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IFSO-EC MBS in Europe: current trends, up-and-coming doubts

Combined Roles of Drugs and MBS in Patients with Obesity

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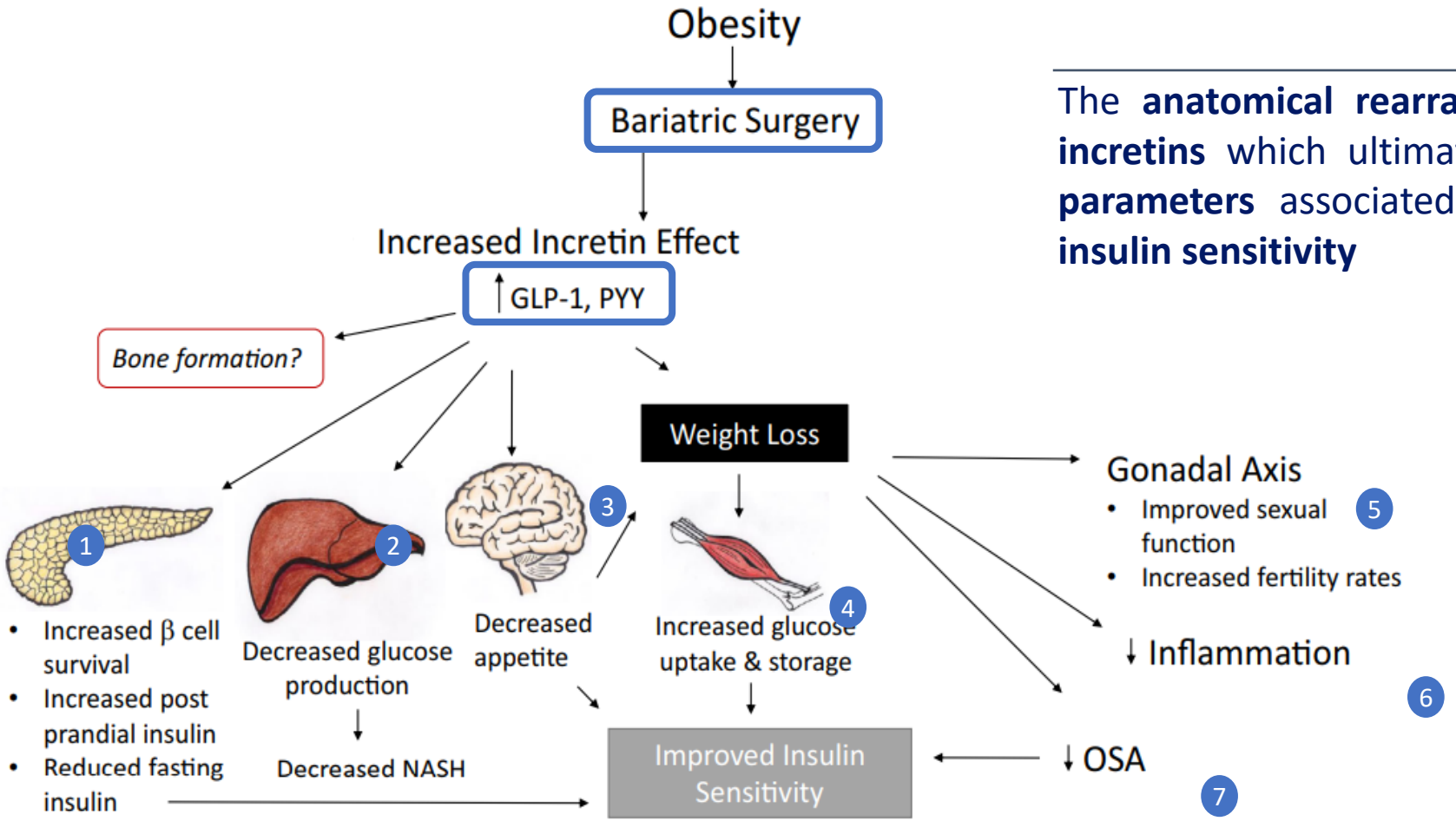
Scientific Committee International Federation for Surgery of Obesity and Metabolic Disorders (IFSO)
Scientific Commitee Italian Society of Obesity (SIO)
Scientific Commitee The Upper Gastrointestinal Surgeons (TUGS)

CONFLICT OF INTEREST DISCLOSURE

I have no potential conflict of interest to report

MBS is the most effective treatment for sustained weight loss in morbid obesity



The **anatomical rearrangements** lead to an **increase in incretins** which ultimately result in **improved metabolic parameters** associated with **weight loss** and **improved insulin sensitivity**

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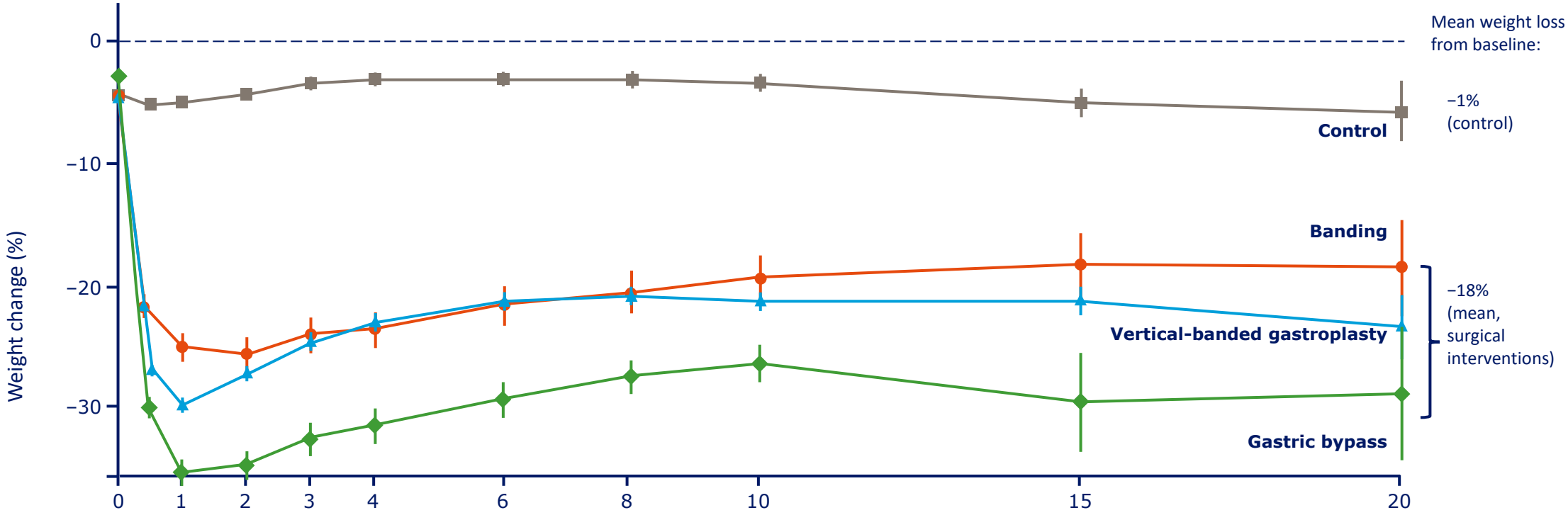
GLP-1, glucagon-like peptide-1; OSA, obstructive sleep apnoea; PYY, peptide YY.

Casimiro I, et al. Physiol Rep. 2019;7(10):e14111.

Benefits of bariatric surgery: sustained weight loss over 20 years

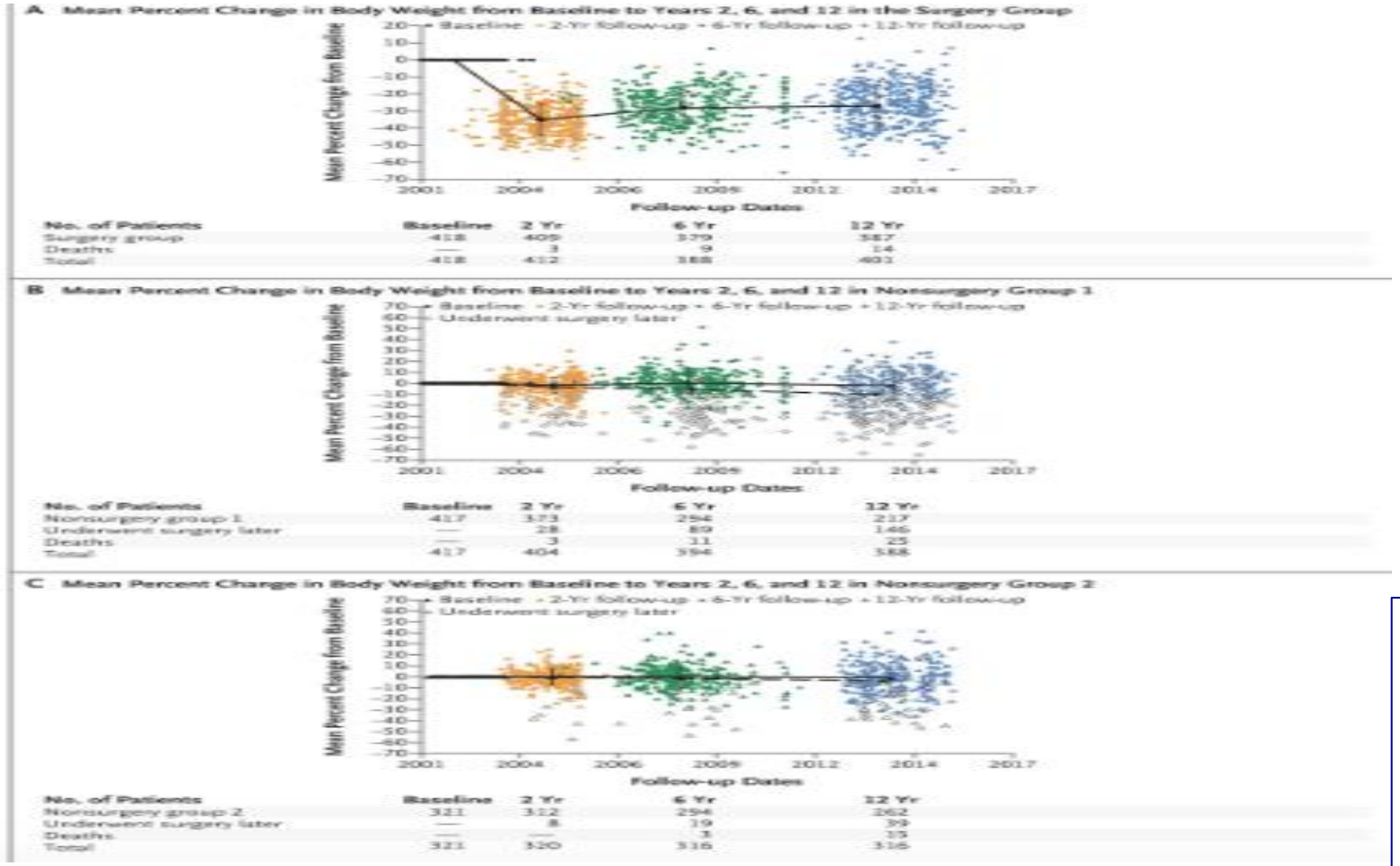
SOS study is a nonrandomized, prospective, controlled study
2010 surgical patients, 2037 matched obese controls who received usual care.
Recruitment: September 1987 and January 2001



Data are mean ±95% confidence interval

Sjöström *et al. JAMA* 2012;307:56–65

Bariatric surgery is associated with variable weight loss outcomes



- Observational prospective controlled study

- 1156 pts
- **12 years follow up**
- 418 pts RYGB
- 417 non surgical group 1 (followed up to obesity clinic)
- 321 non surgical group 2 (followed up to obesity clinic)

