

Anti Obesity Drugs in Bariatric Patients

Updating Obesity Management Strategies: an Audit of Italian Specialists

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Scientific Committee Italian Society of Obesity (SIO)

Scientific Committee The Upper Gastrointestinal Surgeons (TUGS)

Bari, 18 Maggio 2023

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Eating and Weight Disorders - Studies on Anorexia, Bulimia and Obesity
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ORIGINAL ARTICLE



Updating obesity management strategies: an audit of Italian specialists

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Appendix: Expert panel

Carmela Bagnato (ASM Matera)

Luigi Barrea (Università degli Studi di Napoli Federico II)

Maurizio Battino (Università Politecnica delle Marche, Ancona)

Rocco Barazzoni (Ospedale Cattinara—Università di Trieste)

Silvia Bettini (Università degli Studi di Padova)

Simona Bo (Università di Torino, Città della Salute e della Scienza di Torino)

Giovanni Casella (Università di Roma La Sapienza)

Stefano Celotto (AAS3 Alto Friuli—Collina—Medio Friuli, Udine)

Cristiano Crisafulli (ASP Catania, Distretto di Acireale)

Monica D'Adamo (Università di Roma Tor Vergata)

Riccardo Dalle Grave (Casa di Cura Villa Garda, Garda, Verona)

Nicola Di Lorenzo (Università di Roma Tor Vergata)

Diego Foschi (Ospedale L. Sacco, Università degli Studi di Milano)

Lucia Frittitta (Ospedale Garibaldi, Catania)

Simona Frontoni (Ospedale Fatebenefratelli-Isola Tiberina, Università di Roma Tor Vergata)

Alfredo Genco (Università di Roma La Sapienza)

Ilenia Grandone (Ospedale Santa Maria Terni)

Ignazio Grattagliano (Università degli Studi di Bari Aldo Moro)

Chiara Graziadio (AOU Federico II Napoli)

Valeria Guglielmi (Università di Roma Tor Vergata)

Valeria Lagattola (ASL Bari)

Carla Lubrano (Università di Roma La Sapienza)

Lucio Lucchin (Azienda Sanitaria dell'Alto Adige Comprensorio di Bolzano)

Giovanni Merola (Ospedale San Giovanni di Dio, Fratamaggiore, Napoli)

Fausta Micanti (Università degli Studi di Napoli Federico II)

Fabrizio Muratori (Ospedale Sant'Anna ASST Lariana, Como)

Giovanna Muscogiuri (Università degli Studi di Napoli Federico II)

Giuseppe Navarra (AOU Policlinico di Messina)

Barbara Neri (Azienda Ospedaliera S Camillo-Forlanini Roma)

Barbara Paolini (Ospedale S Maria Alle Scotte, Università di Siena)

Maria Letizia Petroni (Alma Mater Studiorum Università di Bologna, IRCCS Policlinico Sant'Orsola, Bologna)

Giacomo Piatto (Ospedale di Montebelluna, ULSS 2 Marca Trevigiana, Treviso)

Stefano Pintus (ARNAS GBrotzu, Cagliari)

Angelo Michele Schettino (Clinica S Lorenzino Cesena)

Roberto Serra (Azienda Ospedaliera Università di Padova)

Roberto Vettor (Università degli Studi di Padova)

Luisella Vigna (Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milano)













Mikiko Watanabe (Università di Roma La Sapienza)

Maria Grazia Zenti (Azienda Ospedaliera di Verona)

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Most NCDs are not diagnosed on a pathophysiological basis

Diabetes		 Glucose		7.0 mmol/l
Hypertension		 Pressure		140/90 mmHg
COPD		 FEV1/FVC		0.70
Obesity		 BMI		30 kg/m²

Obesity: we need to move beyond BMI

BMI has a relatively poor performance for the diagnosis and the staging of obesity at the individual clinical level.

