QUERI

Evidence Brief: The Comparative Effectiveness of Bariatric Surgery in Super Obesity (BMI > 50 kg/m^2)

Supplemental Materials

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SEARCH STRATEGIES

Database: Ovid MEDLINE (June 19, 2015)

1. Obesity, Morbid/su [Surgery]
2. exp Bariatric Surgery/
3. 1 and 2
4. limit 3 to (english language and humans)
5. 4 not (child$ or pediatric$ or adolescen$ or pregnan$).mp.
6. limit 5 to yr="2013 - 2015"
7. 6 not (editorial or letter or case reports or review).pt

Database: Ovid MEDLINE (July 15, 2015)

1. Obesity, Morbid/su [Surgery]
2. exp Bariatric Surgery/
3. 1 and 2
4. limit 3 to (english language and humans)
5. 4 not (child$ or pediatric$ or adolescen$ or pregnan$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6. limit 5 to yr="2013 - 2015"
7. 6 not (editorial or letter or case reports or review).pt.
8. limit 5 to (meta analysis or systematic reviews)
9. limit 8 to yr="2010 - 2015"
10. 9 not 7

Database: Cochrane Database of Systematic Reviews (July 15, 2015)

1. Bariatric Surgery/
2. Obesity, Morbid/su [Surgery]
3. 1 and 2
4. 1 and (morbid$ or super$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
5. 3 or 4
6. limit 5 to yr="2013 - 2015"

Database: Ovid MEDLINE (August 12, 2015)

1. bariatric surgery/ or gastric bypass/ or gastroplasty/ or jejunoileal bypass/ or lipectomy/ or (bariatric adj2 surger*).ti,ab.
2. (superobes* or (super adj2 obes*) or >47 or >48 or >49 or >50 or >55 or >60).ti,ab.
3. Healthcare Disparities/ or Health Services Accessibility/ or Insurance Coverage/ or (barrier* or inequal* or disparit* or inequit* or cost or costs or financial* or insur* or demographic* or stigma or stigmas or cover* or obstacle* or issue* or access*).ti,ab.
4. 1 and 2 and 3
5. limit 4 to english language

Database: PsychINFO (August 12, 2015)

1. bariatric surgery/ or (bariatric adj2 surger*).ti,ab.
2. obesity/ and surgery/
3. or/1-2
4. (super-obes* or >47 or >48 or >49 or >50).ti,ab.
5. 3 and 4
6. barrier*.ti,ab.
7. 3 and 6
8. or/5,7
9. limit 8 to english language

LIST OF EXCLUDED STUDIES

Exclude reasons: 1 = Ineligible population, 2 = Ineligible intervention, 3 = Ineligible comparator, 4 = Ineligible outcome, 5 = Ineligible timing, 6 = Ineligible study design, 7 = Ineligible publication type, 8 = Outdated or ineligible systematic review

#	Citation	Exclude reason
1	Aasheim ET, Bjorkman S, Sovik TT, et al. Vitamin status after bariatric surgery: a randomized study of gastric bypass and duodenal switch. *American Journal of Clinical Nutrition.* Jul 2009;90(1):15-22.	4
2	Afonso BB, Rosenthal R, Li KM, Zapatier J, Szomstein S. Perceived barriers to bariatric surgery among morbidly obese patients. *Surg Obes Relat Dis.* 2010;6(1):16-21.	1
3	Albeladi B, Bourbao-Tournois C, Huten N. Short- and midterm results between laparoscopic Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy for the treatment of morbid obesity. *Journal of Obesity.* 2013;2013:934653.	1
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8	Arterburn D, Bogart A, Coleman KJ, et al. Comparative effectiveness of bariatric surgery vs nonsurgical treatment of type 2 diabetes among severely obese adults. *Obesity Research & Clinical Practice.* Jul-Aug 2013;7(4):e258-268.	1
9	Arterburn D, Powers JD, Toh S, et al. Comparative effectiveness of laparoscopic adjustable gastric banding vs laparoscopic gastric bypass. *JAMA Surgery.* Dec 2014;149(12):1279-1287.	1
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11	Arterburn DW, Emily O; Terrell, Andrew. . Weight control practices of severely obese patients who are not seeking bariatric surgery. . *Obesity.* 2013;21(8):1509-1513.	2
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13	Blazeby JM, Byrne J, Welbourn R. What is the most effective operation for adults with severe and complex obesity? *BMJ.* 2014;348:g1763.	1
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	longitudinal study. *Annals of Surgery.* Nov 2014;260(5):893-898; discussion 898-899.	
16	Carlin AM, Zeni TM, English WJ, et al. The comparative effectiveness of sleeve gastrectomy, gastric bypass, and adjustable gastric banding procedures for the treatment of morbid obesity. *Annals of Surgery.* May 2013;257(5):791-797.	1
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87	Runkel N, Colombo-Benkmann M, Huttl TP, Tigges H, Mann O, Sauerland S. Bariatric surgery. *Deutsches Arzteblatt International.* May 2011;108(20):341-346.	1
88	Samaras K. Bariatric surgery for type 2 diabetes: to whom and when? *Minerva Endocrinologica.* Mar 2013;38(1):47-58.	1
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101	Trastulli S, Desiderio J, Guarino S, et al. Laparoscopic sleeve gastrectomy compared with other bariatric surgical procedures: a systematic review of randomized trials. *Surgery for Obesity & Related Diseases.* Sep-Oct 2013;9(5):816-829.	1
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109	Viana EC, Araujo-Dasilio KL, Miguel GPS, et al. Gastric bypass and sleeve gastrectomy: the same impact on IL-6 and TNF-alpha. Prospective clinical trial. *Obesity Surgery.* Aug 2013;23(8):1252-1261.	1
110	Vilarrasa N, de Gordejuela AGR, Gomez-Vaquero C, et al. Effect of bariatric surgery on bone mineral density: comparison of gastric bypass and sleeve gastrectomy. *Obesity Surgery.* Dec 2013;23(12):2086-2091.	1
111	Vix M, Diana M, Liu K-H, et al. Evolution of glycolipid profile after sleeve gastrectomy vs Roux-en-Y gastric bypass: results of a prospective randomized clinical trial. *Obesity Surgery.* May 2013;23(5):613-621.	1
112	Vix M, Liu K-H, Diana M, D'Urso A, Mutter D, Marescaux J. Impact of Roux-en-Y gastric bypass versus sleeve gastrectomy on vitamin D metabolism: short-term results from a prospective randomized clinical trial. *Surgical Endoscopy.* Mar 2014;28(3):821-826.	1
113	Wang BCM, Furnback W. Modelling the long-term outcomes of bariatric surgery: A review of cost-effectiveness studies. *Best Practice & Research in Clinical Gastroenterology.* Dec 2013;27(6):987-995.	1
114	Wang MC, Guo XH, Zhang YW, Zhang YL, Zhang HH, Zhang YC. Laparoscopic Roux-en-Y gastric bypass versus sleeve gastrectomy for obese patients with Type 2 diabetes: a meta-analysis of randomized controlled trials. *American Surgeon.* Feb 2015;81(2):166-171.	1
115	Wang S, Li P, Sun XF, Ye NY, Xu ZK, Wang D. Comparison between laparoscopic sleeve gastrectomy and laparoscopic adjustable gastric banding for morbid obesity: a meta-analysis. *Obesity Surgery.* Jul 2013;23(7):980-986.	1
116	Wang W, Liou T-H, Lee W-J, Hsu C-T, Lee M-F, Chen H-H. ESR1 gene and insulin resistance remission are associated with serum uric acid decline for severely obese patients undergoing bariatric surgery. *Surgery for Obesity & Related Diseases.* Jan-Feb 2014;10(1):14-22.	1
117	Waters DL, Ward AL, Villareal DT. Weight loss in obese adults 65years and older: a review of the controversy. *Experimental Gerontology.* Oct 2013;48(10):1054-1061.	2
118	Wee CCH, Karen W; Bolcic-Jankovic, Dragana; Colten, Mary Ellen; Davis, Roger B; Hamel, MaryBeth. Sex, race, and consideration of bariatric surgery among primary care patients with moderate to severe obesity. . *Journal of General Internal Medicine. .* 2014: 68-75.	1
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121	Williams GJ, Georgiou PA, Cocker DM, Bonanomi G, Smellie J, Efthimiou E. The safety and efficacy of bariatric surgery for obese, wheelchair bound patients. *Annals of the Royal College of Surgeons of England.* Jul 2014;96(5):373-376.	1
122	Worni M, Ostbye T, Shah A, et al. High risks for adverse outcomes after gastric bypass surgery following failed gastric banding: a population-based trend analysis of the United States. *Annals of Surgery.* Feb 2013;257(2):279-286.	1
123	Yang X, Yang G, Wang W, Chen G, Yang H. A meta-analysis: to compare the clinical results between gastric bypass and sleeve gastrectomy for the obese patients. *Obesity Surgery.* Jul 2013;23(7):1001-1010.	1
124	Yip S, Plank LD, Murphy R. Gastric bypass and sleeve gastrectomy for type 2 diabetes: a systematic review and meta-analysis of outcomes. *Obesity Surgery.* Dec 2013;23(12):1994-2003.	1
125	Yip S, Signal M, Smith G, et al. Lower glycemic fluctuations early after bariatric surgery partially explained by caloric restriction. *Obesity Surgery.* Jan 2014;24(1):62-70.	1
126	Yorke S. How can nurses improve care for obese Albertans? *Alberta RN.* 2013;69(1):32-33.	1
127	Young MT, Gebhart A, Khalaf R, et al. One-year outcomes of laparoscopic sleeve gastrectomy versus laparoscopic adjustable gastric banding for the treatment of morbid obesity. *American Surgeon.* Oct 2014;80(10):1049-1053.	1
128	Yu EW, Bouxsein ML, Roy AE, et al. Bone loss after bariatric surgery: discordant results between DXA and QCT bone density. *Journal of Bone & Mineral Research.* Mar 2014;29(3):542-550.	1
129	Zarate X, Arceo-Olaiz R, Montalvo Hernandez J, Garcia-Garcia E, Pablo Pantoja J, Herrera MF. Long-term results of a randomized trial comparing banded versus standard laparoscopic Roux-en-Y gastric bypass. *Surgery for Obesity & Related Diseases.* May-Jun 2013;9(3):395-397.	1
130	Zellmer JD, Mathiason MA, Kallies KJ, Kothari SN. Is laparoscopic sleeve gastrectomy a lower risk bariatric procedure compared with laparoscopic Roux-en-Y gastric bypass? A meta-analysis. *American Journal of Surgery.* Dec 2014;208(6):903-910; discussion 909-910.	1
131	Zhang N, Maffei A, Cerabona T, Pahuja A, Omana J, Kaul A. Reduction in obesity-related comorbidities: is gastric bypass better than sleeve gastrectomy? *Surgical Endoscopy.* Apr 2013;27(4):1273-1280.	1