Adams *et al. N Engl J Med* 2017;377:1143–55

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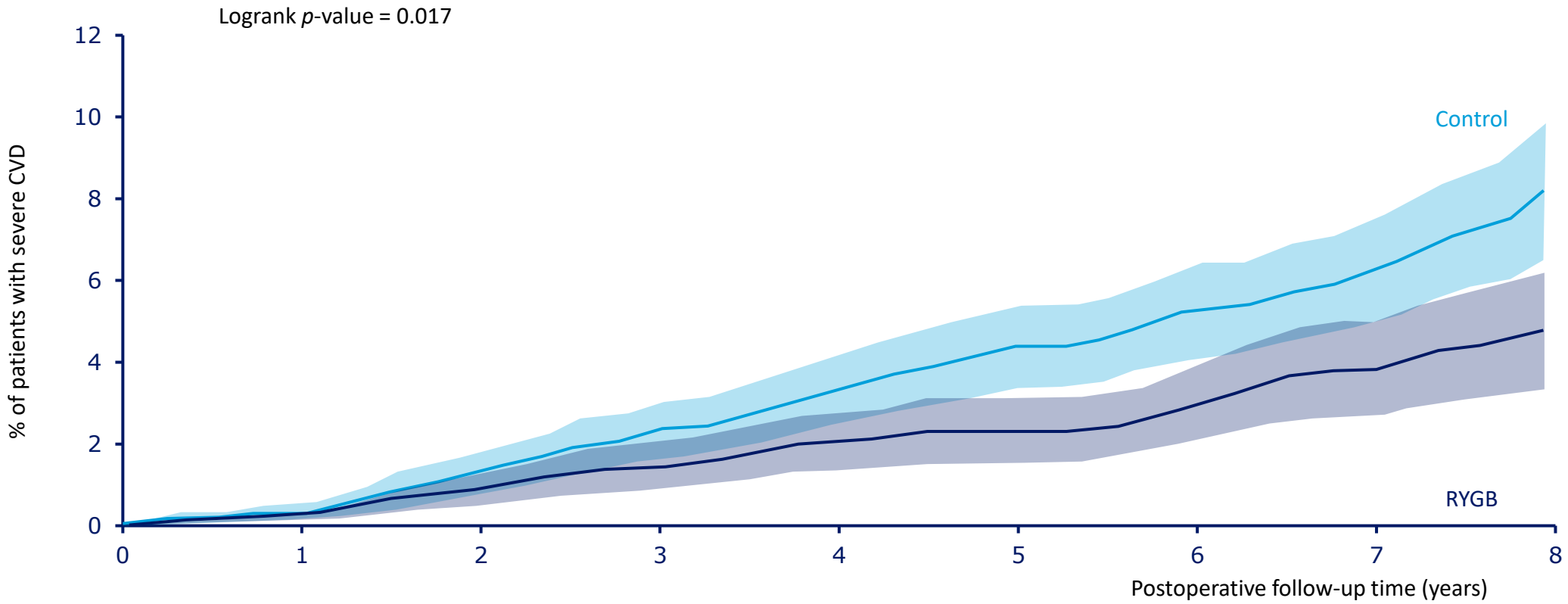
Benefits of bariatric surgery: reduction of the incidence of severe CVD events

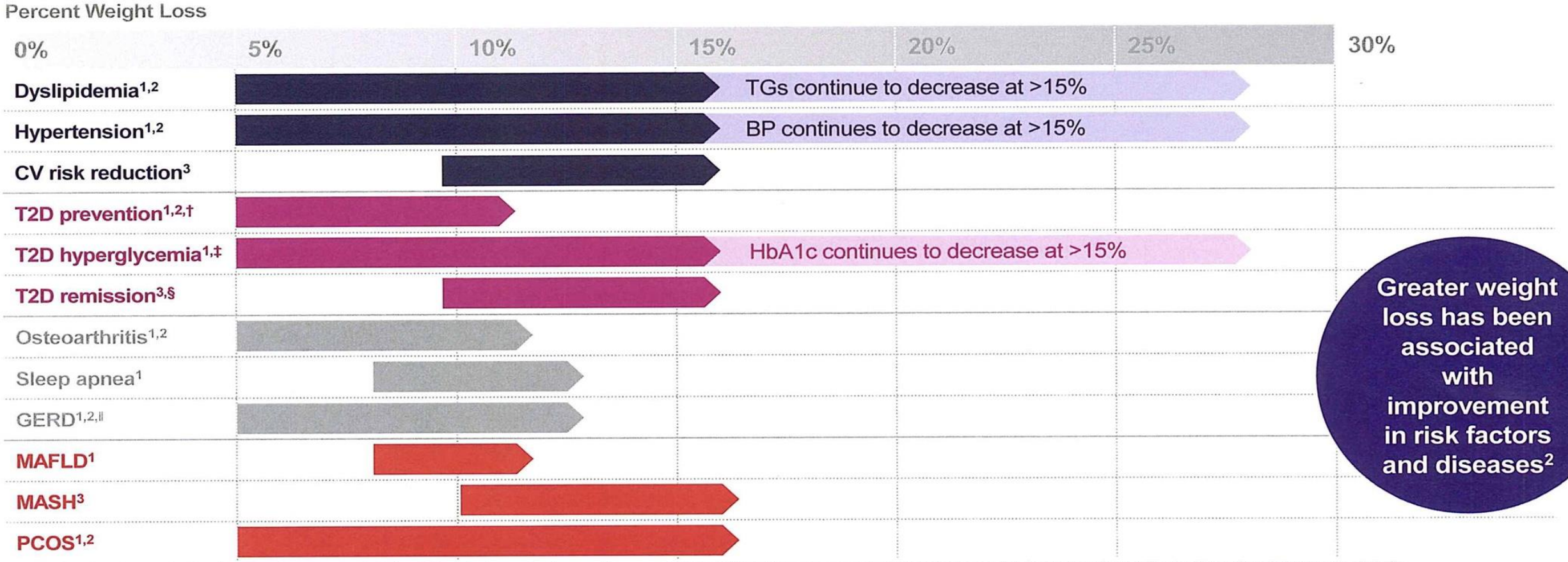


Study in 3448 people with obesity. Severe CVD = development of stroke, MI or CHF
CHF, congestive heart failure; **CVD, cardiovascular disease**; MI, myocardial infarction; RYGB, Roux-en-Y gastric bypass

Benotti *et al. J Am Heart Assoc* 2017;6:e005126

Obesity Is a Chronic Disease That Can Impact Diverse Obesity-Related Complications*

Reversing Obesity May Improve or Prevent Significant Detrimental Effects[1–3]



Greater weight loss has been associated with improvement in risk factors and diseases[2]

*"Obesity-related complications" are used as synonymic to "weight-related complications and/or comorbidities." †Weight loss to prevent progression to overt diabetes in patients with obesity and prediabetes or metabolic syndrome.[1,2] ‡Reductions in fasting glucose and HbA1c.[1] §Achieving HbA1c ≤6.5%.[3] ‖Females 5%–10%; males 10%.[1]
BP=blood pressure; CV=cardiovascular; GERD=gastroesophageal reflux disease; HbA1c=glycated hemoglobin; MAFLD=metabolic dysfunction-associated fatty liver disease; MASH=metabolic dysfunction-associated steatohepatitis; PCOS=polycystic ovarian syndrome; T2D=type 2 diabetes; TGs=triglycerides.

1. Cefalu WT, et al. Diabetes Care. 2015;38(8): 1567–1582. 2. Horn DB, et al. Postgrad Med. 2022;134(4): 359–375. 3. Garvey WT. J Clin Endocrinol Metab. 2022;107(4): e1339–e1347.

Obesity Surgery
https://doi.org/10.1007/s11695-022-06332-1

ORIGINAL CONTRIBUTIONS

2022 American Society of Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Indications for Metabolic and Bariatric Surgery

Dan Eisenberg[1] · Scott A. Shikora[2] · Edo Aarts[3] · Ali Aminian[4] · Luigi Angrisani[5] · Ricardo V. Cohen[6] · Maurizio de Luca[7] · Silvia L. Faria[8] · Kasey P.S. Goodpaster[4] · Ashraf Haddad[9] · Jacques M. Himpens[10] · Lilian Kow[11] · Marina Kurian[12] · Ken Loi[13] · Kamal Mahawar[14] · Abdelrahman Nimeri[15] · Mary O'Kane[16] · Pavlos K. Papasavas[17] · Jaime Ponce[18] · Janey S. A. Pratt[1,19] · Ann M. Rogers[20] · Kimberley E. Steele[21] · Michel Suter[22,23] · Shanu N. Kothari[24]

Major updates to 1991 National Institutes of Health guidelines for bariatric surgery

Surgery for Obesity and Related Diseases ■ (2022) 1–12

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

2022 American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): Indications for Metabolic and Bariatric Surgery

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- **MBS is recommended for individuals with BMI > 35, regardless of presence, *absence*, or severity of co-morbidities**
- **MBS is recommended in patients with T2D and BMI≥30**
- **MBS should be considered in individuals with BMI of 30-34.9 who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.**
- Clinical obesity in the **Asian** population is recognized in individuals with BMI≥25.
- **Older individulas, ≥ 70 years,** who could benefit from MBS should be considered for surgery after careful asessment of co-morbidities and *frialty*
- **Children or adolescents with BMI ≥ 120% of 95° percentile and major co-morbidity**, or BMI ≥ 140% of the 95° percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center.

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Obesity Surgery
https://doi.org/10.1007/s11695-024-07370-7

ORIGINAL CONTRIBUTIONS

Scientific Evidence for the Updated Guidelines on Indications for Metabolic and Bariatric Surgery (IFSO/ASMBS)

Maurizio De Luca[1] · Scott Shikora[2] · Dan Eisenberg[3] · Luigi Angrisani[4] · Chetan Parmar[5] · Aayed Alqahtani[6] · Ali Aminian[7] · Edo Aarts[8] · Wendy Brown[9] · Ricardo V. Cohen[10] · Nicola Di Lorenzo[11] · Silvia L. Faria[12] · Kasey P. S. Goodpaster[13] · Ashraf Haddad[14] · Miguel Herrera[15] · Raul Rosenthal[16] · Jacques Himpens[17] · Angelo Iossa[18] · Mohammad Kermansaravi[19] · Lilian Kow[20] · Marina Kurian[21] · Sonja Chiappetta[22] · Teresa LaMasters[23] · Kamal Mahawar[24] · Giovanni Merola[25] · Abdelrahman Nimeri[2] · Mary O'Kane[26] · Pavlos Papasavas[27] · Giacomo Piatto[28] · Jaime Ponce[29] · Gerhard Prager[30] · Janey S. A. Pratt[3] · Ann M. Rogers[31] · Paulina Salminen[32] · Kimberley E. Steele[33] · Michel Suter[34] · Salvatore Tolone[35] · Antonio Vitiello[36] · Marco Zappa[37] · Shanu N. Kothari[38]

Received: 14 May 2024 / Accepted: 21 May 2024

- **TEAM ONE**: SYSTEMATIC REVIEW OF LITERATURE ACCORDING TO **PRISMAs**
- TEAM TWO: **DELPHI** CONSENSUS TO RESOLVE ISSUES NOT RESOLVED BY SYS REV

Approved by IFSO and ASMBS Executive Councils
Approved by IFSO and ASMBS Scientific Committees

In press

MBS: complications

	Gastric bypass	Sleeve gastrectomy	Adjustable gastric band	One anastomosis gastric bypass
Complication rate	↑ complication rates vs. AGB + LSG	Higher early complication rate than AGB	Lowest early complication; highest re-operation rate	Less complication rates vs LSG, RYGB
Mean hospital stay	2-3 days	2-3 days	1–2 days	2-3 days*
Mortality risk	0.1-0.2%	0.1-0.2%	0.05-0.1%	0.1-0.2%*
Deficiencies	Protein/Vitamin/mineral	Vitamin	Vitamin/mineral (lowest risk)	Protein/vitamin/mineral
Other complications	Vomiting, dumping syndrome, ulcers	Vomiting, RGE, Barrett (?) Non-reversible	Vomiting, Band slippage, erosion, mechanical problems	Vomiting, Ulcers, Vitamin supplementation

Doble *et al*. *Obes Surg* 2017;27:2179–92
Gounder *et al. N Z Med J* 2016;129:43–52
Edholm *et al. Scand J Surg* 2017;106:230–4
Buchwald *et al. Surgery* 2007;142:621–32

OAGB, One anastomosis gastric bypass,
AGB, adjustable gastric band
BPD/DS, biliopancreatic diversion, with duodenal switch
LAGB, laparoscopic adjustable gastric band
LSG, laparoscopic sleeve gastrectomy
RYGB, Roux-en-Y gastric bypass

Combined Roles of Drugs and MBS in Patients with Obesity

- Role of AOM before MBS
- Role of AOM in case of weight regain and insufficient weight loss after MBS
- Combined Treatment

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The rationale of AOMs for preoperative bariatric surgery preparation

For patients with very high obesity (BMI >50 kg/m^2), pre-surgical weight loss is mandatory to reduce intra-abdominal volume and achieve operability in laparoscopic technique[1]

For some individuals, this is difficult to achieve with diet and exercise alone[2]

As such, the use of weight loss medication may be considered as a treatment option[2]