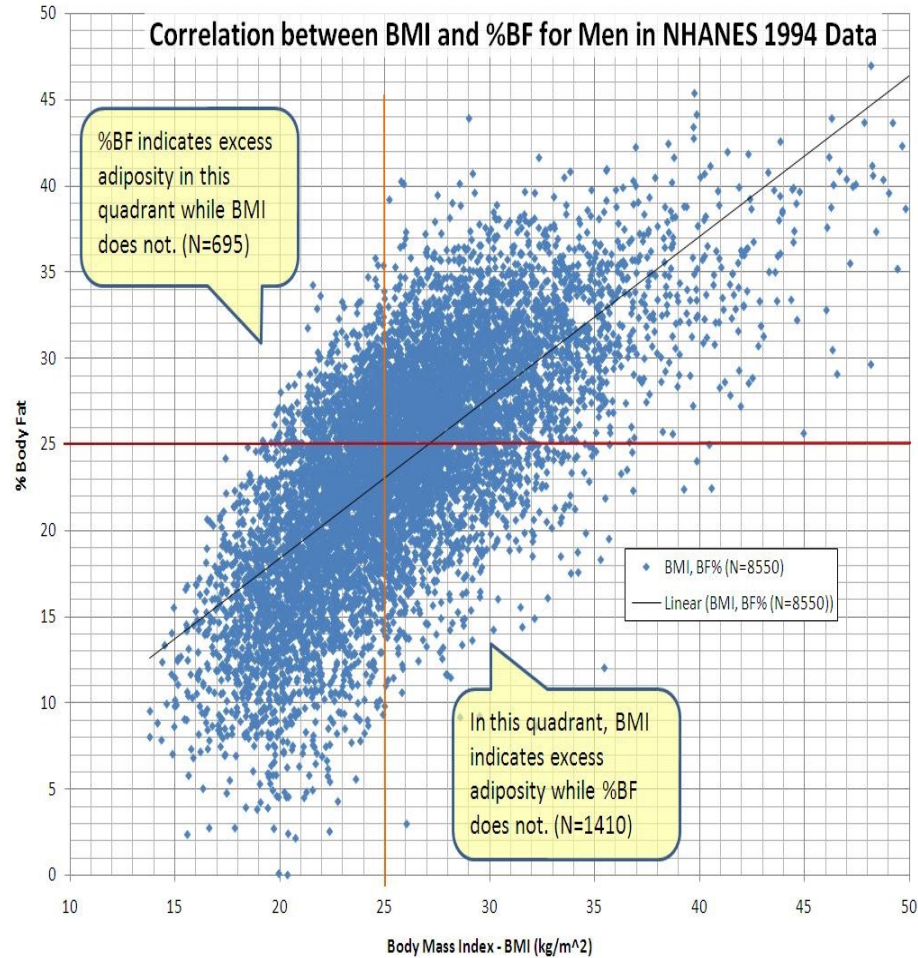
- 1) BMI does not precisely reflect body composition and adiposity level
- 2) BMI does not fully reflect the risk of complications