EVIDENCE TABLES

DATA ABSTRACTION OF INCLUDED SYSTEMATIC REVIEWS

Author Year	Aims Search details Eligibility criteria	Numbers and designs of included studies applicable to present review; sample sizes	Patient characteristics from included studies applicable to present review	Intervention characteristics from included studies applicable to present review	Overall Results Stratified by subgroup characteristics?
Hedberg 2014[1]	Comparison of DS and RYGB outcomes Medline, PubMed, Scopus Morbidly obese adult patients; single center; > 1 -year follow-up	4 RCTs (Sample size range: 40-60) 12 observational (Sample size range: 18-452)	BMI range: 44-64 Age range: 35-48 % male range: 10-60 Race and co-morbidities: NR	RYGB and DS	DS yielded 6.2 (CI: 5.0-7.5) BMI units additional weight loss compared with RYGB. Larger differences in weight with increasing baseline BMI (P<0.05). DS lead to longer operative time, length of stay, and post-operative leaks. No difference in mortality.

DATA ABSTRACTION OF INCLUDED PRIMARY STUDIES

Data Abstraction of Observational Studies

Author Year N	Follow-up	Patient Characteristics	Intervention(s)	Efficacy/Effectiveness Outcomes	Harms	Setting; Timeframe
Arterburn 2015[2] 2860	1 year >1 to 5 yrs. > 5 to 14 yrs.	NR for super obese subgroup	RYGB, LSG, LAGB	Mortality surgery vs non-surgery: 1 year: 4.93% vs 2.77% (HR 1.57; 95% CI, 1.08-2.76) >1 to 5 yrs: 5.48% vs 11.4% (HR 0.46; 95% CI, 0.33-0.64) >5 to 14 yrs: 9.5% vs 17.5% (HR 0.45; 95% CI, 0.34-0.60)	NR	USA 2000-2011

Author Year N	**Follow-up**	**Patient Characteristics**	**Intervention(s)**	**Efficacy/Effectiveness Outcomes**	**Harms**	**Setting; Timeframe**
Bowne 2006[3] 106	LRYGB: 13 mos. LAGB: 17.7 mos.	LRYGB vs LAGB: Mean age: 42.8 vs 41.9 (p=.45) Male (%): 23.9 vs 16.7, (p=.35) BMI: 56.7 vs 55.4 (p=.18) Hypertension (%): 56.5 vs 40 (p=.07) T2DM (%): 17.4 vs 18.3 (p=.55) Dyslipidemia (%): 37.0 vs 18.3 (p=.03) CAD (%): 4.3 vs 5 (p=.63) Asthma (%): 33.0 vs 28.3 (p=.75) Sleep apnea (%): 54.3 vs 47.0 (p=.27) Arthritis (%): 46.0 vs 23.3 (p=.13)	LRYGB, LAGB	LRYGB vs LAGB: Mean BMI change: 26.5 vs 9.8 (p<.001) EWL (%): 52 vs 31 (p<.001) Hypertension (%): 21 vs 29 (p=.35) T2DM (%): 0 vs 11 (p=.05) Dyslipidemia: 21 vs 11 (p=.24) Asthma: 10.2 vs 25 (p=.1) Sleep apnea: 8 vs 31 (p=.01) Arthritis: 38 vs 20 (p=.07)	LRYGB vs LAGB: Early complications [<30 days] (%): 17 vs 18 (p=.33) Late complications [≥30 days] (%): 28 vs 78 (p<.05) Mortality (%): 0 vs 1.7	USA 2001-2004

Author Year N	Follow-up	Patient Characteristics	Intervention(s)	Efficacy/Effectiveness Outcomes	Harms	Setting; Timeframe
Daigle 2015[4] 30	Median 37 months	Overall: Mean age: 67.1 Male (%): 13.3 BMI: 55.9 Dyslipidemia (%): 53.3 T2DM (%): 30 Hypertension (%): 90 Sleep apnea (%): 46.7	LRYGB, LSG, LAGB	EWL (%): 54.4 LRYGB vs 48.3 LSG vs 26.2 LAGB	Early complications [<30 days] (%): 12.5 LRYGB vs 33.3 LSG vs 12.5 LAGB No mortalities No late complications	US 2006-2012
Giordiano 2015[5] 181	12 mos.	LRYGB vs LAGB: Mean age: 42.6 vs 41.0 (p=.81) Male (%): 36.3 vs 35.4 (p=.94) BMI: 56.3 vs 53.4 (p=.56)	LRYGB, LAGB	LRYGB vs LAGB at 6 mo. follow-up: EWL (%): 44.75 vs 26.2 (p<.001) BMI: 43.57 vs 46.06 (p<.001) LRYGB vs LAGB at 12 mos. follow-up: EWL (%): 54.71 vs 31.55 (p<.001) BMI: 34.96 vs 41.75 (p=.008)	LRYGB vs LAGB: Early complications [<30 days] (%): 17.65 vs 10.12 (p=.2) Late complications NR Mortality NR	Finland 2006-2009

Author Year N	**Follow-up**	**Patient Characteristics**	**Intervention(s)**	**Efficacy/Effectiveness Outcomes**	**Harms**	**Setting; Timeframe**
Heneghan 2014[6] 268	2 yrs.	Banded vs non-banded LRYGB: Mean age: 45.4 vs 46.8 (p=.282) Male (%): 33 vs 27 (p=.32) BMI: 54.6 vs 52.8 (p=.084) Super-obese (%): 78 vs 63 (p=.005) Diabetes (%): 43 vs 37 (p=.319) Hypertension (%): 74 vs 72 (p=.681) Dyslipidemia (%): 63 vs 46 (p=.003)	Banded and non-banded LRYGB	Banded vs non-banded LRYGB: EWL (%): 58.6 vs 51.4 (p=.015) EWL for super obese subgroup (%): 57.5 vs 47.6 (p=.003)	Banded vs non-banded LRYGB: Early complications [<30 days] (%): 19.4 vs 19.4 Late complications [≥30 days] (%): 10.4 vs 13.4 (p=.451) Mortality (%): .7 vs .7	USA 2007-2010
Mognol 2005[7] 290	2 yrs.	LRYGB vs LAGB: Mean age: 40 vs 40 Male (%): 31 vs 17 (p<.01) BMI: 59 vs 54 (p<.01)	LRYGB, LAGB	LRYGB vs LAGB at 1 yr. follow-up: EWL (%): 63 vs 41 LRYGB vs LAGB at 2 yr. follow-up: EWL (%): 73 vs 46	LRYGB vs LAGB: Early complications (%): 9.9 vs 2.8 (p<.01) Late complications (%): 16.2 vs 24.6 (p<.05) Mortality (%): .9 vs .6 (non-significant)	France 1994-2004