AOM: Anti-Obesity Medication

Stier *et al. Diabetes* 2015;64:A43; 2. Malone *et al. Ann Pharmacother* 2012;46:779–84

Few studies have investigated **preoperative WL** using pharmacological intervention

Study	Year	Study type	Intervention
1	2018	Case studies	Liraglutide 3.0 mg
2*	2017	RCT	Liraglutide 1.8 mg
3	2016	Retrospective	Various AOM**
4*	2015	Retrospective	Lorcaserin
5	2015	Prospective	Exenatide
6*	2015	Retrospective	Liraglutide 1.8 mg
7	2012	Prospective	Orlistat

AOM = bupropion/naltrexone, phentermine/topiramate, liraglutide, phentermine or a combination of the aforementioned medications
AOM, anti-obesity medication; RCT, randomised controlled trial

1. Modi *et al. Obes Surg* 2018;28:2113–6; 2. Shah *et al. Obes Surg* 2017;27:137; 3. Morton *et al. Surg Obes Relat Dis* 2016;12:S126; 4. Wang *et al. Value in Health* 2015;18:A295; 5. Iglesias *et al. Obes Surg* 2015;25:575–8; 6. Stier *et al. Diabetes* 2015;64:A43; 7. Malone *et al. Ann Pharmacother* 2012;46:779–84

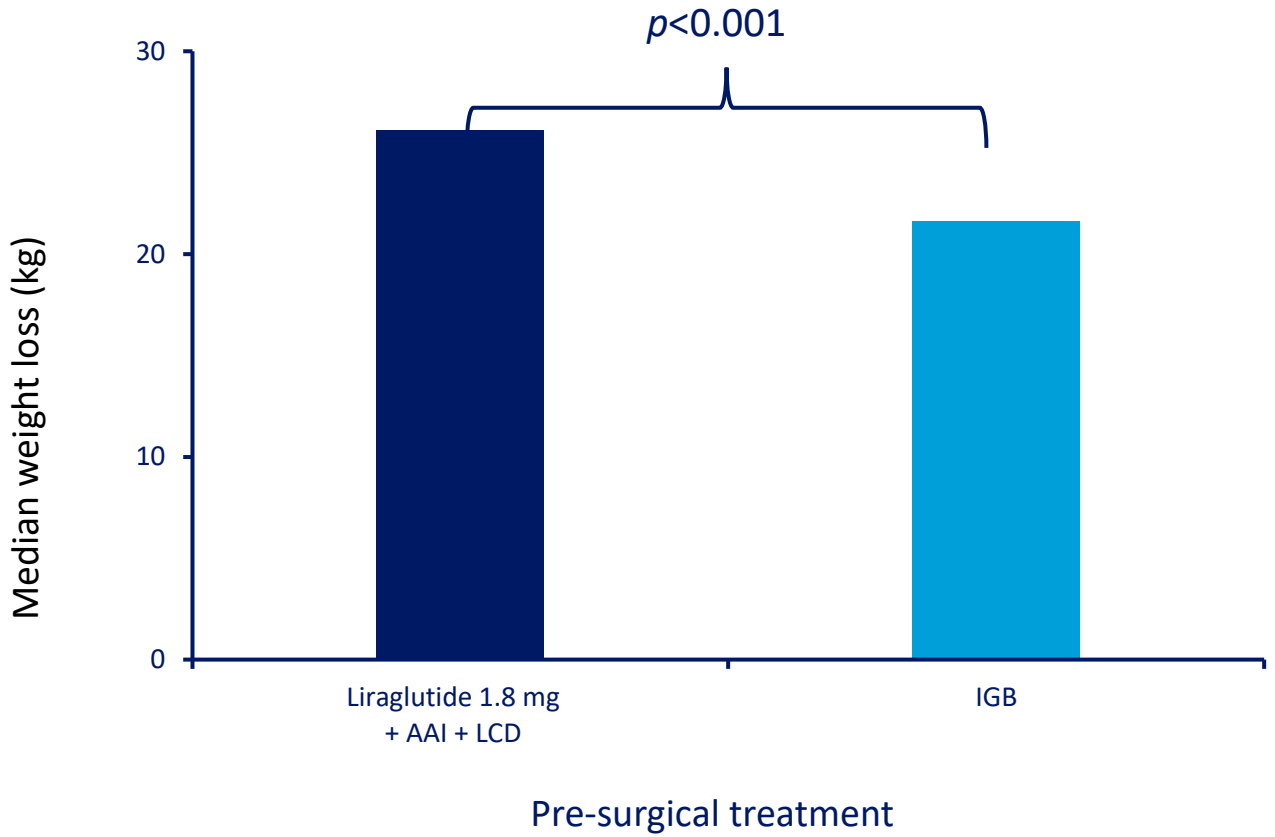
Preoperative AOM may reduce the risks for bariatric surgery

Drugs versus Intragastric Balloon (IGB)

The liraglutide group lost more pre-surgical weight than the IGB group:
26.1 kg vs. 21.6 kg ($p<0.001$)

The liraglutide group achieved the aim of feasible bariatric surgery considerably **faster** than the IGB group:
21 days vs. 213 days

Study in 46 patients with extreme obesity (BMI >65 kg/m^2) waiting for bariatric surgery. Liraglutide group = pre-surgical liraglutide, AAI and LCD; IGB group = pre-surgical IGB. AAI, amino acid infusion; IGB, intragastric balloon; LCD, low-calorie diet



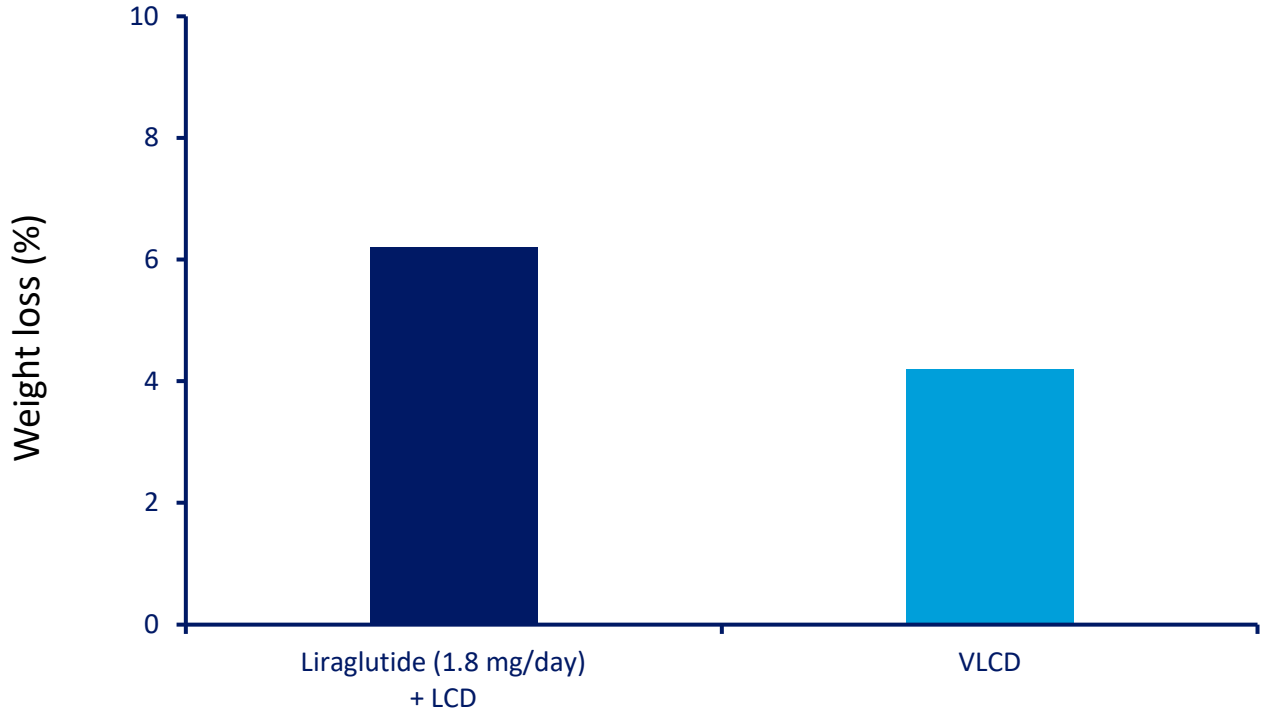
Stier *et al. Diabetes* 2015;64:A43

AOM may be superior to dietary intervention alone for preoperative weight loss

Patients often need VLCD for 2 weeks for liver preparation prior to bariatric surgery

However, diet compliance is often an issue

Compliance with dietary intervention was better in the liraglutide group



Study in 60 patients with BMI >35 kg/m^2 and T2D waiting for bariatric surgery. Patients were randomised 1:1 to receive either VLCD or liraglutide (1.8 mg/day) with LCD for 2 weeks. AOM, anti-obesity medication; LCD, low-calorie diet; T2D, type 2 diabetes; VLCD, very low-calorie diet

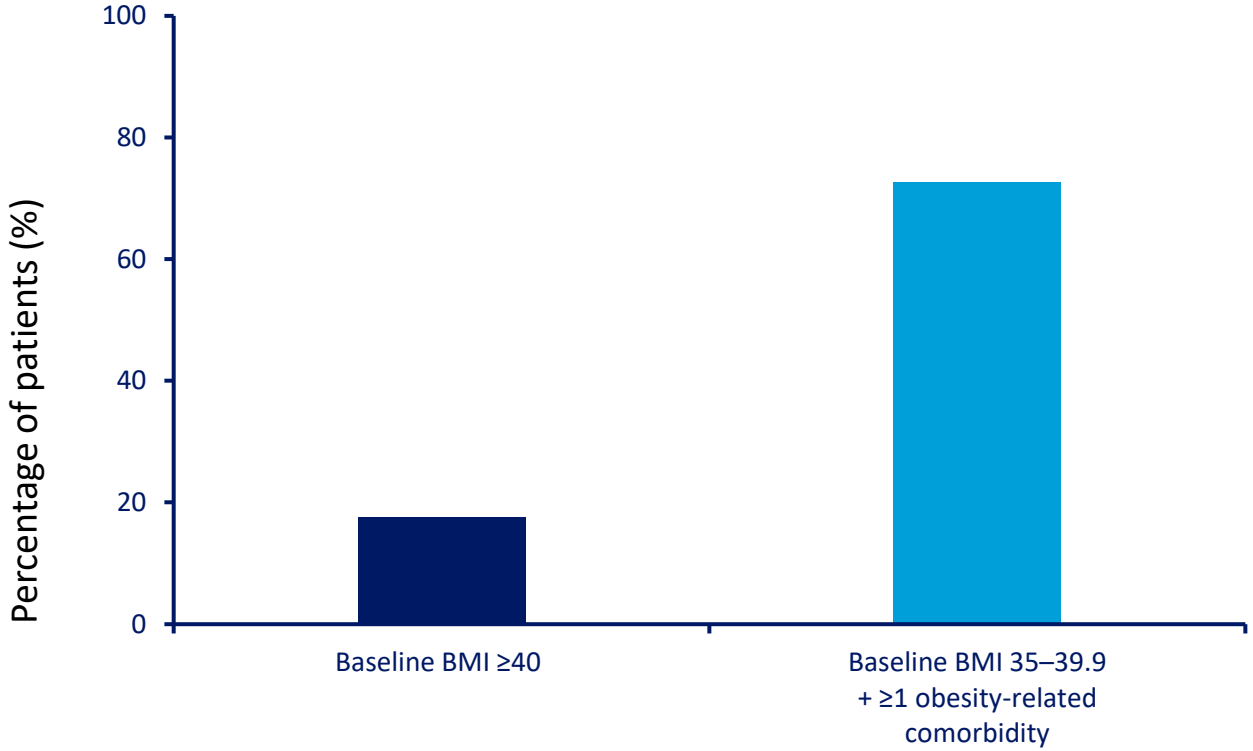
Shah *et al. Obes Surg* 2017;27:137

Preoperative AOM may reduce the risks for bariatric surgery

Retrospective analysis evaluating WL data for **lorcaserin** from three clinical trials (BLOSSOM, BLOOM, BLOOM-DM)

Patients whose preoperative BMI is reduced to **<35 can avoid bariatric surgery altogether**

Figure: Percentage of **lorcaserin** responders who reduced their BMI to <35 after 1 year



Wang *et al. Value in Health* 2015;18:A295

Lorcaserin responder = ≥5% WL at week 12. AOM, anti-obesity medication; BMI, body mass index; WL, weight loss

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Tirzepatide for Weight Management Is Being Evaluated in a Robust Clinical Trial Program[1–5]

Overview of Phase 3 trials assessing the efficacy and safety of tirzepatide*

Trial	SURMOUNT-1[1]	SURMOUNT-2[2]	SURMOUNT-3[3]	SURMOUNT-4[4]	SURMOUNT-5[5]
Comparator*	vs placebo (N=2539)	vs placebo (N=938)	vs placebo after an intensive lifestyle program (N=806)	vs placebo for maintenance of weight loss (N=783)	vs semaglutide 2.4 mg (N=~700)
Patient population†	Adults with obesity or overweight and without T2D‡	Adults with obesity or overweight and T2D‡	Adults with obesity or overweight and without T2D‡	Adults with obesity or overweight and without T2D‡	Adults with obesity or overweight and without T2D‡
Treatment period	72 weeks	72 weeks	72 weeks	88 weeks	72 weeks
Completion date	April 2022	April 2023	May 2023	May 2023	December 2024§

Trials cannot be compared due to differences in study design, population, and key inclusion/exclusion criteria.

