listed in the CIGNA formulary.

Humana

http://apps.humana.com/tad/tad_new/home.aspx?type=provider

Humana covers open and laparoscopic RYGB, BPD with or without DS, VSG, and LAGB for adults with a BMI ≥40 kg/m^2 or a BMI ≥35 kg/m^2 with one or more comorbidities. Candidates for surgery must have failed prior medical treatment for obesity and be cleared for the procedure through psychological evaluation within 12 months of the planned surgery to rule out major psychiatric disorders. Humana does not cover open AGB, intragastric balloon, duodenal-jejunal bypass liners,

and vagus nerve blocking or stimulation. Lorcaserin, N/B, and P/T are not covered, and there is no listing for liraglutide in Humana's publicly accessible drug list.

UnitedHealthcare

https://www.unitedhealthcareonline.com

UnitedHealthcare (UHC) covers RYGB, BPD with or without DS, VSG, and LAGB for adults with a BMI >40 kg/m^2 or a BMI >35 kg/m^2 with one of the following: T2DM, cardiovascular disease, coronary artery disease with a prior surgical intervention, cardiopulmonary problems, or a history of cardiomyopathy. All patients must also show documented attempts to lose weight through a structured diet program that includes provider notes or weight loss logs for at least six months, and they must undergo a psychological evaluation to rule out major mental health disorders that could interfere with compliance and follow-up requirements after surgery. UHC covers bariatric procedures for adolescents who meet the above criteria if the adolescent patient has reached 95% of their estimated adult height and has a Tanner stage of at least 4 (a level of near-adult development on the Tanner scale).

UHC considers intragastric balloon, gastrointestinal liners, and vagus nerve stimulation or blocking to be unproven and medically unnecessary. All appetite-suppressing medications are in the third formulary tier.

Representative Regional Private Insurer Policies

Health Net

https://www.healthnet.com/portal/provider/content/iwc/provider/unprotected/working_with_HN/content/medical_policies.action

Health Net covers laparoscopic VSG and open or laparoscopic RYGB and AGB for adults who have been severely obese for at least two years with a BMI ≥40 kg/m^2 or a BMI ≥ 35kg/m^2 and at least one comorbidity expected to improve through obesity surgery. The same procedures are covered for physiologically mature adolescents with a BMI >40 kg/m^2 and a serious obesity-related comorbidity or a BMI >50 kg/m^2 with a less severe comorbidity.

Other bariatric procedures are covered with restrictions. Long limb (between 100 and 200 cm) RYGB is restricted to patients with a BMI >50 kg/m^2, and BPD with DS is limited to patients with a BMI >50 kg/m^2 who will receive a common channel ≥ 100 cm. For high risk patients, laparoscopic VSG may only be performed as part of a "planned staged approach." Health Net's policy notes that

laparoscopic procedures are contraindicated in patients with a BMI >70 kg/m^2 and hepatomegaly. LAGB is not considered medically necessary in patients with a BMI between 30 and 35 kg/m^2; BPD without DS and intragastric balloons are not considered medically necessary in any patient. Lorcaserin and P/T are specialty-tier drugs, per the public formulary document.

Blue Shield of California

https://www.blueshieldca.com/provider/content_assets/documents/download/public/bscpolicy/Bariatric_Surgery.pdf

Blue Shield of California (BSCA) covers open and laparoscopic RYGB with limb length up to 150 cm, LAGB, and VSG for patients with a BMI ≥40 kg/m^2 or a BMI ≥35 kg/m^2 and one or more obesity related comorbidities unmanageable through medication. Patients with a BMI ≥50 kg/m^2 are eligible for BPD with DS. Adolescents are eligible for the same procedures with a BMI >40 kg/m^2 and at least one significant comorbidity that medication has failed to manage or a BMI ≥50 kg/m^2 with less severe comorbidities. All patients must be psychologically cleared for bariatric surgery, receive a recommendation from a bariatric surgeon for the procedure, and provide documentation of failure from a previous weight loss attempt lasting at least six of the past 18 months.