Author Year N	Follow-up	Patient Characteristics	Intervention(s)	Efficacy/Effectiveness Outcomes	Harms	Setting; Timeframe
Nelson 2012[8] 26510	DS mean: 8.8 mos. GB mean: 8.9 mos.	NR for super obese subgroup	Laparoscopic or open DS Laparoscopic or open GB	NR for super obese subgroup	DS vs GB for super obese subgroup: Mortality (%): 1.8 vs .4 (p<.001) Marginal ulcer (%): .1 vs 1.2 (p=.002) Any infection (%): 5.2 vs 2.3 (p<.001) Pneumonia (%): .9 vs .4 (p=.003) Leak (%): 2.4 vs .9 (p<.001) Any nutritional deficiency (%): 5.5 vs 2.3 (p<.001)	Bariatric Outcomes Database 2007-2010
Parikh 2005[9] 332	3 yrs.	Mean age: 42 (NS) Male (%): 20 (p=.02) Caucasian (%): 83 African American (%): 11 BMI: 55.7 (NS)	LAGB, LRYGB, BPD	LAGB vs LRYGB vs BPD at 1-year follow-up: EWL (%): 35.3 vs 57.7 vs 60.6 (p<.05 LAGB vs BPD) LAGB vs LRYGB vs BPD at 2-year follow-up: EWL (%): 45.8 vs 54.7 vs 69.4 (p<.05 LAGB vs BPD) LAGB vs LRYGB vs BPD at 3-year follow-up: EWL(%): 49.5 vs 56.8 vs 77.4 (p<.05 LAGB vs BPD)	LAGB vs LRYGB vs BPD: Early complications [<30 days] (%): 4.7 vs 11.3 vs 16.3 (p=.02, LAGB vs RYGBP & BPD) No mortalities	USA 2000-2004

Author Year N	Follow-up	Patient Characteristics	Intervention(s)	Efficacy/Effectiveness Outcomes	Harms	Setting; Timeframe
Roland 2011[10] 89	2 yrs.	Open vs laparoscopic RYGB: Mean age: 41 vs 44 Male (%): 38 vs 29 BMI: 80 vs 77 Hypertension (%): 65 vs 61 Sleep apnea (%): 46 vs 37 Diabetes (%): 40 vs 45 GERD (%): 15 vs 24 Arthritis (%): 17 vs 34 No significant differences	Open RYGB, Laparoscopic RYGB	Open vs Laparoscopic RYGB: 3 mo. follow-up: EWL (%): 17.5 vs 22.7 (p=.016) 6 mo. follow-up: EWL (%): 30.8 vs 37.6 (p=.037) 12 and 24 mos. follow-ups: No significant differences	Open vs Laparoscopic RYGB: Mortality (%): 1.9 vs 0 Hernia (%): 19 vs 3 No other significant differences in complications	USA 2003-2007
Sekhar 2006[11] 967	2 yrs.	Open vs Laparoscopic RYGB: Mean age: 42.9 vs 42.9 Male (%): 24 vs 14 (p=.001) BMI: 58.9 vs 49.1 (p=.001)	Open RYGB, Laparoscopic RYGB	Open vs Laparoscopic RYGB: Overall: 1 yr. follow-up: EWL(%): 57 vs 66.9 (p=.01) 2 yr. follow-up: EWL (%): 67.3 vs 71.3 (p=.03) Stratified by pre-operative BMI: EWL (%): BMI 51-60: 67 vs 62 (NS) BMI >61: 65 vs 75 (NS)	Open vs Laparoscopic RYGB: 30 day follow-up: Mortality (%): .5 vs .17 (p=.37) Wound infection (%): 9.2 vs 1.7 (p=.001) No other significant differences in complications	USA 2001-2005

Author Year N	Follow-up	Patient Characteristics	Intervention(s)	Efficacy/Effectiveness Outcomes	Harms	Setting; Timeframe
Serrano 2015[12] 135	1 yr.	LRYGB vs LSG: Mean age: 33.1 vs 38.2 NS Male (%): 29 vs 48 NS White (%): 6 vs 14 NS BMI: 66.3 vs 68.4 NS No difference in comorbidities	LRYGB, LSG	LRYGB vs LSG: %EWL Success (> 30% EWL): At 3 months: 28.95 vs 25 At 6 months: 72.22 vs 59.09 At 12 months: 94.59 vs 100	LRYGB vs LSG: Complications (%): 15.1 vs 4.8 Mortality: 1 death LRYGB, 0 deaths LSG	US 2008-2013
Zerrweck 2014[13] 77	1 yr.	LRYGB vs LSG: Mean age: 35.4 vs 37.5 (p=.354) Male (%): 4 vs 45 (p<.001) BMI: 52.7 vs 53.8 (p=.087) Hypertension: 21 vs 28 (p=.601) Dyslipidemia: 12 vs 8 (p=.508)	LRYGB, LSG	LRYGB vs LSG: 6 mo. follow-up: EWL (%): 51.6 vs 40 (p<.05) BMI: 38.6 vs 41.7 (p<.05) 9 mo. follow-up: EWL (%): 56.5 vs 45.1 (p<.05) BMI: 36.9 vs 40 (NS) 12 mo. follow-up: EWL(%): 63.9 vs 43.9 (p<.05) BMI: 34.8 vs 40.9 (p<.05)	LRYGB vs LSG: Early complications [<30 days] (%): 9 vs 22 (p=.217) No mortalities	Mexico 2010-2012

*Laurenius 2010, O'Rourke 2006, Prachand 2006, Topart 2013 not abstracted; included in Hedberg 2014

Data Abstraction of RCTs

Author Year N	Follow-up	Patient Characteristics	Intervention(s)	Efficacy/Effectiveness Outcomes	Harms	Setting; Timeframe
Risstad 2015[14] 60	5 yrs.	RYGB vs DS Mean age: 35.2 vs 36.1 Male (%): 26 vs 34 BMI: 54.8 vs 55.2 T2DM (%): 16 vs 21 Hypertension: 26 vs 28 Dyslipidemia (%): 77 vs 83 Sleep apnea (%): 16 vs 21 Metabolic syndrome (%): 65 vs 79 No significant differences	RYGB, DS	RYGB vs DS 5-year follow-up: BMI change: -13.6 vs -22.1 (p<.001) Metabolic syndrome (%): 11.1% vs 3.6 (P=.28)	RYGB vs DS 30 days to 5-year follow-up: Mean adverse events per patient: 1.7 vs 2.7 (p=.09)	Norway & Sweden 2006-2007
Sovik 2013[15] 60	2 yrs.	RYGB vs DS Mean age: 35.2 vs 36.1 Male (%): 26 vs 34 BMI: 54.8 vs 55.2 No significant differences	RYGB, DS	NR	RYGB vs DS: Days w/o defecation: 61 vs 19 (p=.002) Leakage of stool (%): 18 vs 50 (p=.015) DS increased diarrhea and number of daytime defecations compared with GB (P=.0002, p=.007)	Norway & Sweden 2006-2007

* Sovik 2010, Sovik 2011 not abstracted; included in Hedberg 2014

QUALITY ASSESSMENT OF INCLUDED SYSTEMATIC REVIEWS

Author Year	Was an 'a priori' design provided?	Was there duplicate study selection and data extraction?	Was a comprehen-sive literature search performed?	Was the status of publication (*ie*, grey literature) used as an inclusion criterion?	Was a list of studies (included and excluded) provided?	Were the character-istics of the included studies provided?	Was the scientific quality of included studies assessed and documented?	Was the scientific quality of included studies used appropriately in formulating conclusions?	Were the methods used to combine the findings of studies appropriate?	Was the likelihood of publication bias assessed?	Was the conflict of interest stated?	Quality
Hedberg 2014[1]	Can't answer *No info on a priori methods or in-depth inclusion criteria*	Yes	Yes	No	No *Only included studies provided*	Yes	No *Only include notes on missing details in the included studies*	No	Yes	Yes	Yes	Fair.