*SURMOUNT 1–4 (placebo controlled) and SURMOUNT-5 (active controlled) are multicenter, double-blind, randomized, and QW administered trials. SURMOUNT-J and SURMOUNT-CN trials are not listed in this table as they are specific to Japan and China, respectively, and therefore not relevant to US payers. †All participants are adults 18 years or older with obesity (BMI ≥30 kg/m^2) or overweight (BMI ≥27 kg/m^2) with 1 or more obesity-related complications.¶ ‡These studies included patients who reported ≥1 unsuccessful dietary effort to lose weight. §Estimated study completion date. ¶"Obesity-related complications" are used as synonymic to "weight-related complications and/or comorbidities."[6]

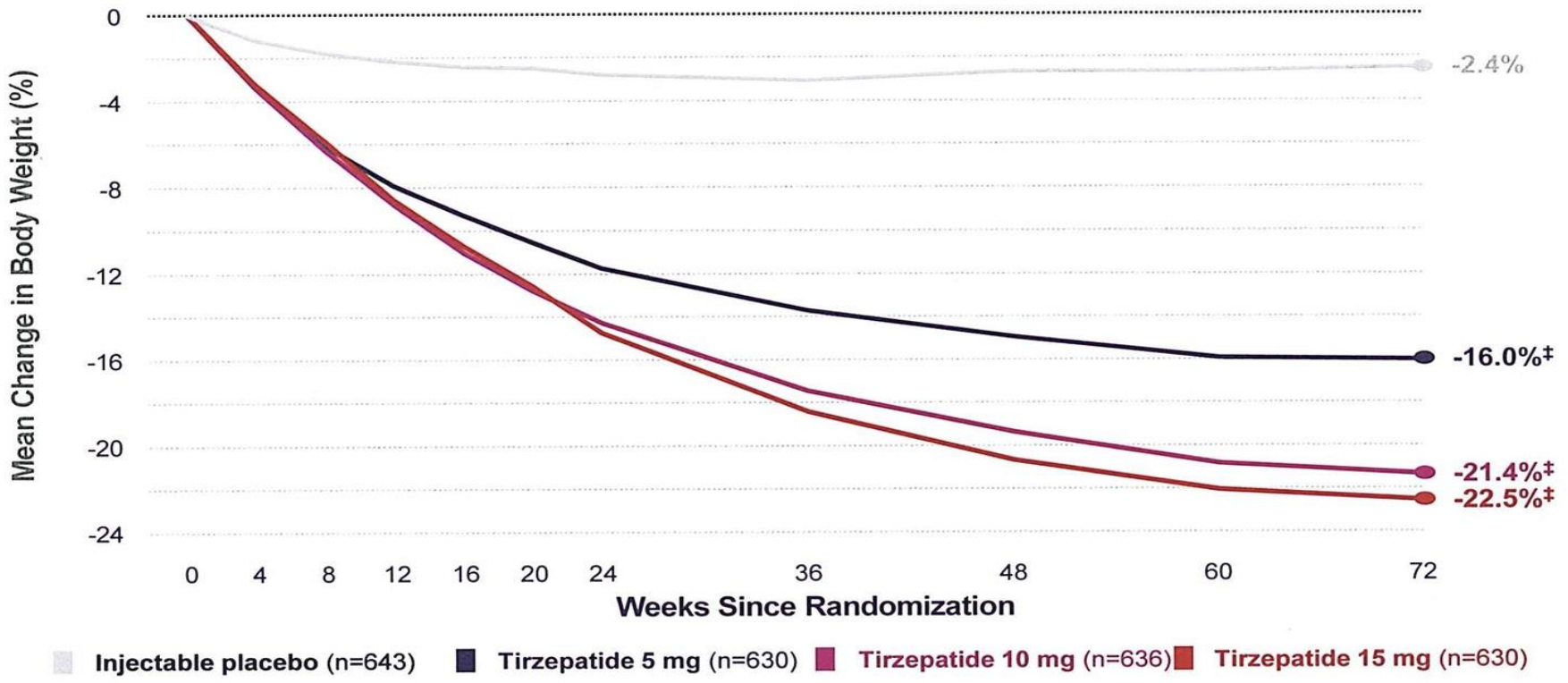
BMI=body mass index; QW=once weekly; T2D=type 2 diabetes.

1. Jastreboff AM, et al. N Engl J Med. 2022;387(3): 205–216 (and supplementary appendix). 2. Garvey TW, et al. Lancet. 2023;402(10402): 613–626. 3. Wadden TA, et al. Nat Med. 2023;29(11): 2909–2918. 4. Aronne LJ, et al. JAMA. 2024;331(1): 38—48. 5. SURMOUNT-5. ClinicalTrials.gov identifier: NCT05822830. Updated May 6, 2023. https://clinicaltrials.gov/ct2/show/NCT05822830. Accessed April 2024. 6. Tirzepatide [Summary of Product Characteristics]. February 2024.

Results Seen as Soon as 4 Weeks and Continued Through 72 Weeks With Tirzepatide[1,2,*]

Percentage Change in Body Weight Over Time From Baseline to Week 72*,†

Mean baseline weight=104.8 kg



22.5%
average reduction in body weight
with Tirzepatide 15 mg at 72 weeks‡

Figure modified from Jastreboff AM, et al. 2022.[2]

*Studied in adults with obesity (BMI of ≥30 kg/m2) or with overweight (BMI of ≥27 kg/m2) with at least 1 obesity-related complication, excluding type 2 diabetes.1,2,§ All participants received lifestyle intervention, including a reduced-calorie diet and increased physical activity.2 †Efficacy estimand, MMRM analysis, mITT population (efficacy analysis set).2 ‡P<0.001 vs placebo. Mean % change in weight vs baseline (co-primary endpoint) at 72 weeks was -16.0% and -21.4% for the 5 mg and 10 mg doses respectively. Mean % change in weight vs placebo at 72 weeks was -13.5%, -18.9%, -20.1% for the 5 mg, 10 mg and 15 mg doses respectively (P<0.001 vs placebo, adjusted for multiplicity).1,2 §"Obesity-related complications" are used as synonymic to "weight-related complications and/or comorbidities."[1]

BMI=body mass index; mITT=modified intent-to-treat; MMRM=mixed model for repeated measures.

1. Tirzepatide [Summary of Product Characteristics]. February 2024. 2. Jastreboff AM, et al. N Engl J Med. 2022;387(3): 205–216 (and supplementary appendix).

Combined Roles of Drugs and MBS in Patients with Obesity

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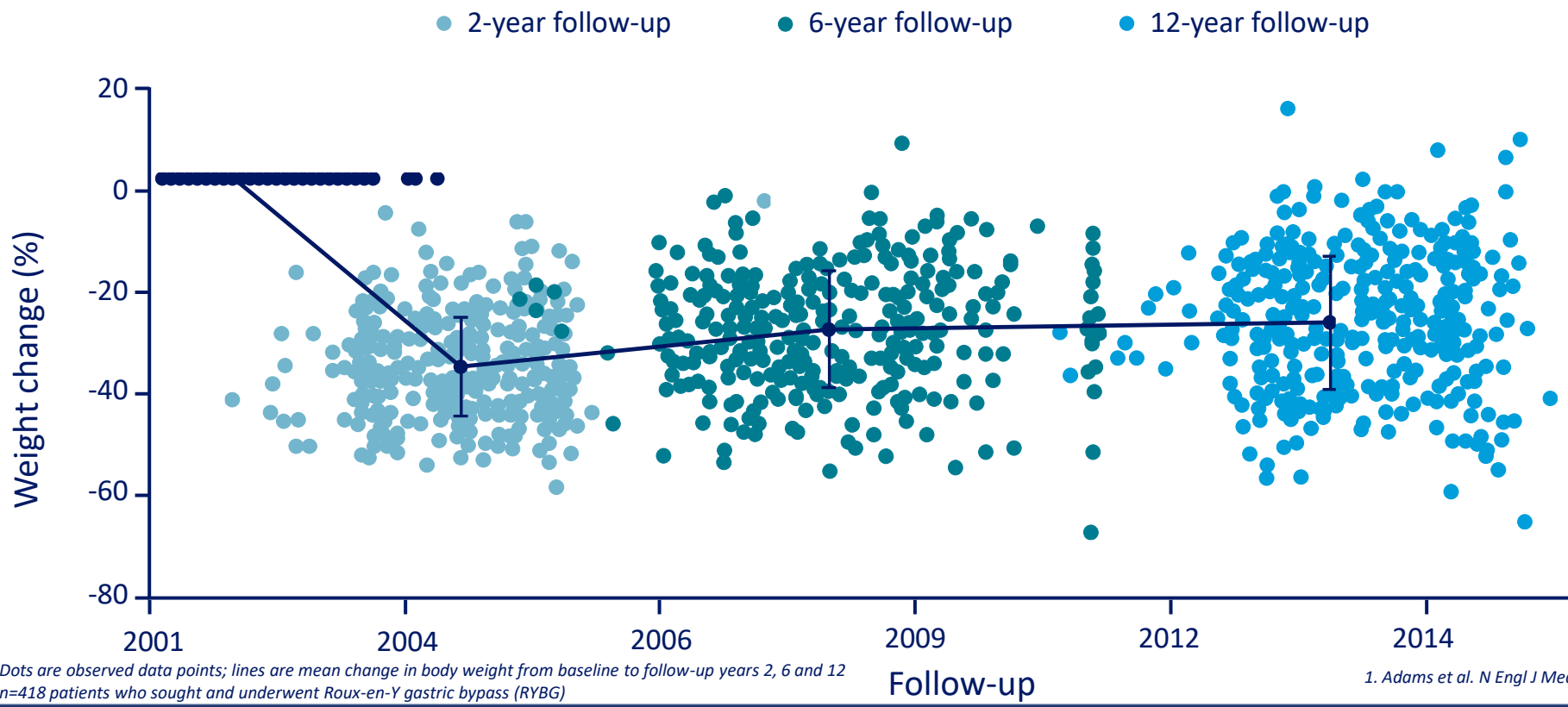
Bariatric surgery is associated with variable weight loss outcomes



Dots are observed data points; lines are mean change in body weight from baseline to follow-up years 2, 6 and 12
n=418 patients who sought and underwent Roux-en-Y gastric bypass (RYBG)

Weight loss maintenance at 12y: [1]

- **93%** of patients **≥ 10% WL**
- **70%** of patients **≥ 20% WL**
- **40%** of patients **≥ 30% WL**

1/3 patients experienced **weight regain** (≥ 25 weight loss) from postoperative year 1. [2]

Dots observed in a post-operative follow up period of 7±5 years
n=300 patients who underwent Roux-en-Y gastric bypass (RYBG)

1. Adams et al. N Engl J Med 2017;377:1143–55; 2. Cooper TC et al. Obes Surg. 2015;25(8):1474-81.

Aetiology of inadequate weight loss and weight regain after bariatric surgery

Patient-specific factors	Surgery-specific factors
Amount of physical activity	Dilation of gastrojejunal stoma
Mental health issues	Gastro-gastric fistula
Nutritional compliance	Gastric pouch length
Follow-up	Greater residual gastric volume
Preoperative variables	Dilation of gastric sleeve
Hormonal imbalance	Retained fundus
Support group attendance	
Control of food urges/emotional eating	

BMI, body mass index; EWL, excess weight loss; WR, weight regain

Cooper *et al. Obes Surg* 2015;25:1474–81; Karmali *et al. Obes Surg* 2013;23:1922–33; Complications in bariatric surgery. Springer 2018