BSCA considers BPD without DS and vagus nerve stimulation to be investigational and does not cover them. All anti-obesity drugs require prior authorization, regardless of formulary inclusion; in addition, P/T, lorcaserin, and N/B are all currently excluded from the BSCA formulary.

Appendix J. Previous Systematic Reviews

We identified six systematic reviews of surgical and non-surgical interventions of interest for this review.

Buchwald 2004

Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA*. 2004; 292(14):1724-1737.

A systematic review and meta-analysis evaluated 136 studies comparing the effectiveness and safety of bariatric surgery procedures for impact on weight loss, mortality, and obesity-related comorbidities (i.e., diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea). The overall treatment effect for EWL was 61.2% for all procedures; patients undergoing LAGB, RYGB, VSG, and BPD (with or with DS) had a mean EWL of 47.5%, 61.6%, 68.2%, and 70.1%, respectively. Perioperative mortality ranged from 0.1% to 1.1%. All comorbid conditions either improved or were resolved in at least 62% of patients across all procedures.

Colquitt 2014

Colquitt JL, Pickett K, Loveman E, Frampton GK. Surgery for weight loss in adults. *Cochrane Database Syst Rev*. 2014; 8:CD003641.

A systematic review and meta-analysis of 22 RCTs conducted by the Cochrane Collaboration found that bariatric surgery is associated with greater improvements in weight loss outcomes and comorbidities for all procedures (LAGB, RYGB, BPD with DS, VSG, and VSG with duodenal-jejunal bypass) compared to nonsurgical treatments. Both RYGB and VSG produced greater weight reductions than LAGB, with comparable efficacy between them, and BPD±DS was associated with the greatest weight loss. AEs, including reoperations, were poorly reported and most studies were of short duration (1 to 2 years) so the long-term impact of surgery is unclear. There is a lack of evidence for resolution of comorbidities in people who do not meet the current standards for undergoing bariatric surgery.

Chan 2013

Chan EW, He Y, Chui CSL, Wong AYS, Lau WCY, Wong Ick. Efficacy and safety of lorcaserin in obese adults: a meta-analysis of 1-year RCTs and narrative review on short-term RCTs. *Obesity Reviews*. 2013; 14:383-392.

Chan and colleagues conducted a systematic review and meta-analysis of five RCTs to assess the efficacy and safety of lorcaserin in obese adults. At one-year follow-up, patients lost an average of 3.23 kg (95% confidence interval [CI]: 2.70, 3.75) and had a BMI reduction of 1.16 kg/m^2 (95% CI: 0.98, 1.34) compared with placebo; lorcaserin also decreased waist circumference, blood pressure, total cholesterol, low-density lipoprotein-cholesterol, and triglycerides. Although the majority of AEs were minor, lorcaserin patients experienced significantly more events of headache, nausea, and dizziness.

Chang 2013

Chang SH, Stoll CR, Song J, Varela JE, Eagon CJ, Colditz GA. The effectiveness and risks of bariatric surgery an updated systematic review and meta-analysis, 2003-2012. *JAMA Surg*. 2014; 149(3):275-287.

Chang and colleagues published a systematic review and meta-analysis of 164 studies evaluating the effectiveness and safety of bariatric surgery; meta-analyses for RCTs and observational studies were conducted separately. Perioperative and postoperative mortality rates were low in both RCT and observational study analyses, with the lowest mortality rate associated with LAGB. Complications were lower in observational studies compared with RCTs, with the lowest rates for VSG and LAGB. However, reoperation rates were the lowest with RYGB and highest with LAGB in both RCT and observational study evaluations. Across the RCTs, EWL increased in years one and two following surgery, but declined in year three. Similarly, observational studies showed that EWL increased between years 1 and 2, but there was no change between years 2 and 3. For comorbidity outcomes, all procedures were associated with significant improvements.

Imaz 2008

Imaz I, Martínez-Cervell C, García-Álvarez EE, Sendra-Gutiérrez JM, González-Enríquez J. Safety and Effectiveness of the Intragastric Balloon for Obesity. A Meta-Analysis. *Obes Surg*. 2008; 18:841-846.