QUALITY ASSESSMENT OF INCLUDED PRIMARY STUDIES

Quality Assessment of Observational Studies

Author Year	Risk of selection bias? (High, medium, low)	Risk of performance bias? (High, medium, low)	Risk of attrition bias? (High, medium, low)	Risk of detection bias? (High, medium, low)	Risk of reporting bias? (High, medium, low)	Overall risk of bias (High, medium, low)
Arterburn 2015[2]	Medium *Comorbidities identified using ICD-9 codes, which don't account for severity*	Medium *Lacked data on self-efficacy, diet and exercise*	Low for 1-year and 5-year analyses Medium for 14-year analysis *Censoring for unknown reasons was 56% in surgical group and 45% in control group*	Medium *Comorbidities identified using ICD-9 codes, which can be inaccurate*	Low	Medium
Bowne 2006[3]	Medium *Balanced at baseline for age, sex, BMI, and comorbidities except dyslipidemia (higher in LRYGB), no other statistical approaches used, no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Low *Loss to follow-up 9-16%*	Low	Low	Medium
Daigle 2015[4]	High *Unclear, baseline characteristics reported for whole group, but not for each surgery, no other statistical approaches used, no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Medium *Loss to follow-up 16.7% at 1 year, 40% at 2 years, 53.3% at 3 years*	Low	Low	High

Author Year	Risk of selection bias? (High, medium, low)	Risk of performance bias? (High, medium, low)	Risk of attrition bias? (High, medium, low)	Risk of detection bias? (High, medium, low)	Risk of reporting bias? (High, medium, low)	Overall risk of bias (High, medium, low)
Giordiano 2015[5]	High *No control for comorbidities (presence of at least one comorbidity 91.1% vs 74.7%), no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Low *Loss to follow-up 7.5%*	Low	Low	High
Heneghan 2014[6]	Medium *Balanced at baseline for age, sex, BMI, and comorbidities except dyslipidemia and %super-obese (higher in banded), no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Medium: *Loss to follow-up 39%*	Low	Low	Medium
Laurenius 2010[16]	Medium *Balanced at baseline for age, sex, BMI, and comorbidities (T2DM, sleep apnea), no other statistical approaches used, no info on smoking*	Medium *Differences in energy intake postop, no data on exercise or other potential co-interventions*	Low *Loss to follow-up 7.6-15.8%*	Low	Low	Medium
Mognol 2005[7]	High *Balanced at baseline for age, more males and higher baseline BMI in LRYGB group, no other statistical approaches, no info on comorbidities or smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Medium *No clear data on follow-up*	Medium *No info on methods of outcome assessment*	Low	High

Author Year	Risk of selection bias? (High, medium, low)	Risk of performance bias? (High, medium, low)	Risk of attrition bias? (High, medium, low)	Risk of detection bias? (High, medium, low)	Risk of reporting bias? (High, medium, low)	Overall risk of bias (High, medium, low)
Nelson 2012[8]	High *Imbalanced at baseline (DS higher BMI, more comorbidities), no other statistical approaches used, no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	High *Loss to follow-up 72% at 1 year, 97% at 2 years*	Medium *Blinding of assessors unknown; unknown exactly how tracking data (especially demographic) are collected reliably and validly*	Low	High
O'Rourke 2006[17]	Medium *Imbalanced at baseline for BMI (DS more super obese), multivariate logistic regression including age and BMI, no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Low *No missing data*	Low	Low	Medium
Parikh 2005[9]	High *Balanced at baseline for age and BMI, BPD group fewer males (10% vs 22-30%) and African Americans (5% vs 11-14%), no other statistical approaches used, no info on medical or psychiatric comorbidities or smoking*	Medium *No data on diet, exercise, other potential co-interventions*	High *Loss to follow-up 13-24% at 1 year, 24-77% at 2 years, 28-46% at 3 years*	Low	Low	High
Prachand 2006[18]	High *Balanced at baseline for age and sex, imbalanced for weight and BMI (DS higher), no info on comorbidities or smoking, no other statistical approaches used*	Medium *No data on diet, exercise, other potential co-interventions*	Medium *Loss to follow-up 51.8-55.3 at 3 years*	Low	Low	High

Author Year	Risk of selection bias? (High, medium, low)	Risk of performance bias? (High, medium, low)	Risk of attrition bias? (High, medium, low)	Risk of detection bias? (High, medium, low)	Risk of reporting bias? (High, medium, low)	Overall risk of bias (High, medium, low)
Roland 2011[10]	Medium *Balanced at baseline for age, sex, BMI and comorbidities, no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Medium *No clear data on follow-up*	Low	Low	Medium
Sekhar 2006[11]	High *Unclear, subgroup baseline characteristics NR, imbalances reported for overall group (LRYGB group more females and lower baseline BMI) without any statistical adjustment, no info on comorbidities or smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Low *Loss to follow-up 16-21%*	Low	Low	High
Serrano 2015[12]	Medium *Balanced at baseline for age, sex, BMI, race, and comorbidities, no other statistical approaches used, no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	High *Loss to follow-up 60-76% at 1 year*	Low	Low	High
Topart 2013[19]	High *Balanced at baseline for age, gender, and BMI, imbalanced for comorbidities (sleep apnea, hypertension, presence of multiple comorbidities higher in DS), no other statistical approaches used, no info on smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Medium *Loss to follow-up 33%*	Low	Low	High

Author Year	Risk of selection bias? (High, medium, low)	Risk of performance bias? (High, medium, low)	Risk of attrition bias? (High, medium, low)	Risk of detection bias? (High, medium, low)	Risk of reporting bias? (High, medium, low)	Overall risk of bias (High, medium, low)
Zerrweck 2014[13]	Medium *Balanced at baseline for diabetes, hypertension or dyslipidemia at baseline, LRYGB group more females (96% vs 55%), analysis by gender showed no differences, no other statistical approaches used, no info on medical or psychiatric comorbidities or smoking*	Medium *No data on diet, exercise, other potential co-interventions*	Medium *Loss to follow-up 25-33%*	Medium *No info on methods of outcome assessment*	Low	Medium

Quality Assessment of RCTs

Author Year Country	Adequate sequence generation?	Adequate allocation concealment?	Blinding of participants, personnel and outcome assessors?	Formal assessment of adequacy of the blind?	Incomplete outcome data adequately addressed?	Study reports free of suggestion of outcome reporting bias?	Study free of other sources of bias?	Risk of bias?
Sovik 2010[20] *Sovik 2011[21]* *Sovik 2013[15]* *Risstad 2015[14]* *(Studies report on single trial)* *Norway/ Sweden*	Yes	Yes	No *Doctors and patients un-blinded*	Unknown	Yes *Loss to follow-up 3% at 1 year, 4.9% at 2 years, 8% at 5 years*	Yes	No *Surgeons have greater experience w/ GB than DS*	Low

STRENGTH OF EVIDENCE FOR INCLUDED STUDIES

Strength of Evidence for KQ2

SOE Grade	Study Design: No. Studies (N)	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Mortality: Baseline to 1 year								
Low	1 (2860)[2]	Medium (post-hoc subgroup analysis of retrospective cohort)	Indirect (vs usual care)	Unknown	Precise; OIS=2490	Undetected	None	Increased risk with surgery: 4.93% vs 2.77% (HR 1.57; 95% CI, 1.08-2.76)
Mortality: >1 to 5 years								
Low	1 (2423)[2]	Medium (post-hoc subgroup analysis of retrospective cohort)	Indirect (vs usual care)	Unknown	Precise	Undetected	None	Decreased risk with surgery: 5.48% vs 11.4% (HR 0.46; 95% CI, 0.33-0.64)
Mortality: > 5 to 14 years								
Low	1 (2054)[2]	Medium (post-hoc subgroup analysis of retrospective cohort)	Indirect (vs usual care)	Unknown	Precise	Undetected	None	Decreased risk with surgery: 9.5% vs 17.5% (HR 0.45; 95% CI, 0.34-0.60)

Strength of Evidence for KQ3

Duodenal switch versus gastric bypass

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Long-term outcomes								
Low	1 RCT (N=55)[14]	Low; good-quality RCT	Direct	Unknown	Imprecise	Undetected	None	% patients with BMI > 40: DS=14% vs GB=55.3%, *P*=0.001 Diabetes remission: 100% vs 80%; *P*=0.45 Mortality: 3% vs 0%; *P*=0.48 Patients with surgeries related to the initial procedure: 45% vs 10%; *P*=0.002 Patients with hospital admissions: 59% vs 29%; *P*=0.02
Short-term outcomes								
Leak in retrospective studies: low-strength of more leaks with duodenal switch	2 retrospective studies (N=632)[17,19]	Medium (retrospective studies with medium ROB)	Direct	Consistent	Precise	Undetected	None	7.3% vs 2.2%; OR 3.41 (95% CI, 1.45, 8.02)

Gastric bypass versus gastric banding

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
%EWL: 6mo – 3yr								
Low	Retrospective cohort: 4 studies (909)[3,5,7,9]	High (retrospective studies with medium-high RoB)	Direct	Consistent	Imprecise	Undetected	None	Increased %EWL with LRYGB vs LAGB (range 44.75% vs26.2% at 6 mo. to 56.8% vs 49.5% at 3 yr)
Mortality: 12mo - 3yr								
Low	Retrospective cohort: 3 studies (728)[3,7,9]	High (retrospective studies with medium-high RoB)	Direct	Consistent	Imprecise	Undetected	None	No difference in 12mo-3yr mortality with LRYGB vs LAGB (range 0-0.9% vs 0-1.7%)
% early complications (<30 days)								