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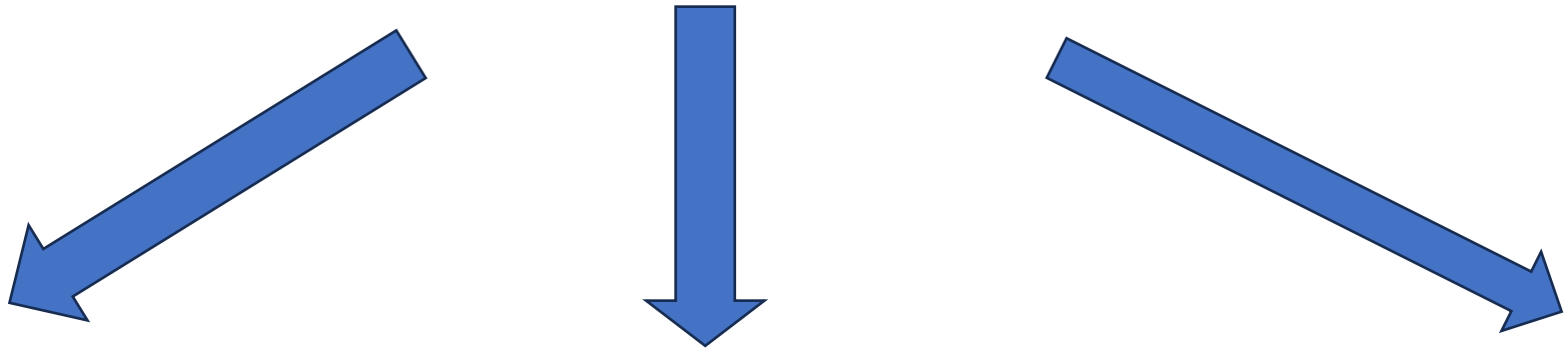
DEFINITIONS

REVISIONAL MBS



CONVERSION

changing the primary surgery to a different type of MBS

CORRECTIVE

repairing a primary MBS

REVERSAL

returning to original anatomy

Brethauer SA, Kothari S, Sudan R, et al. Systematic review on reoperative bariatric surgery. SOARD. 2014; 10:952–972.

Combined Roles of Drugs and MBS in Patients with Obesity

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- Combined Treatment

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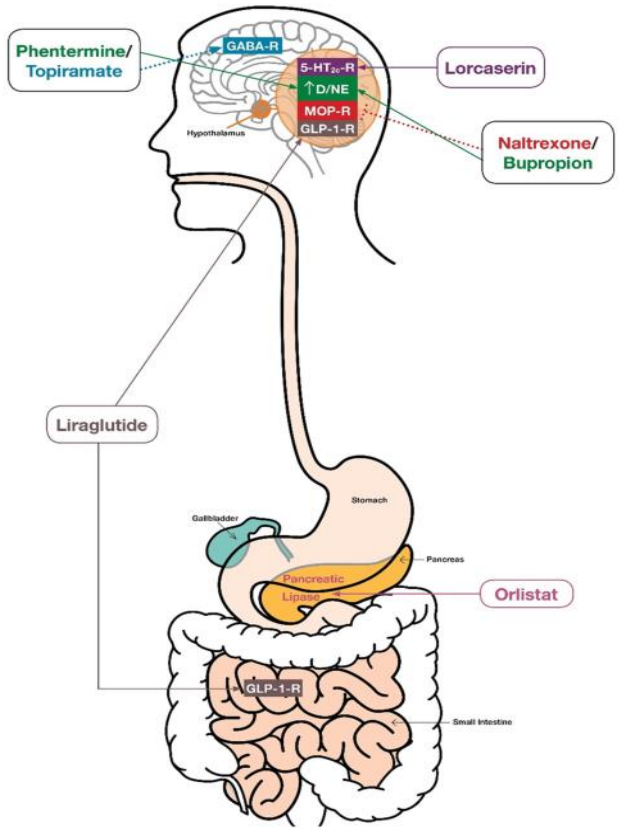
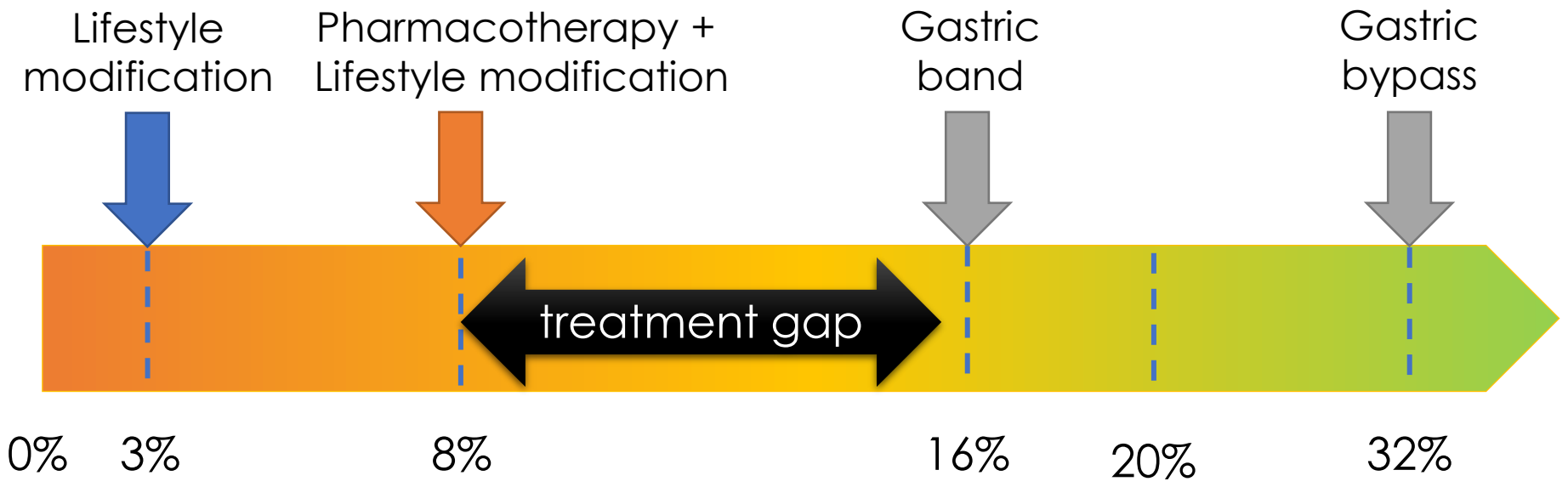
Farmaci autorizzati per il trattamento dell'obesità



- Orlistat
- Lorcaserin
- Phentermine + Topiramate
- Naltrexone + Buproprione
- Liraglutide 3.0 mg
- Semaglutide
- Tirzepatide
- Cotadutide
- Retratutide
- Setmelanotide

Treatment options for people with obesity



«A treatment gap existes for those patients who do not repond sufficiently to behavioural and lifestyle interventions and who are not viable candidates for, or do not wish to undergo, bariatric surgery. Such patients need additional options for treatment. Used appropriately, effective prescription drugs could potentially help fill that gap»

N Gesundheit, Int J Obes Suppl. 2012 Jul; 2(Suppl 1): S39–S42

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Anti Obesity Medications **after** MBS

Study	Study type	Study duration	Intervention	Post-surgical weight loss
Rye	Retrospective	28 weeks	Liraglutide 3.0 mg	Median = 9.7%
Suliman	Prospective	Median 213 days*	Liraglutide 3.0 mg	Median = 6.1%
Palecki	Retrospective	Average 4.2 months	Liraglutide 1.8 mg	Range = 2–18 kg
Jirapinvo	Prospective	12 months	Various AOMs**	Mean TWL = 6.8%
Rigas	Retrospective	7 months	Liraglutide 1.8–3.0 mg	Median = 13.4%
Nor Hanipah	Retrospective	12 months	Various AOM†	37% achieved >5% TWL 19% achieved >10% TWL
Stanford	Retrospective	>12 months	Various AOM‡	30.3% achieved ≥10% TWL 15% achieved ≥15% TWL

*Median duration of treatment. **Average 2 AOM per patient – phentermine (44%), phentermine plus topiramate (43%), topiramate (40%), metformin (19%), liraglutide (15%), zonisamide (15%), lorcaserin (9%), bupropion plus naltrexone (9%), bupropion (5%), orlistat (2%) and naltrexone (0.5%). †Phentermine (74.6%), phentermine/topiramate extended release (12%), lorcaserin (8.6%), and naltrexone slow-release/bupropion slow-release (4.8%). ‡Phentermine, topiramate, zonisamide, metformin, bupropion, orlistat, sibutramine, liraglutide, exenatide, pramlinitide, naltrexone, lorcaserin, phentermine/topiramate, canagliflozin and bupropion/naltrexone. TWL, total weight loss

1. Rye *et al. Obes Surg* 2018;28:3553–8;
2. Suliman *et al. Diabetes Obes Metab* 2019; doi:10.1111/dom.13672;
3. Pajecki *et al. Rev Col Bras Cir* 2013;40:191–5;
4. Jirapinyo *et al. Gastrointestinal Endoscopy* 2018;87:AB68;
5. Rigas *et al. Obes Facts* 2018;11:241;
6. Nor Hanipah *et al. Surg Obes Relat Dis* 2018;14:93–8;
7. Stanford *et al. Surg Obes Relat Dis* 2017;13:491–500

Post-operatory Pharmacoterapy

1. **Weight Regain** [1] (≥ 25 weight loss)
2. **Insufficient Weight Loss** [1] (< 50% EWL)
3. **Patients desiring further weight loss** [2]

1. Vinciguerra F, et al. 2021 Apr 1. doi: 10.23736/S2724-6507.21.03311-3;
2. Thakur U, et al. Obes Surg. 2021;31(1):84-92;.

AOM for IWL or WR

GLP1-RA as adjunct treatment for weight loss

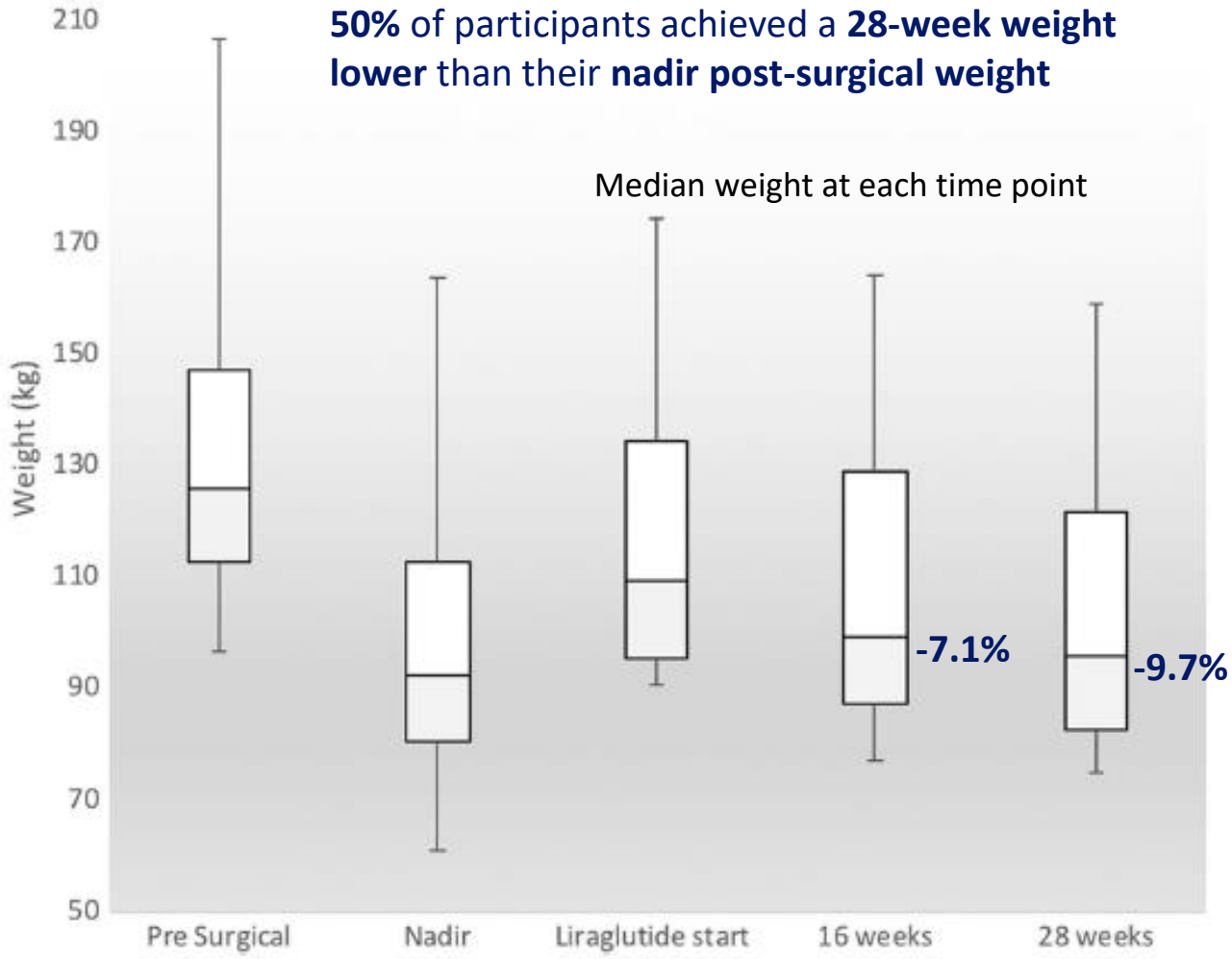
Retrospective - 28 weeks - Liraglutide 3.0 mg/die