Obesity: we need to move beyond BMI

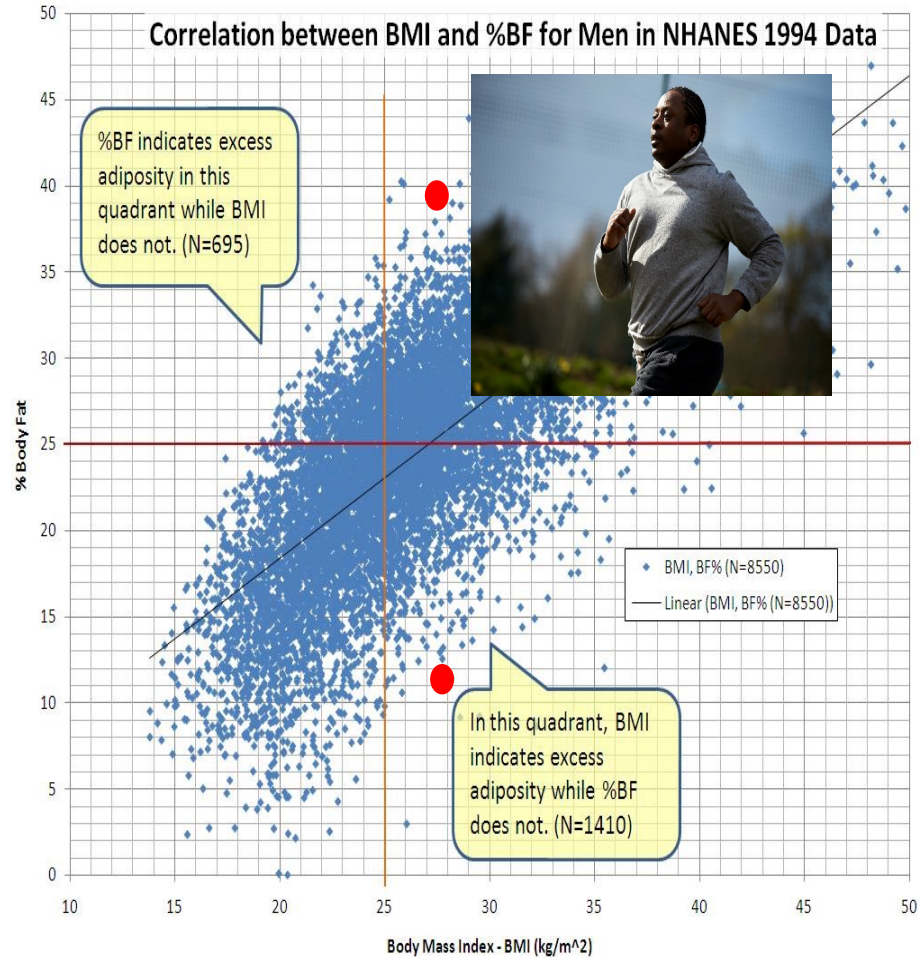
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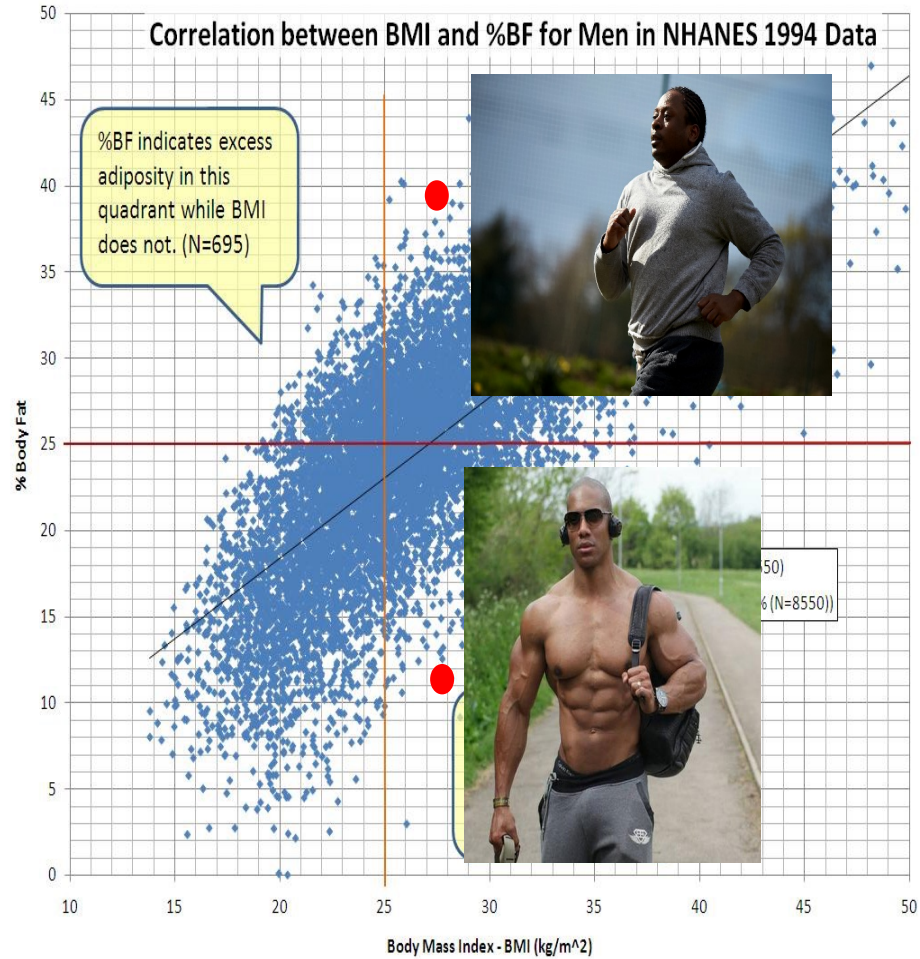
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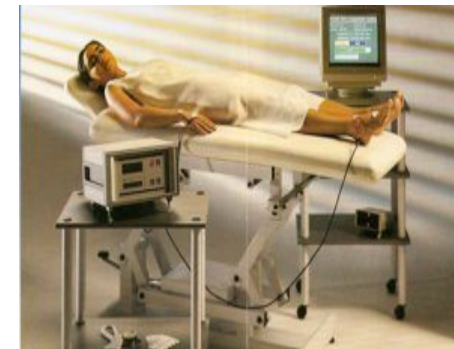
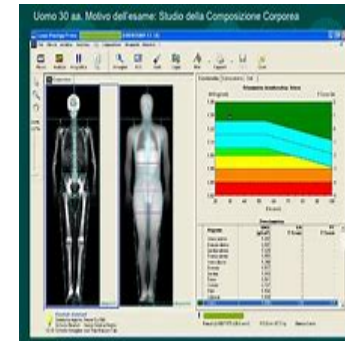
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Updating Obesity Management Strategies: an Audit of Italian Specialists