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Medium RoB								
Low	Retrospective cohort: 1 study (106) [3]	Medium	Direct	Unknown	Imprecise	Undetected	None	No difference in early complications with LRYGB vs LAGB (range 17 vs 18%)
High RoB								
Low	Retrospective cohort: 3 studies (803)[5,7,9]	High (retrospective studies with high RoB)	Direct	Consistent	Imprecise	Undetected	None	Higher early complications with LRYGB vs LAGB (range 9.9-17.65% vs 2.8-10.12%)
% late complications (≥30 days)								
Low	Retrospective cohort: 2 studies (396)[3,7]	High (retrospective studies with medium-high RoB)	Direct	Consistent	Imprecise	Undetected	None	Decreased late complications with LRYGB vs LAGB (range 16.2-28% vs 24.6-78%)
Prevalence of comorbidities at follow-up (median 16.2mo)								
Low	Retrospective cohort: 1 study (106) [3]	Medium	Direct	Unknown	Imprecise	Undetected	None	Lower prevalence of type 2 diabetes (0% vs 11%, p=0.05) and sleep apnea (8% vs 31%, p=0.01) at follow-up with LRYGB vs LAGB. No difference in hypertensions, dyslipidemia, asthma, or arthritis at follow-up.
Elderly (≥ 65 years)								
%EWL								
Insufficient	Retrospective cohort: 1 study (30)[4]	High (retrospective study with high RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	Higher %EWL with LRYGB vs LAGB (54.1% vs 26.2%) Statistical significance NR.
% early complications (<30 days)								
Insufficient	Retrospective cohort: 1 study (30)[4]	High (retrospective study with high RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	No difference in early complications (<30 days) with LRYGB vs LAGB (12.5% vs 12.5%)

Gastric bypass versus sleeve gastrectomy

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
%EWL: 6-12mo								
Low	Retrospective cohort: 1 study (77)[13]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	Increased 6-12mo %EWL with LRYGB vs LSG (51.6% vs40% at 6 mo., p<0.05 and 63.9% vs 43.9% at 12 mo., p<0.05)
Mortality: 12mo								
Low	Retrospective cohort: 1 study (77)[13]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	No deaths reported in either group
% early complications (<30 days)								
Low	Retrospective cohort: 1 study (77)[13]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	No difference in early complications with LRYGB vs LSG (9% vs 22%, p=0.217)
Super super obese (BMI > 60 kg/m^2)								
%EWL Success: > 30% EWL								
Low	Retrospective cohort: 1 study (135)[12]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	No difference in %EWL success(>30% EWL) with LRYGB vs LSG (28.95% vs 25% at 3 mo., 72.22% vs 59.09% at 6 mo., 94.59% vs 100% at 1 year)
% complications								
Low	Retrospective cohort: 1 study (135)[12]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	Higher complications with LRYGB vs LSG (15.1% vs 4.8%). Statistical significance NR
Elderly (≥ 65 years)								
%EWL								
Insufficient	Retrospective cohort: 1 study (30)[4]	High (retrospective study with high RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	No difference in %EWL with LRYGB vs LSG (54.1% vs 48.3%) Statistical significance NR.
% early complications (<30 days)								

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Insufficient	Retrospective cohort: 1 study (30)[4]	High (retrospective study with high RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	Lower early complications (<30 days) with LRYGB vs LSG (12.5% vs 33.3%)

Surgical technique comparisons

Banded versus non-banded gastric bypass

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
%EWL: 2 yr								
Low	Retrospective cohort: 1 study (268)[6]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	Increased 2yr %EWL among super-obese with banded vs non-banded LRYGB (57.5% vs47.6%, p=0.003)

Laparoscopic vs open gastric bypass

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
%EWL: 2 yr								
Insufficient	Retrospective cohort: 1 study (967)[11]	High (retrospective study with high RoB)	Direct	Unknown	Unknown	Undetected	None	No difference in 2 year %EWL between surgical groups (62% laparoscopic vs 67% open., BMI 51-60; 75% laparoscopic vs 65% open, BMI >61 [estimated from Figure 1])
Mega obese (BMI>70)								
%EWL: 3mo-2yr								
Low	Retrospective cohort: 1 study (89)[10]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise	Undetected	None	Increased 3-6mo %EWL with laparoscopic vs open gastric bypass (22.7% vs 17.5%, p=0.016 at 3mo; 37.6% vs 30.8%, p=0.037 at 6mo). No difference in % EWL between surgical groups at 1 and 2 years (%s not reported)
Mortality: 30 day								

SOE Grade	Study Design: No. Studies (N)	Study limitations	Directness	Consistency	Precision	Reporting Bias	Other Issues	Findings
Low	Retrospective cohort: 1 study (89)[10]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	One death reported in open surgery group vs no deaths reported in laparoscopic group.
% complications								
Low	Retrospective cohort: 1 study (89)[10]	Medium (retrospective study with medium RoB)	Direct	Unknown	Imprecise (small sample size)	Undetected	None	Increased hernia with open surgery (19% vs 3%, p=0.02). No differences in any other complications between surgical groups.

PEER REVIEW COMMENTS TABLE

Comment #	Reviewer #	Comment	*Author Response*
Are the objectives, scope, and methods for this review clearly described?			
1	1	Yes	*None*
2	2	Yes	*None*
3	3	Yes	*None*
4	4	Yes	*None*
5	5	Yes	*None*
6	6	Yes	*None*
7	7	Yes	*None*
8	8	Yes	*None*
Is there any indication of bias in our synthesis of the evidence?			
9	1	No	*None*
10	2	No	*None*
11	3	No	*None*
12	4	No	*None*
13	5	No	*None*
14	6	No	*None*
15	7	No	*None*
16	8	No	*None*
Are there any published or unpublished studies that we may have overlooked?			
17	1	Yes - It isn't clear how they searched for barriers studies and whether barriers to bariatric surgery in general are informative -- there was a recent systematic review of barriers in JAMA surgery http://www.ncbi.nlm.nih.gov/pubmed/26222655 although it isn't particularly informative.	*Added details of barriers search to Methods section and full strategy is available in Supplemental materials. Added Funk 2015 JAMA systematic review of barriers.*
18	2	No	*None*
19	3	No	*None*
20	4	Yes - Recently published studies: 1) A cohort study of 135 patients with BMI>60 kg/m2 comparing results of bypass vs sleeve (Serrano OK et al., SurgEndosc. 2015 Aug 25.Epub ahead of print). Non-VA population. 2) Outcomes in super obese elderly (BMI>50 kg/m2, Age>65 years). Cohort of 30 patients. Weight loss success and diabetic medication reduction compared between bypass vs sleeve vs band. (Daigle CR, et al., SurgObesRelat Dis. 2015 Apr 15 Epub ahead of print). Non-VA population.	*Added to synthesis under KQ3*

21	5	No	*None*
22	6	No	*None*
23	7	Yes - I made some suggestion in my comments.	*Addressed in additional comments*
24	8	Yes: Obes Surg. 2010 Feb;20(2):173-80. doi: 10.1007/s11695-009-0001-x. Epub 2009 Oct 28	*Added to Introduction to introduce the concept that presurgical requirements, such as substantial preoperative weight loss, may be an area to explore to improve bariatric surgical outcomes in the super obese.*
Additional suggestions or comments can be provided below. If applicable, please indicate the page and line numbers from the draft report.			
25	1	The report provides a clear and concise overview of the literature. ITs methods are sounds and the description complete. I have only a few comments/questions: One additional reason to consider super obese separately is the assumption that there is a higher prevalence of mental health issues/severe eating disorders in this group than in obese which may affect outcomes. Is there any evidence on that?	*Although we didn't find any evidence on prevalence of mental health disorders specific to the super obese subpopulation, we did find a study by Petry and colleagues from 2008 that demonstrated that the odds of mood, anxiety, and personality disorders have been shown to increase by 3% for each one BMI unit increase (95% confidence interval range, 1.02 to 1.04). We added this to the Introduction.*
26	1	It would seem that the major concern about the cohort studies comparing surgery to usual care in super obese would be confounding by indication, namely that the non-surgery group would include some patients felt not to be surgical candidates due to life-threatening conditions. The description of those studies don't say enough about whether matching would have eliminated patients with severe CHF, pulmonary problems, severe CAD, etc. which would skew mortality results. Matching just on presence of conditions would seem prone to residual confounding. THis seems more important to call out than references to missing data on smoking status, or surgical volume.	*Added text to better emphasize this point:* *"information from administrative data about many key covariates was either unavailable or missing, including severity of comorbid conditions and smoking. We can't rule out the possibility that the greater mortality risk factors characteristic of surgical ineligibility were overrepresented in the nonsurgery group."*
27	1	The comparisons between duodenal switch and REYGB state "their findings (of higher complications w DS) were more likely due to the more severe underlying disease at baseline than the gastric bypass group (Table 4).45" However, no data are provided to support that assertion that risk was higher.	*Added data: However, as BOLD did not use any methods to account for important confounding, the poorer outcomes in the duodenal switch group were more likely due to their worse congestive heart failure (CHF class 1=2.3% vs 1.4%, 2=1.4% vs 0.6%, 3=0.5% vs 0.3% and 4=0 vs 0.1, overall=4.2% vs 2.4%; P<0.001), hypertension (63.4% vs 60.2%; P=0.01) and obstructive sleep apnea (60.5% vs 47.8%; P<0.001) than in the gastric bypass group (Table 4).[45]*