Table 1 Baseline patient characteristics

		($n = 20$)
Age (years ± standard deviation)		49.6 ± 8.3
Female sex (%)		95.0
Diabetes (%)		25.0
Type of surgery (%)		
RYGB		35.0
LSG		35.0
VBG		15.0
AGB		15.0
Indication for liraglutide (%)		
Recidivism		50.0
Inadequate weight loss		35.0
Weight plateau	(> 10% weight regain from NADIR)	15.0
Mean liraglutide dose (mg ± standard deviation)	(< 20% weight loss) (patients desire further weight loss)	2.9 ± 0.2
Time between surgery and liraglutide (months ± standard deviation)		76.3 ± 72.9

Rye P, et al. Obes Surg. 2018;28(11):3553-3558.

50% of participants achieved a **28-week weight lower** than their **nadir post-surgical weight**



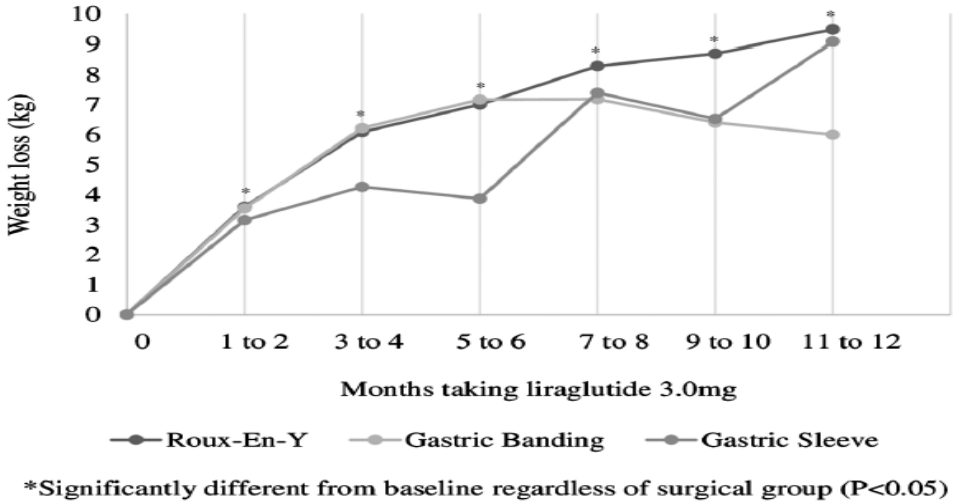
Effectiveness of GLP1-RA in post-bariatric surgery patients

117 patients underwent bariatric surgery

- Roux-en-Y Gastric Bypass (n = 53)
- Gastric band (n = 50)
- Gastric sleeve (n = 14)

4-10 years after bariatric surgery

Liraglutide 3.0 mg → 1 year treatment



Wharton S, et al. Epub 2019 May 1. Clinical Obesity. 2019;9:e12323..

Variable	Roux-en-Y bypass	Gastric band	Gastric sleeve
Sample size (n)	53	50	14
Age (y)	49.9 ± 9.1	52.5 ± 9.5	51.4 ± 10.3
Men (n, %)	3 (5.7)[a]	8 (16.0)	4 (28.6)
Pre-bariatric surgery BMI (kg/m^2)	50.8 ± 11.2	47.6 ± 13.1[e]	52.2 ± 11.9
Maximum weight change post-bariatric surgery (kg)	−51.6 ± 23.5[a,b]	−29.8 ± 23.3[e]	−34.7 ± 19.5
Weight change from lowest post-bariatric surgery weight to initiation of liraglutide 3.0 mg (kg)	19.0 ± 13.5	25.4 ± 20.4[e]	15.8 ± 14.1
Weight change from lowest post-bariatric surgery weight to initiation of liraglutide 3.0 mg (%)[c]	44.8 ± 54.9[a]	80.0 ± 79.7[f]	48.4 ± 31.7[g]
Preliraglutide BMI (kg/m^2)	39.0 ± 7.0[a,b]	45.4 ± 11.0	45.4 ± 9.6
Weight change on liraglutide 3.0 mg (kg)	−7.1 ± 8.7[d]	−6.0 ± 7.2[d]	−4.5 ± 4.5[d]
Weight change on liraglutide 3.0 mg (%)	−6.6 ± 7.1	−4.9 ± 5.6	−3.6 ± 3.0
Attained 5% weight loss (n, %)	25 (47.2)	19 (38.0)	5 (35.7)
Attained 10% weight loss (n, %)	13 (24.5)[a]	6 (12.0)	0 (0.0)
Treatment time (mo)	8.0 ± 7.6	6.8 ± 6.7	8.6 ± 7.3
Reported nausea with liraglutide 3.0 mg (n, %)	15 (28.3)	12 (24.0)	5 (35.7)

- Post-bariatric surgery patients can lose a significant amount of weight while taking **liraglutide 3.0 mg** regardless of the type of surgery they had
- Post-bariatric surgery patients taking **liraglutide 3.0 mg** may experience gastrointestinal side effects such as nausea and **can continue to lose weight up to 1 year**

Maurizio De Luca

GLP1-RA or Surgical Revision in Long-Term Weight Regain After RYBG

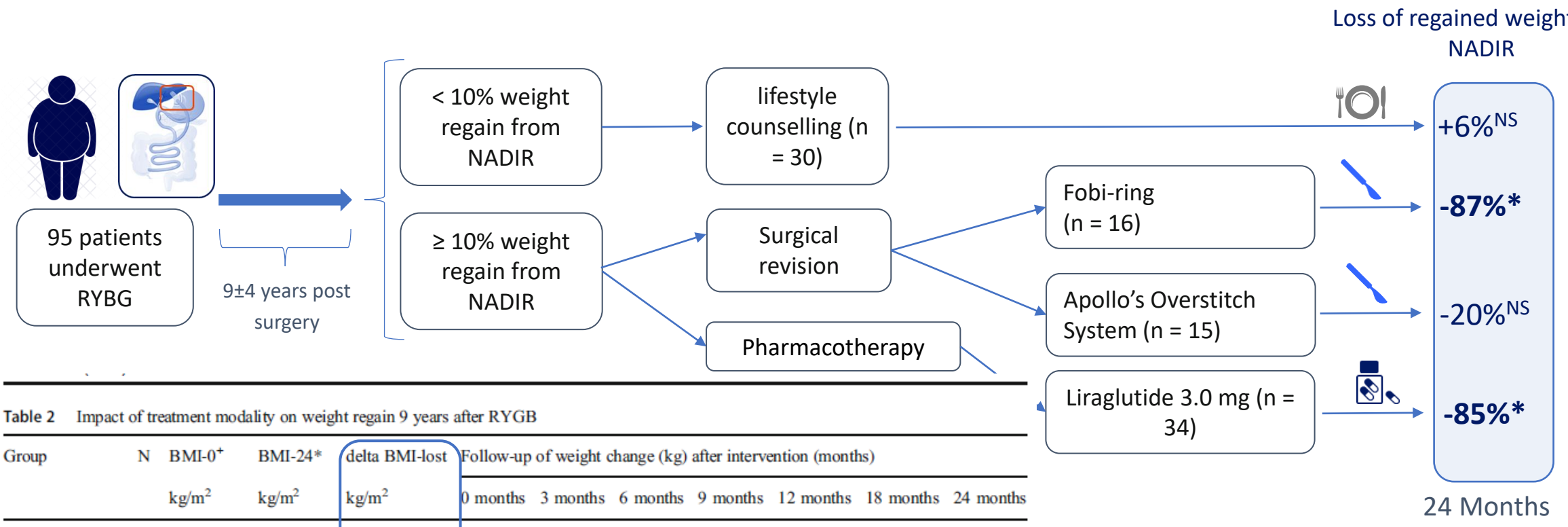


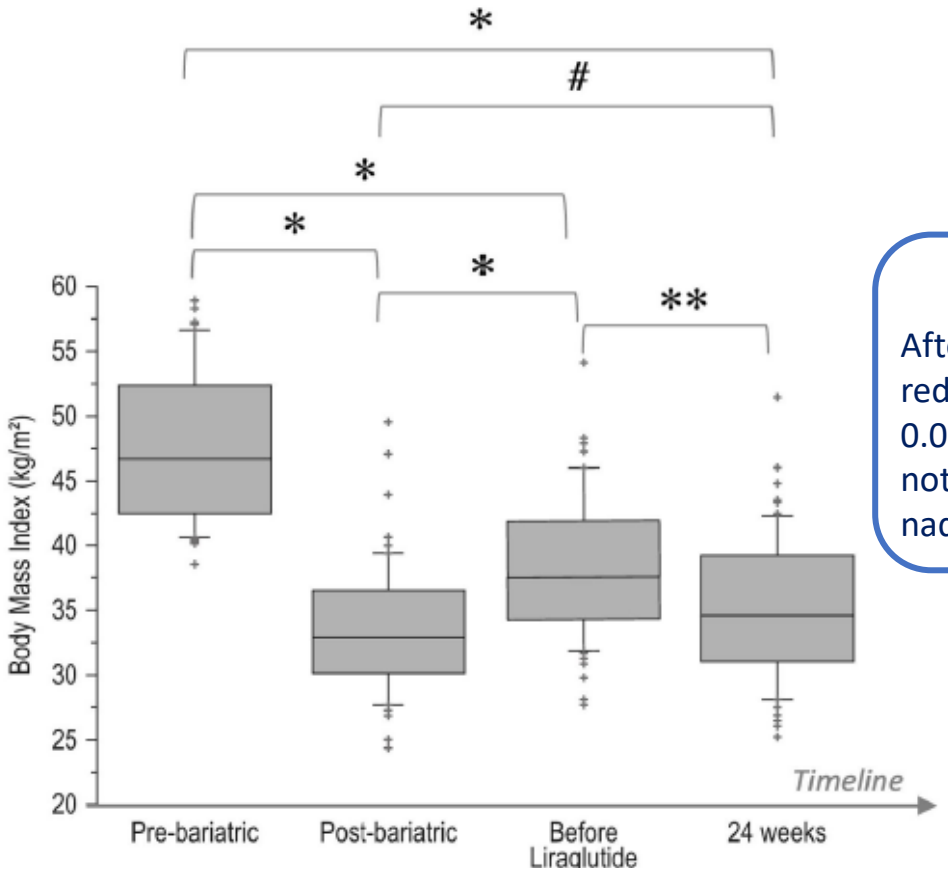
Table 2 Impact of treatment modality on weight regain 9 years after RYGB

Group	N	BMI-0+ kg/m²	BMI-24* kg/m²	delta BMI-lost kg/m²	Follow-up of weight change (kg) after intervention (months) 0 months	3 months	6 months	9 months	12 months	18 months	24 months
DC (controls)	30	27.1 ± 5.0	27.2 ± 4.5	− 0.1 ± 1.7	75 ± 15	75 ± 15	75 ± 15	76 ± 14	76 ± 13	75 ± 13	75 ± 13
LG (liraglutide)	34	31.2 ± 4.0#	26.4 ± 3.5	4.8 ± 2.9£	84 ± 13#	80 ± 13	77 ± 12	76 ± 12	74 ± 11	73 ± 10	72 ± 9£
ES (endosurgery)	15	31.0 ± 4.2#	30.0 ± 4.4$	1.0 ± 0.9	83 ± 14#	80 ± 14	80 ± 14	80 ± 14	80 ± 14$	--------	--------
FP (Fobi)§	16	34.2 ± 4.9#	28.7 ± 4.6	5.5 ± 2.9£	96 ± 12#	90 ± 12	88 ± 12	85 ± 12	83 ± 11	82 ± 12	79 ± 10£

Horber FF, et al. Epub 2020 Jul 21. Erratum in: Obes Surg. 2021;31(7):3386.