Imaz and colleagues conducted a meta-analysis of 15 articles (3,608 patients) to evaluate the efficacy of the intragastric balloon for weight loss. The authors estimated that at balloon removal, patients lost 14.7 kg (12.2% of initial weight), reduced BMI by 5.7 kg/m^2, and lost 32.1% of excess weight; however, only two RCTs reported weight loss data at time points after balloon removal. Complications were predominantly mild, and the early removal rate was 4.2%. The sustainability of such weight loss over longer periods of time (i.e., ≥ 1 year) is unclear.

Zechmeister-Koss 2014

Zechmeister-Koss I, Huic M, Fischer S. The Duodenal-Jejunal Bypass Liner for the Treatment of Type 2 Diabetes Mellitus and/or Obesity: a Systematic Review. *Obes Surg*. 2014; 24:310-323.

A systematic review of 10 studies with a total of 342 patients evaluated the efficacy and safety of the duodenal-jejunal bypass liner (DJBL) in both diabetic patients with Grade 1 (BMI 30.0-34.9) obesity and patients with Grade II or higher (BMI>=35.0 with comorbidities) obesity. In higher-BMI patients, 12-22% EWL was observed up to 12 weeks after implementation. For the remaining patient-relevant endpoints and patient populations, evidence was either not available or inconsistent. AEs occurred in 64–100% of DJBL patients compared to 0–27 % in the control groups. The authors concluded there is still a lack of sufficient evidence available to recommend the device for routine use.

Appendix K. Ongoing Studies

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
Gastric bypass					
Effect of Long Biliopancreatic Limb RYBG on Weight Loss and Comorbidities (Elegance) NCT01686997	RCT	RYGB 75cm limb RYGB 150cm limb Primary and repeat surgery	N = 280 Age 18 – 65 Men and women BMI >40 or BMI > 35 with comorbidity All BMI levels accepted in case of repeat surgery	Weight reduction Secondary Outcomes: Decrease in comorbidities QOL Complications Reoperations	December 2018
Effects of Laparoscopic Roux-en-Y Gastric Bypass on Non-severe Obesity with Type 2 Diabetes Mellitus NCT02091323	Non-RCT	RYGB for patients with BMI < 28 RYGB for patients with BMI 28 – 35	N = 200 Age 18 – 65 Men and women T2DM for less than 15 years No T1DM	Fasting plasma glucose up to 36 months post-surgery Other outcomes: HbA1c and weight loss up to 36 months post-surgery	December 2017
Gastric Banding					
HERO Study: Helping Evaluate Reduction in Obesity NCT00953173	Obs. Cohort	LAGB (LAP-BAND AP)	N = 1,106 Age > 18 Men and women BMI > 40, BMI > 35 with comorbidity, or weight 100lb over ideal No prior bariatric surgery No type 1 diabetes	Change in weight, waist and hip circumference Change in concomitant medication use Change in health-related quality of life	March 2016
Multiple Procedures or Interventions					
Comparison of Laparoscopic Sleeve Gastrectomy and Roux-Y-gastric bypass in the Treatment of Morbid Obesity	RCT	Sleeve Gastrectomy Gastric Bypass	N = 200 Age 18 – 60 Men and women BMI > 40	Effectiveness in terms of weight loss Reduction of comorbidity QOL	August 2016