28	1	%EWL as an outcome doesn't seem to make sense unless groups being compared are of comparable starting weight. If two groups lose same absolute amount of weight, the group starting at a lower weight will always have a higher %EWL. So unless groups are shown to be comparable at baseline this outcome seems problematic. there was one case on p. 14 comparing LGBP to LSG where this seems to have happened.	*Yes, per the Hatoum and Kaplan 2013 publication in Obesity, we preferred the percent baseline weight loss as it was shown to be the lease associated with preoperative BMI. But, this was not reported in the LGBP vs LSG study you are referencing (Zerrweck 2014). As both weight loss outcomes Zerrweck 2014 reported, BMI change and %EWL are equally sensitive to preoperative BMI, we selected %EWL as it was most commonly reported and allowed for comparison across studies.*
29	4	This is a thorough, well written and well organized review of the available evidence for bariatric surgery in the super obese population. Nonsurgical treatments of obesity are increasingly utilizing pharmacotherapy, however this was not mentioned in the review. If this is due to an absence of data, then this should be explicitly stated.	*Yes, we looked for evidence comparing bariatric surgery to lifestyle, dietary changes, and pharmacotherapy, but didn't find any evidence. Added explicit mention to the Executive Summary of the different nonsurgical interventions of interest.*
30	4	In considering the comparative effectiveness of different bariatric surgery treatments, the question of the likelihood for conversion from laparoscopic to open in the super obese population should be addressed.	*Added this to the list other important outcomes that our time frame could not accommodate*
31	4	As the authors point out in the summary, "nonsurgical treatment provided to the controls was poorly defined...". It is further unclear, however, whether a distinction is being made between "nonsurgical treatment" and "no treatment".	*Changed to: "However, the care, nonsurgical or no treatment, provided to the control group was not well defined"*
32	4	Page 4/Line 6: "present" should be "percent"	*Changed*
33	4	Pg 13/Line 34: "super morbidly obese" should be "super obese"	*Changed*
34	4	Pg 14/Line 27: "Laparoscopic Gastric Bypass (LGBP)" should be "Laparoscopic Roux-en-Y Gastric Bypass (LRYGB)" in order to remain consistent.	*Changed*
35	4	Pg 15/Line 42: "Open Laparoscopic Gastric Bypass" should be "Open Gastric Bypass"	*Changed*

36	5	For full disclosure, my team and I have nearly completed a comparison of 10-year weight change between RYGB patients and matched controls (subset from the 2015 mortality paper in JAMA) and a comparison of 4-year weight change between RYGB, LSG and LAGB patients. We hope to submit for SQDUG review by November 1. Before giving point-by-point editorial suggestions, I'd like to note that I disagree with the recommendation in several places to consider surgical volume as an important unobserved confounder. Non-VA work by Dimick and Nicholas has shown that surgical volume is not associated with patient outcomes and CMS stopped using center of excellence certification on the basis of their work, so think it would be more defensible to drop that or downplay it.	*We thank the reviewer for directing us to the work of Dimick and Nicholas showing that surgical volume is not associated with patient outcomes. We have dropped this criticism.*
37	5	1st paragraph of Exec Summ: Add cites to statement about increasing prevalence of super obese and their disproportionate expenditures	*Our Executive Summaries typically do not contain citations. Those statements are replicated in the Background section of the full report along with the supporting citations.*
38	5	4th paragraph of Exec Summ: Maybe start the paragraph with "Non-VA studies" instead of "Studies...". Also, consider adding a comment that DS is the most technically complex of all bariatric procedures for context.	*Done*
39	5	Page 2 of Exec Summ: Name as "VA surgical quality improvement program" and add "(VASQIP)" to note its formal name.	*Done*
40	5	Page 2 of Exec Summ, 5th point in list of features: (5) identify whether there is....	*Done*
41	5	Page 2, Table 1: note that short term is < 5 years and long term is > or = 5 years	*Done*
42	5	Page 3 in Evid Brief: According to NCP stats, 40.7% of VA users were obese in FY13. Might add that to paragraph in Purpose section.	*Added*
43	5	Page 3 in Background: state that these 4 procedures are the ones that are "currently performed"	*Done*
44	5	Page 4 of Evid Brief: Summary of costs associated with super obesity might want to cite Arterburn, Maciejewski &Tsevat 2005 too. Highest BMI we looked at is class III, which isn't exactly the same.	*Added*
45	5	Page 5, Elig Criteria: How many studies were excluded due to having a mean or median BMI > 50?	*None – we didn't identify any new primary studies with mean or median BMI > 50*
46	5	Page 5, Comparator in EligCrit: Want to add "usual care" to comparators?	*Added*
47	5	Page 5, Outcomes in EligCrit: change "disease remission/resolution" to "remission/resolution of physical and mental health conditions". That gives MH conditions an explicit acknowledgement, which is appropriate since it is increasing in visibility in recent years.	*Done*

48	5	Page 10, detailed analysis, last paragraph: change "information about many key covariates was missing" to "information from administrative data about many key covariates was either unavailable or missing"	*Done*
49	5	Page 13, summary bullet: change "increased" to "greater" and "and lower..." to ", fewer long-term" and change "with no" to ", and no"	*Done*
50	5	Page 13, last full sentence at bottom: state time frame of 52% vs 31% %EWL. It is critical to be crystal clear about timeframe for outcome results.	*Added*
51	5	Page 14: change "lack of data or control for" to "lack of data for"	*Done*
52	5	Page 15, summary bullet: Change "increased %EWL" to "greater %EWL at 2 years"	*Done*
53	5	Page 17, summary: Move last sentence about no studies for RQ1 after first sentence starting "Table 5 below summarizes...."	*Done*
54	5	Page 17, summary: change "poorly defined" to "not well defined"	*Done*
55	5	Page 17, summary: chance "expense of more complications" to "expense of more complications because DS is a technically complex procedure."	*Added 'potentially due to its greater technical complexity'*
56	5	Page 18: change "other outcomes that also can have..." to "other outcomes (e.g., depression, substance abuse) that also can have..."	*Done*
57	5	Page 19, Population under KQ2: Consider dropping mention of surgeon experience	*Done*
58	5	Page 19, comparator under KQ2: Note that matching on MOVE! participants requires restriction of sample to 2006 when MOVE! started. We debated doing this in our work, but wanted to examine as many surgical patients as possible.	*Added*
59	5	Page 19-20, study design under KQ2: Since you are suggesting non-randomized studies like the ones we've been doing, it is important to note that people should "address as many threats to internal validity as possible to minimize the risk of bias from these studies".	*Added: "However, as such observational studies are inherently subject to greater risks of bias, they must be carefully designed and executed to address as many threats to internal validity as possible."*
60	5	Page 20, KQ3, outcomes: See Berthauer SA and colleagues' paper from April 2015 in Obesity Surgery that calls for standardized reporting of outcomes. Could cite that here. Note that there is controversy about what the best/least biased weight outcome is (see Hatoum& Kaplan 2013 paper in Obesity for discussion).	*We thank the reviewer for these helpful citations and we have added them.*
61	6	Overall I think the report is fair. I found the writing to be choppy but I realize that it is a draft. I think that the writing should be geared to a manager's needs.	*Executive Summary was revised by our Editor to improve readability.*