- **37%** of **Fobi-ring patients** experienced **serious complications** vs other groups ($p < 0.05$)
  - lead to **hospitalization** in 2 cases
  - **endoscopic dilatation** of the upper anastomosis (up to 32 times) due to an inability to eat and vomiting

GLP1-RA improves metabolic syndrome in poor responder to bariatric surgery



After **liraglutide** treatment, a significant reduction in BMI (35.1 ± 5.6 kg/m2, p = 0.0002) was observed with values that were not different from those of the post-bariatric nadir (p = 0.09).

Clinical and metabolic parameters	Baseline	After 24 weeks	value of *p*
Body weight (kg)	101.8 ± 17.9	93.3 ± 17.6	<0.0001
BMI (kg/m²)	38.2 ± 5.7	35.1 ± 5.6	<0.0001
WC (cm)	123.2 ± 13.3	113.9 ± 13.5	<0.0001
SBP (mmHg)	125.9 ± 10.8	119.2 ± 7.6	<0.0001
DBP (mmHg)	80.5 ± 7.6	75.6 ± 5.2	<0.0001
Glucose (mg/dL)	99.3 ± 12.4	85.8 ± 7.5	<0.0001
Total cholesterol (mg/dL)	186.1 ± 29.2	176.3 ± 29.4	0.009
HDL Cholesterol (mg/dL)	50.7 ± 12.6	51.3 ± 13.5	0.71
Triglycerides (mg/dL)	112.3 ± 47.3	82.5 ± 33.2	<0.0001
LDL Cholesterol (mg/dL)	112.9 ± 30.2	108.6 ± 30.3	0.2
AST (mg/dL)	21.9 ± 8.4	18.1 ± 5.4	<0.0001
ALT (mg/dL)	27.9 ± 15.0	17.2 ± 7.3	<0.0001

Liraglutide improves cardiometabolic risk factors including reductions in waist circumference, blood pressure, glucose, and lipid levels.

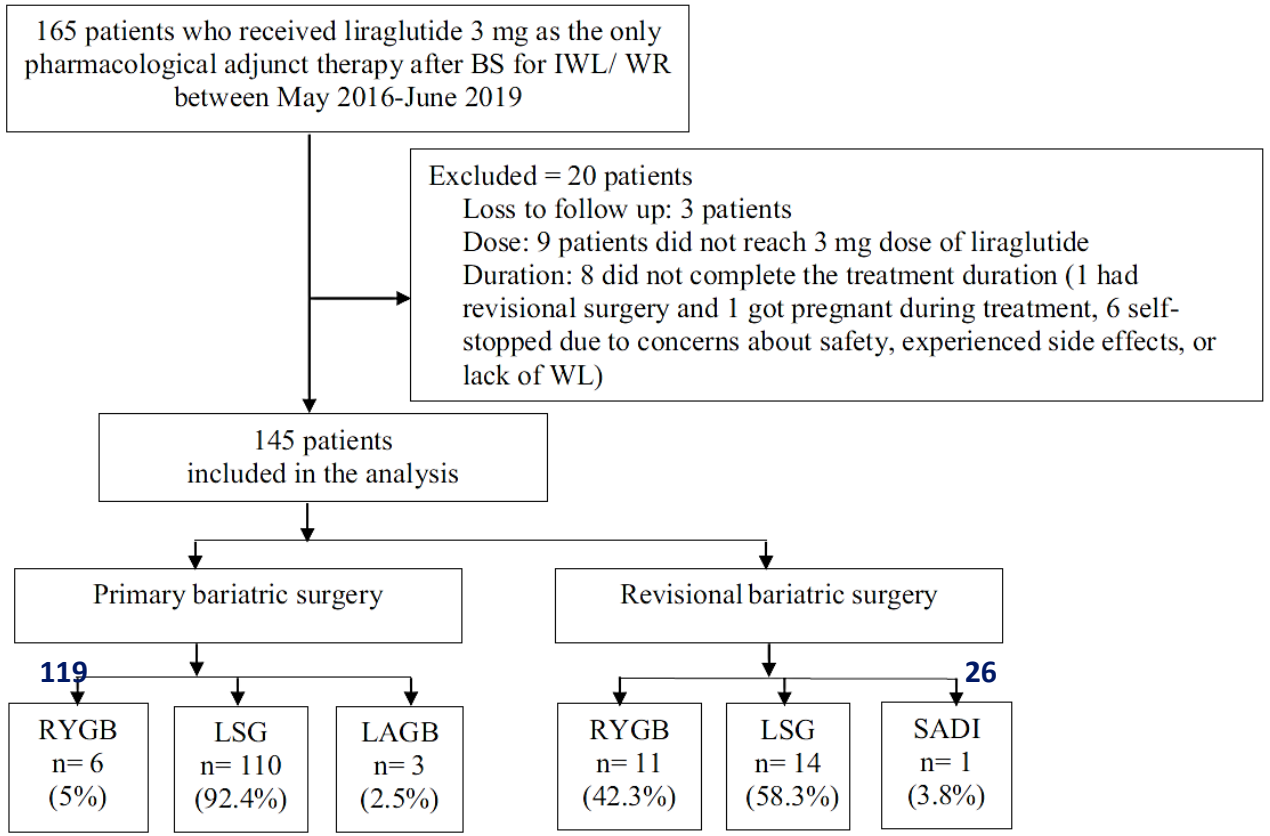
Based on the amelioration of cardiometabolic parameters, the prevalence of **metabolic syndrome** in our cohort decreased significantly

Vinciguerra F et al. Front Nutr. 2023 Sep 13;10:1183899. doi: 10.3389/fnut.2023.1183899..

Maurizio De Luca

AOM for IWL or WR

GLP1-RA 3.0 mg in inadequate weight loss (IWL) or weight regain (WR) after primary or revisional surgery



- 22% inadequate weight loss
- 78% weight regain

Liraglutide start: 56 months postop

- 42% inadequate weight loss
- 58% weight regain

Liraglutide start: 42 months postop

RYGB, Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy; LAGB, laparoscopic adjustable gastric banding; SADI, single-anastomosis duodeno-ileal bypass .

Elhag W, et al. Obes Surg. 2022 Jan 20. doi: 10.1007/s11695-021-05884-y.

Variable	Surgery type		P
	Primary	Revisional	
Weight			
6 m	91.01 ± 17.30	95.68 ± 33.29	0.32
12 m	88.44 ± 15.31	97.65 ± 32.13	*0.03*
Weight change kg (M ± SD)			
6 m	-5.74 ± 6	-6.08 ± 7.27	0.81
12 m	-6.50 ± 7.58	-4.90 ± 8.91	0.35
BMI			
6 m	35.37 ± 5.89	36 ± 10.29	0.68
12 m	34.42 ± 4.82	36.71 ± 9.39	0.08
BMI change kg/m^2 (M ± SD)			
6 m	− 2.23 ± 2.30	− 2.35 ± 2.76	0.83
12 m	− 2.53 ± 2.96	− 1.93 ± 3.40	0.35
TWL% (M ± SD)			
6 m	5.72 ± 5.68	6.41 ± 7.11	0.61
12 m	6.35 ± 7.44	4.81 ± 8.04	0.35
Total weight loss*			
At 6 m			0.78
≥ 15% of weight	6 (5.6)	3 (12)	
≥ 10% of weight	15 (14)	3 (12)	
≥ 5% of weight	35 (32.7)	9 (36)	
0–4.9% of weight	34 (31.8)	6 (24)	
Non responders	17 (15.9)	4(16)	
At 12 m			0.59
≥ 15% of weight	12 (10.9)	3 (11.5)	
≥ 10% of weight	22 (20)	4 (15.4)	
≥ 5% of weight	32 (29.1)	5 (19.2)	
0–4.9% of weight	0 (0)	0 (0)	
Non responders	44 (40)	14 (53.8)	

Obesity Surgery
https://doi.org/10.1007/s11695-023-07053-9

ORIGINAL CONTRIBUTIONS

Efficacy of High-dose Liraglutide 3.0 mg in Patients with Poor Response to Bariatric Surgery: Real-world Experience and Updated Meta-analysis

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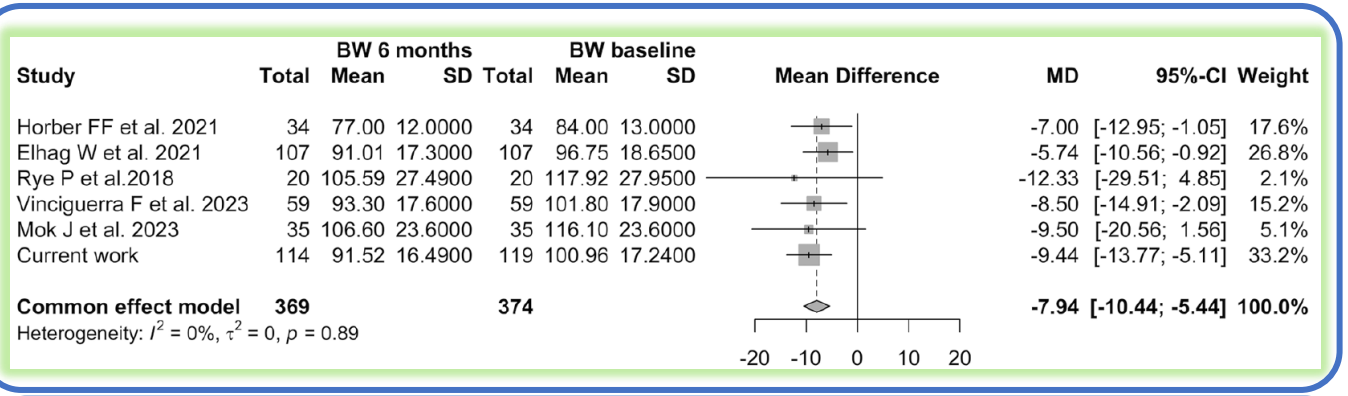

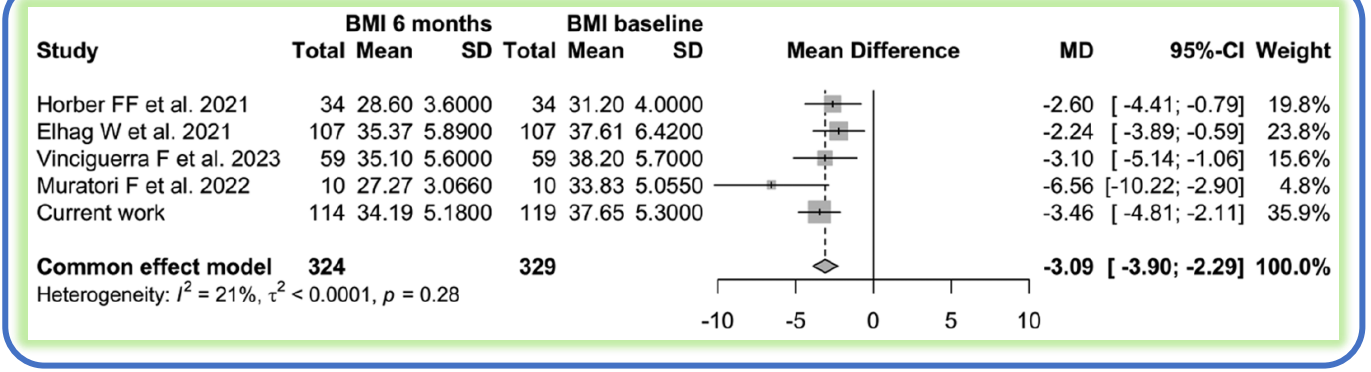

Vinciguerra F, et al. Obes Surg. 2024 Jan 6. doi: 10.1007/s11695-023-07053-9.