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
NCT00356213					
Medication Management					
A Study to Evaluate the Effect of Long-term Treatment with BELVIQ (Lorcaserin HCl) on the Incidence of Major Adverse Cardiovascular Events and Conversion to Type 2 Diabetes Mellitus in Obese and Overweight Subjects with Cardiovascular Disease or Multiple Cardiovascular Risk Factors (CAMELLIA-TIMI) NCT02019264	RCT	Lorcaserin HCl Placebo	N = 12,000 Age ≥ 40 Men and women BMI ≥ 27 Must have established CVD If no CVD, men ≥ 50 or women ≥ 55 with T2DM, no established CVD, and at least one CVD risk factor No moderate or greater congestive heart failure (CHF), pulmonary hypertension, renal impairment Not taking other weight loss drugs No clinically significant disease	Time from randomization to first major adverse cardiovascular event (MACE) Time from randomization to conversion to T2DM	September 2018
A Toolbox Approach to Obesity Treatment in Primary Care NCT01922934	RCT	Commercial weight loss program, group behavioral weight loss program, dietary supplement, Phentermine / topiramate Usual care	N = 350 Age 18 – 80 Men and Women BMI between 30 and 45 Obesity-related comorbidity No heart attack or stroke within 6 months No cancer in past 5 years No substance abuse No bipolar disorder or schizophrenia	Weight change at 1 year	December 2016
Cardiovascular Outcomes Study of Naltrexone SR/Bupropion SR in Overweight and Obese Subjects with Cardiovascular Risk Factors (The Light Study)	RCT	Naltrexone SR / bupropion SR and behavioral weight management program	N = 10,400 Women aged ≥ 50, men aged ≥ 45 BMI 27 – 50 CVD with at least one of: History of myocardial infarction (MI)	Time from randomization to first confirmed occurrence of MACE	July 2017

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
NCT01601704		Placebo and behavioral weight management program	History of coronary, carotid, or peripheral revascularization And/or T2DM with two of the following: Hypertension Dyslipidemia Low HDL cholesterol Current tobacco smoker No planned bariatric surgery No history of psychosis, anorexia nervosa, bulimia No history of stroke No MI within past 3 months No angina pectoris Grade 3 or 4 No history of stroke		
Intragastric Balloon					
Intragastric Balloon, Air Versus Fluid Filled: Randomized Prospective Study NCT02129296	RCT	Air-filled intragastric balloon Liquid-filled intragastric balloon	N = 300 Men and women Morbid obesity No mental health disorder No esophageal varices, big hiatus hernia, ulcers No gastric vascular malformations	Tolerability of device for 6 months Secondary outcome: Weight loss by kg and BMI at 6 months	August 2016
Effect of Gastric Balloon in Morbid Obesity: A Prospective Study NCT02128165	Non-RCT	Intragastric balloon for BMI between 35 and 45 Intragastric balloon for BMI > 45	N = 300 Men and women Morbid obesity No esophageal or gastric abnormalities No psychological health issues	Effect of weight loss each month for 6 months	December 2016

Title/ Trial Sponsor	Study Design	Comparators	Patient Population	Primary Outcomes	Estimated Completion Date
Duodenal-jejunal bypass liner					
Safety and Efficacy of EndoBarrier in Subjects With Type 2 Diabetes Who Are Obese (ENDO) NCT01728116	RCT	Duodenal-jejunal bypass liner (EndoBarrier) Sham device	N = 500 Age 21 – 65 Men and women BMI from 30 – 55 HbA1c from 7.5% to 10% No T1DM No previous GI surgery or GI anatomical findings No prescription antithrombotic therapy	Improvement in HbA1c at 12 months Secondary Outcome: Weight loss at 12 months Improvement in cardiovascular risk factors at 12 months	December 2016
Vagus nerve block devices					
ReCharge Clinical Trial NCT01327976	RCT	Implantable vagus nerve stimulator (MAESTRO RC2) Sham device	N = 234 Age 18 – 65 Men and women BMI 40 – 45 BMI 35 – 39.9 and at least one severe obesity-related comorbidity T2DM allowable if well-controlled Failed diet and exercise program in past 5 years No GI surgery No weight-loss medication during or 3 months before participation No history of pulmonary embolism, Crohn's disease, ulcerative colitis	Number of patients achieving ≥ 10% EWL at 1 year post-randomization Rate of serious AEs	December 2016