62	7	The report states that there is a lack of evidence of the risks and benefits of bariatric surgery in patients with BMI >50, which I would respectfully argue is not the case. The majority of studies looking at the comparative effectiveness of surgery vs non-surgery includes those patients (BMI >35), usually with a mean BMI of 47-49 kg/m2 with standard deviation of 8-10. So limiting the summary of evidence to studies that separate out the subgroup neglects much of the available data, in my opinion. It is much different issue than assessing the low BMI patients (BMI 30-35), as they weren't included in the standard bariatric studies. In fact, the way the report's conclusions are written the authors challenge the appropriateness of doing these procedures in this weight range (BMI>50), which concerns me and is not, in my opinion, supported by the data. To further explain, BMI ">50" issue is a somewhat artificial threshold. BMI is a continuous variable and, as mentioned, most bariatric studies report a mean BMI of around 47-49 with some standard deviation, and these studies report benefits in terms of weight loss and control of comorbidities. Consider an example, if the mean BMI was around 47, then likely a substantial proportion, like 30%, that had a BMI over 50. How likely is that the results for these 30% (or whatever) are clinically different than for the included 70%? Therefore these studies would have included xx% of their patients with a BMI over than 47-49. Then one would need to assess how different the results would have needed to be in that proportion of patients such that their results would have been clinically different than the main study population. Seems important to include this literature in the assessment of BMI > 50 patients – as they are in these studies. The authors only list one VA study for key question #2 about the comparative effectiveness of surgery versus non-surgical treatment. Unless the main goal was to limit only to the VA population, then I don't believe this gives the large amount of data on this topic its credit. If you change this key question to focus only on the VA patient population, then that is a different situation, but I didn't read the report as such. (And key question #3 assesses primarily non-VA population studies, so that would be inconsistent). Also, as the authors are aware, the VA patient population for bariatric surgery lacks some generalizability to the non-VA population – in terms of gender (>80% of patients in the general bariatric population are women) and comorbidities (VA patients have more comorbidities). However, the VA has adopted the standard NIH criteria for appropriateness criteria for receipt of these operations. And when there is lack of evidence in direct VA patients, the non-VA studies are still reasonable to consider.	*No, our conclusion was not meant to challenge the appropriateness of the bariatric surgery in patients with BMI > 50. Our objective was to evaluate studies that exclusively focused on the super obese or separated out the subgroup to determine the most precise estimates in this subpopulation. We concluded that there is limited evidence exclusively focused on the super obese. But this does not say anything one way or another about the applicability of the large body of studies with broader populations of patients with BMI > 35 that included a proportion of patients with BMI > 50, but for which subgroup analyses were not provided. We added a statement to the Discussion to clarify this. We also added a statement that the best way to most definitively answer the question about the applicability of the large body of broader obesity literature would be to do an individual patient data meta-analysis.* *We agree that non-VA studies are reasonable to consider and we did so for this review. For Key Question 2, though, about the comparative effectiveness of surgery versus non-surgical treatment, we did not find any non-VA studies that focused exclusively on super obese patients or provided a subgroup analysis.*

		While the constraints of time and resources for these reports are limited, I would encourage the authors to find a way to include some of the comparative effectiveness literature on surgical vs non-surgical treatment – even when the subgroup analyses was not provided. One option would be to select the handful of highest quality studies with reasonable follow-up – then determine the percent of the patients falling in with BMI>50 and perform a stepwise analyses to determine if that group had no effect in terms of weight loss from the surgery, would the overall finding still have been positive. Or the authors may have other options for assessing the impact on this BMI group.	
63	7	Also, there is the general observation that in most interventional procedures, whether surgery or PTCA or whatever, what has normally been found when it has been looked for is that the patients who are more severely affected by the disease gain more, not less, than less severely affected patients, although at a cost of higher peri-op complications. This is likely the same relationship for bariatric surgery. There are studies showing that the higher the starting BMI, the greater the weight loss, for example (usually as a continuous variable).	*Agreed. However, the weight loss, durability and complications are variable and more research is needed to identify predictors of the most favorable balance of benefits and harms in this population.*
64	7	The use of EWL as the main outcome of interest in the report is arguably not the best to assess weight loss. The bariatric literature has transitioned to instead use change in BMI and kg weight lost, and EWL has taken more of a back seat. EWL relies on the ideal weight tables which are not the best estimates, especially for these obese patients. This should be reconsidered. Maybe the authors could consider using in addition change in BMI or kg for certain sections/main points (and not have to completely redo their data/tables).	*Agreed. Added change in BMI or kg.*
65	7	The authors didn't address the differences in the range of patients that "BMI>50" includes. This patient population is quite diverse group in comparison to the BMI 35-49, for example. A patient with a BMI of 51 compared to BMI of over 60 are very different in terms of operative risk and but also benefit. The authors should comment and at least introduce this difference at least in the introduction or discussion, perhaps.	*Added reference to super super obese in Introduction.*

66	7	The authors claim that for answering the key question #1 on barriers to access of bariatric surgery for high BMI patients that there is no data. Think it may be reasonable to at least provide some information on this topic, even if it is not directly on target. There are several papers on barriers to access for bariatric surgery in general and then state that they didn't separate out the high BMI patients. Something to consider, and again, this could go in the discussion section if they didn't want to add it to the results. There is a recent review by Funk et al that describes provider and patient level barriers. And higher BMI is associated as being a barrier. (Funk LM, Jolles S, Fischer LE, Voils CI. Patient and Referring Practitioner Characteristics Associated With the Likelihood of Undergoing Bariatric Surgery: A Systematic Review. JAMA Surg. 2015 Jul 29). It also wasn't entirely clear to me whether the question was interested in patient, system, provider or insurance level access barriers, so it might be helpful to first clarify the question a bit more.	*We added clarification to our Key Questions that we were interested in patient, system, and provider barriers and we added Funk 2015 to Key Question 1.*
67	7	The sentence starting at line 60 (page 3) that continues onto page 4 is not clear. The authors comment here about studies showing less weight loss in the higher BMI patients, but no references are provided. There are studies showing the opposite direction – greater weight loss with higher preop BMI. But, regardless, one can still make a strong case that a significant amount of weight loss in these patients can be beneficial and greatly impact obesity related morbidities. So the benefits are still apparent, even if they are less.	*References are provided in subsequent sentences with specific data: Washington State Health Care Authority. Bariatric Surgery: Final Evidence Report. Institute for Clinical and Economic Review. 2015. And Livhits M, Mercado C, Yermilov I, et al. Preoperative predictors of weight loss following bariatric surgery: systematic review. Obesity Surgery. Jan 2012;22(1):70-89. But, we are agree that benefits may still be apparent at lower weight loss levels and have called for more research to evaluate the correlation between weight loss and longevity and comorbidity resolution to help inform this issue.*
68	7	I struggled with the authors' use of short-term as being less than 5 years. In the literature for bariatric surgery, short-term is referred to typically as 2 years. 2-5 is the gray area. It is hard to call studies with 4 year follow=up "short-term" in my opinion. At the least, in the tables the authors should define these categories, as they aren't standard, in my opinion.	*We added the time frame definition to the tables. We defined 'long-term' as ≥5 years based on the recent NIH Funding Opportunity Announcement # PAR-14-262 for long-term outcomes and noted this in our inclusion criteria.*
69	7	Table 1 is hard to follow. The headings are confusing. Also, this table shows the use of multiple different terms for the procedures. The authors need to correct this throughout the tables and the text. Please have a common abbreviation for gastric bypass, gastric sleeve etc. this table includes comparisons between surgery vs non-surgery and between different procedures, which are very different questions.	*Improved table 1 as suggested*

70	7	One big concern with the bariatric literature is the quality of the studies. Issues of bias and generalizability of the studies should be assessed, such as consecutive versus non-consecutive, single versus multi-institutional, and probably the most important, percent of patient following up at the endpoint (often low for many of these studies). The authors comment that this was done and summarize the findings in the text, but due to its importance they may want to consider a table(s). Both the quality of the individual studies (key questions #2 and #3) as well as the overall GRADE assessment (key question #3). This should be taken into account before pooling data – in my opinion, or should be documented. It was hard to assess the appropriateness of the studies that were pooled together.	*Yes, we are providing a supplemental materials document with our final report that contains tables with all the quality assessments of the individual studies and the GRADE assessments of all the outcomes.*
71	7	As mentioned, I find the use of the short-term category that includes 1-<5 years postoperatively a bit non-standard in the bariatric literature. The authors need to reconsider this grouping and provide justification. Also, as this isn't standard grouping in the bariatric literature, they need to define it better in Table 1. The tables should be able to stand alone such that the reader can understand them almost in isolation from the manuscript. Nowhere in the title of Table 1 does it state that these are the high BMI patients. In only one study listed in the table is the BMI of the study patients provided. It is a hard table to follow and it reviews the authors' main findings. As it is written now it is hard to follow which rows represent single studies or multiple studies. The table has typos "compilations". Some of the cells of the table provide actual data with CIs while others don't.	*We improved Table 1 as noted. We defined 'long-term' as ≥5 years based on the recent NIH Funding Opportunity Announcement # PAR-14-262 for long-term outcomes and noted this in our inclusion criteria.*
72	7	On page 5 of the report, the authors state that they used the AHRQ methods for assessing quality of comparative effectiveness studies, and outline the different domains. But I couldn't find a table that detailed this assessment and how it was performed (I also commented on this earlier). The quality is described briefly on page 8 (but no table). Think it might be helpful to separate out the quality assessment for the one study in key question 2 versus key question 3. Providing a table with the GRADE assessment would be helpful.	*Yes, we are providing a supplemental materials document with our final report that contains tables with all the quality assessments of the individual studies and the GRADE assessments of all the outcomes.*
73	7	Table 2. The order of the studies is odd within the study design categories. Consider ordering by year of publication or follow-up time. It just appears to be a random order currently – beyond just the study design.	*Modified to be ordered by study design, then alphabetical by author*
74	7	I didn't have access to the evidence tables, which would have been helpful to see.	*Yes, we are providing a supplemental materials document with our final report that contains all the evidence tables*
75	7	The use of the term "surgeries" is always odd to me, but some of the high impact journals use it. But my preference would be "operations", but this is a minor point and more of a style issue.	*We appreciate the comment. No change made.*