119 subjects with WR o IWL

Clinical parameters	Baseline	After 12 weeks	After 24 weeks
Body weight (kg)	100.9 ± 17.2	95.3 ± 16.8*	91.5 ± 16.49*
BMI (kg/m^2)	37.6 ± 5.3	35.6 ± 5.3*	34.2 ± 5.2*
WC (cm)	118.8 ± 13.3	114.5 ± 12.8*	110.5 ± 12.8*

*$p < 0.0001$ vs baseline

Forest plot **body weight** before and after **24 weeks** of liraglutide therapy

Forest plot **BMI** before and after **24 weeks** of liraglutide therapy

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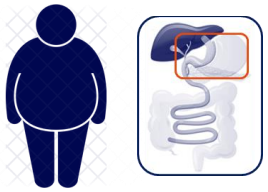
AOM for **further** **weight loss**

Endoscopic sleeve gastroplasty plus GLP1-RA *vs* **Endoscopic sleeve gastroplasty** alone for weight loss



52 patients that performed ESG

Liraglutide (n=26)

No Liraglutide (n=26)

Follow up at 2, 4 and 7 Months

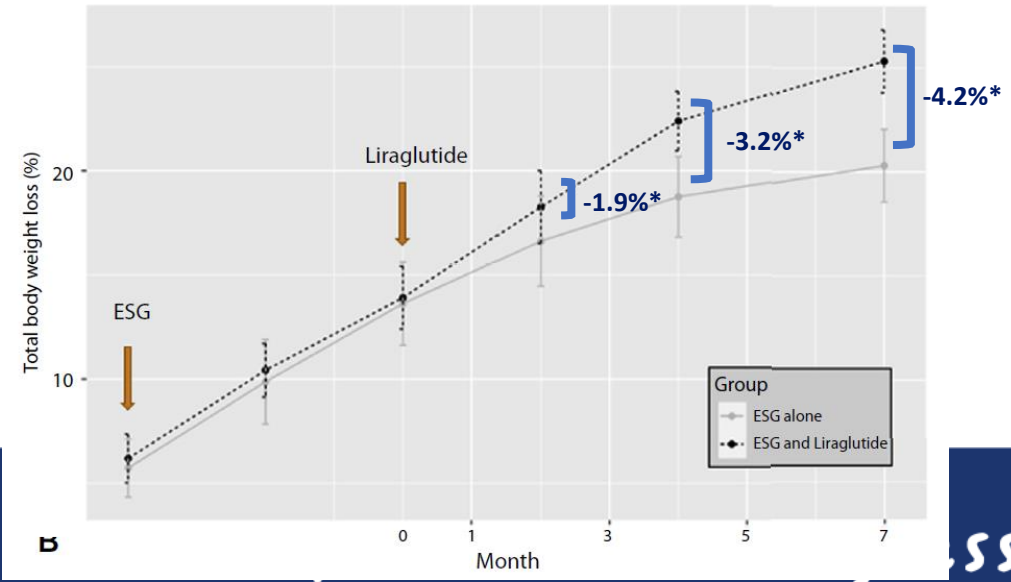


TABLE 2. Comparison of change in absolute weight loss, percent total body weight loss, body mass index loss, percent excess weight loss, visceral fat, and hemoglobin A_{1c} after ESG in patients using or not using liraglutide

Variable	Time (mo)	ESG alone (n = 26)	ESG and liraglutide (n = 26)	*P* value
Absolute weight loss, kg	2	16.93 (3.34)	18.63 (2.62)	.046
	4	19.23 (3.33	22.28 (3.26)	.002
	7	20.95 (3.21)	25.02 (3.80)	<.001
Absolute body mass index, kg/m^2	2	29.65 (1.20)	29.22 (1.88)	.334
	4	28.85 (1.10)	27.93 (1.76)	.028
	7	28.25 (1.06)	26.96 (1.60)	.001
Total body weight loss, %	2	16.57 (2.37)	18.43 (1.55) **-1.9%***	.002
	4	18.82 (2.01)	22.02 (1.84) **-3.2%***	<.001
	7	20.51 (1.68)	24.72 (2.12) **-4.2%***	<.001
Body mass index loss, kg/m^2	2	5.92 (1.00)	6.61 (.77)	.007
	4	6.71 (.93)	7.90 (.95)	<.001
	7	7.31 (.86)	8.88 (1.14)	<.001
Excess weight loss, %	2	56.33 (7.58)	63.12 (12.51) **-6.8%***	.022
	4	64.05 (6.43)	75.32 (14.19) **-11.3%***	.001
	7	69.94 (6.30)	84.33 (14.57) **-14.4%***	<.001
Visceral fat, %	7	10.54 (1.88)	7.85 (1.26)	<.001
Hemoglobin A_{1c}	7	5.40 (.45)	5.09 (.41)	.013

Values are mean (standard deviation).
ESG, Endoscopic sleeve gastroplasty.

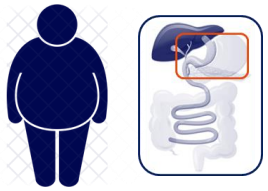
- **Liraglutide** when used in combination with ESG, will likely augment weight loss and promote reduction in **visceral fat**

Badurdeen D, et al. Gastrointest Endosc. 2021;93(6):1316-1324.e1.

Maurizio De Luca

AOM for **further weight loss**

LSG + GLP1-RA for patients desiring further weight loss



32 patients underwent LSG

L-L= LSG + **Liraglutide 3.0mg**

L-L group (n=12)

L-P group (n=11)

L-P= LSG + Placebo

Follow up at 6, 12 and 24 weeks

Parameters	Follow-up	L-L group ($n=12$)	L-P group ($n=11$)	p value
IBW (kg)		60.1 ± 11.6	50.2 ± 6.4	0.069
Weight (kg)	Baseline	118.6 ± 24.6	103.1 ± 16.4	0.190
	6 weeks	103.5 ± 20.3	92.0 ± 32.4	0.237
	12 weeks	94.2 ± 17.6	84.8 ± 11.4	0.258
	24 weeks	85.1 ± 13.5	79.2 ± 10.6	0.381
BMI (kg/m^2)	Baseline	42.6 ± 6.3	41.6 ± 5.1	0.734
	6 weeks	36.5 ± 5.2	37.0 ± 3.9	0.848
	12 weeks	34.0 ± 4.4	34.5 ± 3.5	0.833
	24 weeks	30.9 ± 4.0	32.1 ± 3.0	0.554
EBW (kg)	Baseline	58.5 ± 18.3	52.9 ± 12.5	0.520
TWL (%)	6 weeks	12.7 ± 4.1	10.7 ± 3.9	0.198
	12 weeks	20.6 ± 6.3	17.7 ± 6.1	0.188
	24 weeks	28.2 ± 5.7	23.2 ± 6.2	0.116
BMI loss (kg/m^2)	6 weeks	6.2 ± 2.4	4.6 ± 2.6	0.267
	12 weeks	8.6 ± 3.0	7.1 ± 3.3	0.381
	24 weeks	11.7 ± 3.5	9.5 ± 4.0	0.287
EWL (%)	6 weeks	27.2 ± 10.1	20.4 ± 6.8	0.168
	12 weeks	42.6 ± 10.3	34.1 ± 8.1	0.112
	24 weeks	58.7 ± 14.3	44.5 ± 8.6	0.043*

*$p < 0.05$ was considered significant

L-L, LSG +liraglutide; *L-P*, LSG + placebo

BMI, body mass index

IBW, ideal body weight; *TWL*, total weight loss; *EWL*, excess body weight loss

FEWL
-2 %
-2.9 %
-5 %

FEWL
-7 %
-8.5 %
-14.2 %

- **100%** L-L group resolution dysglycemia vs **50%** L-P group resolution dysglycemia

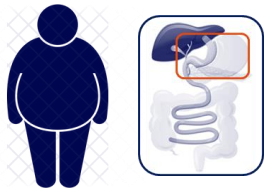
Thakur U, et al. Obes Surg. 2021;31(1):84-92.

Maurizio De Luca

AOM for further weight loss

Safety and Efficacy of GLP1-RA vs Palcebo in Patients with IWL followiong MBS. RCT study.
Jama Surgery. Original Investigation

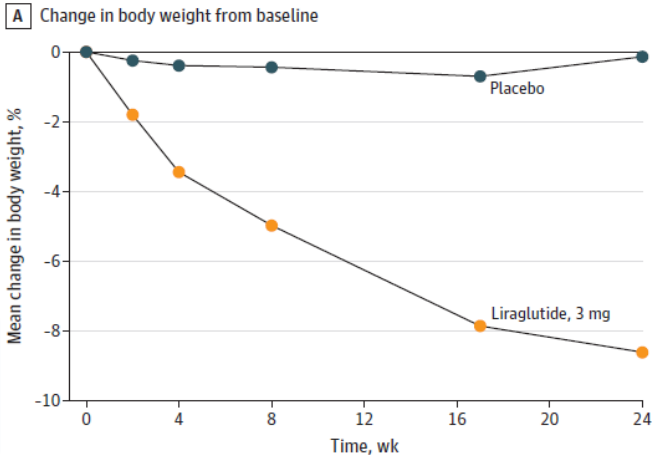
BARI-OPTIMISE



70 patients with poor weight loss following RYBG or SG

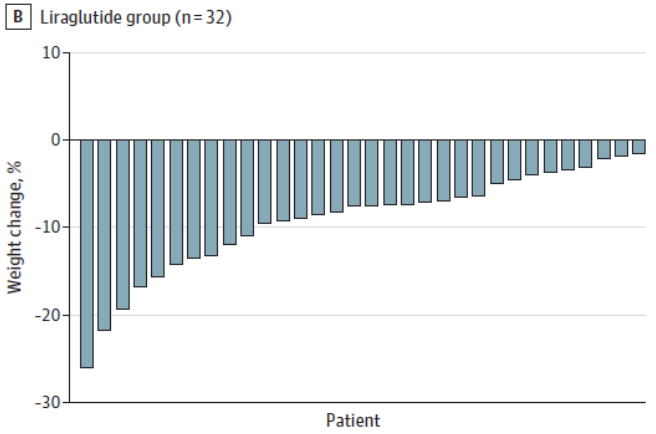
- Liraglutide (n=35)
- Placebo (n=35)

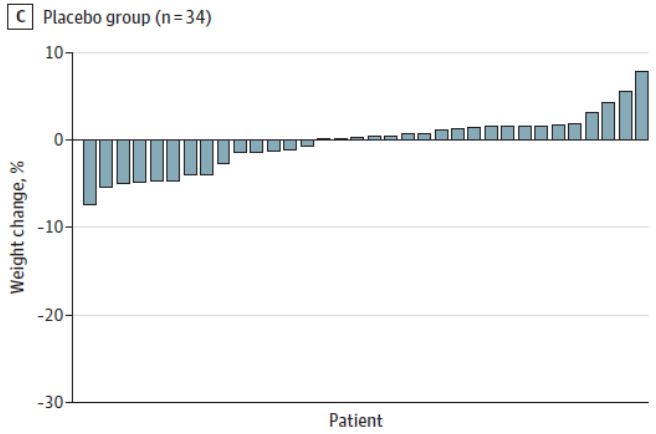
Treatment period of 24 weeks



Loss of regained weight from NADIR

-8.65%





24 weeks of **liraglutide 3.0 mg** in people with **poor weight loss** and a suboptimal GLP-1 response after metabolic surgery, was safe and well tolerated and led to clinically meaningful **reductions in bodyweight**

Mok J et al JAMA Surg. 2023 Oct 1;158(10):1003-1011. doi: 10.1001/jamasurg.2023.2930.

Journal of Clinical Medicine

MDPI

Article

DEVELOPMENT OF INTERNATIONAL FEDERATION FOR SURGERY OF OBESITY AND METABOLIC DISORDERS-EUROPEAN CHAPTER (IFSO-EC) GRADE-BASED GUIDELINES ON THE SURGICAL TREATMENT OF OBESITY USING MULTIMODAL STRATEGIES: DESIGN AND METHODOLOGICAL ASPECTS.

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Panel developed 3 PICOs

GRADE and AGREE II methodology

Recommendation will be expressed

Take home messages

- **Inadequate selection** to MBS is likely to lead to failure
- **Determinant role of drug therapy before MBS** in reducing perioperative complications
- Revisional surgery is not always the answer
- **Combined treatment** options targeted on each patient
- **Drugs** have an important role in postoperative weight regain and insufficient weight loss
- **Role of drugs in enhancing weight loss after MBS and/or ESG**

Maurizio De Luca

Combined Roles of Drugs and MBS in Patients with Obesity

Prof. Maurizio De Luca, *Director Department of Surgery Rovigo,Trecenta and Adria Hospitals– Italy*

IFSO European Chapter 2025

15-17 May 2025, Venice Italy

President of the Congress:
Maurizio De Luca

IFSO-EC MBS in Europe: current trends, up-and-coming doubts

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Thank You for your attention!

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