Appendix L. Outcomes by Baseline Mean BMI Category

Baseline Mean BMI Category									
		30-34.99		35-39.99		40-49.99		>50	
		Median	Range	Median	Range	Median	Range	Median	Range
% Decrease BMI	RYGB	25.4	(19.6-34.3)	26.0	(24.1-33.1)	32.2	(7.5-52.3)	34	(10.1-46.7)
	VSG	21.3	(21.3-21.3)	22.0	(19.1-22.5)	28.4	(15.0-37.1)	30.1	(11.0-39.4)
	LAGB	16.8	(11.8-21.7)	16.8	(13.0-17.5)	20.4	(6.0-46.8)	17.7	(1.0-31.8)
	BPD/DS	31.8	(17.3-46.3)			32.6	(15.9-50.8)	43.4	(39.2-47.7)
	Follow-up (months)	12.0	(3.0-45.2)	15.3	(12.0-60.0)	12.0	(0.5-120.0)	22.6	(1.2-84.0)
	No. Studies	7		6		79		22	
	Good/Fair/Poor	2/3/2		3/1/2		9/34/36		4/10/8	
% EWL	RYGB	70.0		77.0	(61.0-92.9)	67.0	(27.1-88.0)	61.8	(43.8-72.3)
	VSG			58.5	(51.0-66.0)	59.2	(30.7-83.0)	47.5	(25.4-75.0)
	LAGB	87.2		50.1	(34.0-62.5)	43.5	(18.2-78.8)	45.9	(31.0-73.0)
	BPD/DS					52.7	(34.9-70.4)	73.4	63.0-84.0)
	Follow-up (months)	18.0	(12.0-24.0)	30.0	(18.7-60.0)	24.0	(0.47-120)	24.0	(12.0-84.0)
	No. Studies	2		4		57		15	
	Good/Fair/Poor	1/0/1		1/1/2		6/27/24		1/8/6	
% Improvement Hypertension	RYGB			90.0		71.0	(22.0-100.0)	62.6	(60.7-69.2)
	VSG					64.3	(23.5-100.0)		
	LAGB			40.0		57.5	(18.0-100.0)	54.3	(33.3-66.7)
	BPD/DS	67.0				81.4	(68.6-87.0)	68.3	(66.7-69.9)
	Follow-up (months)	36.0		60.0		21.0	(3.5-84.0)	24.0	(12.0-50.4)
	No. Studies	1		1		29		5	
	Good/Fair/Poor	0/1/0		0/0/1		4/12/13		1/3/1	

Baseline Mean BMI Category									
		30-34.99		35-39.99		40-49.99		>50	
		Median	Range	Median	Range	Median	Range	Median	Range
% Improvement T2DM	RYGB	51.1	(33.0-92.3)	73.4	(66.7-80.0)	79.0	(33.0-100.0)	77.1	(40.0-100.0)
	VSG	50.0	(50.0-50.0)			77.3	(36.0-100.0)	88.9	(88.9-88.9)
	LAGB	33.0	(21.1-100.0)	50.0	(25.0-73.0)	50.0	(17.0-100.0)	52.3	(36.4-66.7)
	BPD/DS	84.8	(83.0-84.8)			87.1	(81.5-92.7)	91.4	(82.7-100.0)
	Follow-up (months)	12.0	(3.0-45.2)	24.0	(12.0-60.0)	16.0	(1.0-62.7)	24.0	(1.5-50.4)
	No. Studies	6		3		35		7	
	Good/Fair/Poor	0/3/3		2/0/1		3/14/18		1/4/2	
% Improvement Sleep Apnea	RYGB	89.0				70.5	(10.0-100.0)	56.7	(49.3-88.0)
	VSG					62.0	(6.0-99.0)		
	LAGB					29.0	(3.0-55.0)	46.2	(39.3-66.7)
	BPD/DS	90.0						79.5	(78.9-80.0)
	Follow-up (months)	45.15				21.6	(12.0-36.0)	20.1	(12.0-20.1)
	No. Studies	1		0		11		4	
	Good/Fair/Poor	0/0/1				2/5/4		1/3/0	
% Improvement Dyslipidemia	RYGB			100.0		64.5	(6.0-100.0)	52.9	(27.3-58.8)
	VSG					67.5	(35.0-67.5)		
	LAGB			38.0		36.5	(0.0-36.5)	34.4	(23.3-45.5)
	BPD/DS					90.0	(90.0-90.0)		
	Follow-up (months)			60.0		24.0	(12.0-62.7)	16.2	(12.0-50.4)
	No. Studies	0		1		18		3	
	Good/Fair/Poor	0		0/0/1		2/9/7		1/1/1	

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Note: the references listed below are numbered differently from those in the associated report.

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