76	7	Table 6, my assessment of the literature for the over 50 BMI population differs from the authors that are shown in this table (referring to my comments 1-2 at the beginning of this writeup).	*We agree with your comment above that further insight could be gained from evaluating the very large body of existing evidence of broader patient populations of BMI > 35 that include patients with BMI > 50, but that weren't separately evaluated. We added clarification that our conclusions apply only to the evidence from studies that separated out the super obese subgroup. And added the following detail to the Limitations section:* *Also, given our abbreviated time frame, to obtain the most precise estimates of outcomes in the super obese, we focused on studies that exclusively included super obese patients or that separated out the super obese subgroup. However, given more time, further assessment of the very large body of existing evidence of broader patient populations of BMI > 35 could provide additional information about patients with BMI > 50. As many studies that enrolled patients with BMI > 35 included a subgroup of patients with BMI > 50, another option for evaluating the comparative effectiveness of bariatric surgery in the super obese is to use the large body of data from these existing studies to conduct an individual patient data meta-analysis of included patients with BMI > 50.*
77	8	Page 1 line 39- this sentence has a reference to laparoscopic that doesn't make sense: "Laparoscopic gastric bypass generally resulted in greater short-term proportion of excess weight loss (%EWL) than its comparators, particularly when a laparoscopic approach and banded approaches were used"	*Corrected this sentence to read: Laparoscopic gastric bypass generally resulted in greater short-term proportion of excess weight loss (%EWL) than did other procedures, particularly when banding was used.*
78	8	Page 1 line 46 - This statement should be generalized to most of the literature you reviewed: "However, these findings likely have low applicability to Veterans as patients were primarily females in their mid-30's to 40's"	*Agreed and it was meant to do so there as it was referring to all the literature we reviewed for Key Question 3 on the comparison of different bariatric procedures.*
79	8	Page 2 line 8- I think it is important to evaluate the role of preoperative weight loss on the safety of surgery in this high BMI range. The peri operative complications of very large patients are substantial and under reported in the literature. There is a report from the Dallas VAMC where this was investigated. Obes Surg. 2010 Feb;20(2):173-80. doi: 10.1007/s11695-009-0001-x. Epub 2009 Oct 28.	*Added this study to Introduction and added preoperative weight loss to list of covariates to evaluate in future research.*
80	8	I would also add to investigate the success of long term outcomes in this group of patients. They tend to not do very well for some outcomes.	*Yes, we did look for long-term outcomes, but found very little data.*
81	8	Table 1-define short and long term outcomes	*Added*

82	8	Page 3 line 1-provide a reference for the effectiveness of the MOVE program-I am not aware of any high quality evidence showing MOVE's effectiveness and any claim about its effectiveness should be assessed by the same standard being applied for bariatric surgery. I recommend toning down this statement.	*The 'growing evidence about the effectiveness' statement was intended to apply to bariatric surgery and not MOVE. Rephrased sentence to clarify this: Despite substantial investment of resources in the Veteran's Health Administration's (VHA) national MOVE!® weight management program and growing evidence about the effectiveness of bariatric surgery*
83	8	Page 3 Purpose: It would be helpful to provide the actual number of Veterans who have BMI>50	*Added*
84	8	Page 4 line 27 Change inferior outcomes to less than optimal outcomes	*Changed*
85	8	Page 5 Key questions-One of the major issues with surgery in this very high risk group is safety. There should be a key question regarding the operations safety-this is a major shortcoming since one cannot talk about effectiveness without discussing safety	*Comparative effectiveness encompassed the balance of benefits and harms and we included complications in our analysis.*
86	8	Page 5 line 36- The discussion about BMI > 47 is confusing-need to explain why you used a cutoff that is not what the conventional cutoff is for superobese (BMI>50). To add to the confusion,it is stated "did not include studies that had mean or median BMI > 50 kg/m2…" Were studies of the superobese (BMI>50) excluded?	*We changed our criteria to reflect the conventional cutoff of BMI>50 and removed one study (Hedberg 2012) that described its population as super obese but used a cut-off of 48. Now all included studies include populations exclusively with BMI > 50.*
87	8	Page 5 outcomes: In addition to duration of FU - probably should have looked for completeness of FU-The vast majority of bariatric outcomes studies have less than acceptable FU making the results biased nd generally uninterpretable.	*We did evaluate completeness of follow-up as part of our assessment of risk of bias and it is reported in our evidence tables and we added a note about it to the Overview section of the report. We agree that many studies had unacceptable follow-up and this contributed to high risk of bias ratings.*
88	8	Figure 1- It would be nice to add why studies were excluded to the flow diagram	*In our supplemental materials document provided with the final report, we have listed reasons for exclusion for individual studies.*
89	8	Page 10 line20 - although you refer to the study as having a 'poorly characterized' control group-it was matched to the surgery group and is representative of the exact population of patients you are interested in: Veterans receiving care in the VA system. In this regard, the study is highly relevant to the clinical question you are asking-in fact, more so than an RCT since and RCT would impose artificial conditions for both groups that may not be replicated in actual practice. I think this study shows how the average veteran patient does with bariatric surgery in the VA and informs your question nicely.	*Yes, we agree it is highly representative of the Veteran population. What we mean by poorly characterized is that that was no information about the type of care provided in the control group – what type(s) of nonsurgical treatment or no treatment?*

90	8	The evidence characterized as 'low-strength.' Perhaps, but in reference to what question? In the average evidence hierarchy, the study would result in low strength evidence. However, your question, as I understand it, is if bariatric surgery is beneficial for veterans receiving VA healthcare. In this regard, the study provides high quality informative evidence. The study population was drawn from the entire VA system from veterans receiving VA care. What better evidence could you have to answer the question of the benefits of patients getting an intervention and determining if that intervention is effective in the context of the care they actually receive.	*Yes, we agree that the Arterburn 2015 study provides highly direct evidence in terms of the population of interest. But in applying the remaining GRADE criteria, the strength of the evidence was downgraded due to indirectness of comparator (unknown care in the control group), medium limitations to internal validity (lacked data on important covariates), and unknown consistency (single study). These ratings are detailed in the supplemental materials.*
91	8	Page 10 Line 54-Not sure why institutional or surgeon volume is emphasized. These have been shown to not influence surgical outcomes in the VA system.	*Removed based on findings from Dimick 2013 brought to our attention by peer reviewer #5*
92	8	Page 12 Line 14- 'single small study' Did you mean that there is only one study addressing this question or that is was a single institution? Perhaps both-if so, state that since single institution studies may not generalize well-especially for surgical trials where outcomes may be very dependent on surgeon skill. As a general note, it would be worthwhile assessing the studies you looked at for evidence that surgical skill was accounted for.	*We meant that there was only one study addressing long-term outcomes. This study, Risstad 2015, was a two-center RCT that accounted for surgical skill by stratifying by center and using multiple surgeons with similar levels of experience in both surgical procedures. Yes, we agree that surgical skill is worthwhile to assess and we did so.*
93	8	Page 12 Line 29-Leaks and some of the other complications reviewed here are very dependent on surgeon skill-more so than pre op characteristics. This should be discussed and the value of retrospective analyses that don't account for that is questionable.	*Yes, we agree that BOLD's main limitation was that it did not control for any important covariates. We added specific mention of surgeon skill to the list of important confounders that were not addressed.*
94	8	Page 12 Line 34-The BOLD database is an unreliable source of information. It had no real oversight for data entry and a great deal os missing data. I would not rely on findings reported from BOLD.	*We agree that BOLD has high risk of bias and that its findings provide insufficient basis for drawing conclusions.*
95	8	Page 15 line 4- I would carefully assess the completeness and duration of follow-up in this study. In my experience, banded RYGB in frequently complicated by band erosion into the pouch. Unless there is long term complete FU I would discount any study reporting on its outcomes. Similarly, care need to be applied before concluding anything from lap band studies since very long term outcomes were poor related to mechanical complications from the bands.	*Yes, we agree that this study provides only low-strength evidence of short-term benefit of the banded procedure. Follow-up was 61% at two years.*
96	8	Page 17 line 8-Again-rather than emphasize the negatives about the lack of information about controls, it would probably be more useful to emphasize that the results of the study reflect the outcomes that would be expected in the VA system.	*Edited this sentence to be more balanced: Although a main advantage of this study is that it directly reflects outcomes that would be expected in the VA system, the care provided to the control group was not well defined and information about many key covariates was missing.*

97	8	Page 19 Line 50- I would not say that MOVE is no cost-it was not funded, but each medical center that had to implement it had costs associated with running the program. Because it was not funded, each medical center implemented it in any way they could resulting in inconsistent implementation between medical centers.	*We intended this to mean that MOVE was no cost to the patient. But, we remove that descriptor to avoid confusion as it was not pertinent to the point.*

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