Management strategies in obesity

Statement 1. *If the patient's clinical features make the clinical significance of BMI questionable, the anthropometric assessment of the patient should include instrumental evaluation of fat mass, i.e., dual-energy X-ray absorptiometry (DEXA) or bioimpedance analysis (BIA)*

(Expert panel median consensus estimate: 9)

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- 1) BMI does not precisely reflect body composition and adiposity level
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Body Mass Index, Waist Circumference, and Health Risk: Evidence in Support of Current National Institutes of Health Guidelines



Table 1. Comparison of Anthropometric and Metabolic Variables and Disease Prevalence in Men With Normal vs High WC Values Within Different BMI Categories*

	BMI Categories					
	Normal-Weight		Overweight		Class I Obese	
	Normal WC (n = 3113)	High WC (n = 30)	Normal WC (n = 2230)	High WC (n = 851)	Normal WC (n = 177)	High WC (n = 984)
Anthropometric variables						
Age, y	42.1 ± 20.9	67.4 ± 9.2†	40.9 ± 15.3	55.4 ± 15.5†	33.0 ± 12.4	48.3 ± 15.6†
BMI, kg/m ²	22.5 ± 1.7	24.4 ± 0.7†	26.7 ± 1.3	28.2 ± 1.2†	30.9 ± 98.2	32.0 ± 1.3†
WC, cm	83.5 ± 7.5	103.3 ± 1.1†	94.2 ± 4.9	105.6 ± 3.5†	98.2 ± 3.0	110.3 ± 5.6†
Metabolic variables						
Systolic BP, mm Hg	124.6 ± 18.3	139.2 ± 17.6†	124.7 ± 14.9	132.8 ± 17.9†	125.3 ± 12.0	131.9 ± 17.3†
Diastolic BP, mm Hg	73.9 ± 11.7	79.7 ± 11.5†	77.0 ± 11.0	80.0 ± 10.5†	76.9 ± 10.8	81.2 ± 10.2†
Fasting glucose level, mg/dL§	95.1 ± 27.0	103.1 ± 22.7†	95.7 ± 22.8	102.3 ± 40.4†	97.0 ± 14.5	106.8 ± 39.0†
Total cholesterol level, mg/dL	191.4 ± 120.2	217.8 ± 30.4†	203.3 ± 40.0	213.7 ± 42.7†	205.8 ± 35.7	211.6 ± 39.4†
LDL cholesterol level, mg/dL	120.2 ± 37.1	139.7 ± 36.4	130.5 ± 34.6	138.5 ± 36.2†	147.4 ± 40.6	135.4 ± 35.5†
HDL cholesterol level, mg/dL	51.8 ± 15.3	51.8 ± 14.0	44.9 ± 12.9	42.0 ± 11.2†	44.5 ± 12.9	40.2 ± 11.2†
Triglyceride level, mg/dL¶	115.3 ± 89.9	130.1 ± 46.7	155.4 ± 108.0	194.5 ± 124.8†	188.5 ± 194.6	217.9 ± 229.6†
Prevalence, %						
Hypertension	15.6	61.2#	23.0	44.6#	21.8	42.0#
Type 2 diabetes	1.9	10.6#	2.7	10.6#	5.1	12.0#
Hypercholesterolemia	11.9	21.9	17.2	26.2#	18.1	21.4#
High LDL cholesterol level	14.0	29.3	19.3	27.2#	27.1	24.1
Low HDL cholesterol level	21.9	15.0	35.3	49.0#	44.4	51.8#
Hypertriglyceridemia	9.4	12.2	21.7	36.3#	24.1	37.1#
Metabolic syndrome	5.7	9.7	11.3	29.0#	11.0	29.3#

*The waist circumference (WC) and body mass index (BMI) categories are described in the "Definition of Groups and Terms" subsection of the "Subjects and Methods" section. Unless otherwise indicated, data are given as mean ± SD. BP indicates blood pressure; LDL, low-density lipoprotein; and HDL, high-density lipoprotein.

†P<.05, compared with the normal WC group within the same BMI category before adjusting for age (t test).

‡P<.05, compared with the normal WC group within the same BMI category before (t test) and after (analysis of covariance) adjusting for age.

§To convert to millimoles per liter, multiply by 0.0555.

¶To convert to millimoles per liter, multiply by 0.0259.

||To convert to millimoles per liter, multiply by 0.0113.

#P<.05, compared with the normal WC group within the same BMI category (χ² analysis).

Janssen I et al. Arch Intern Med.
2002;162:2074.

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Association of Normal-Weight Central Obesity With All-Cause and Cause-Specific Mortality Among Postmenopausal Women

Table 2. Association of Different Combinations of Body Mass Index and WC Status With All-Cause and Cause-Specific Mortality Among 156 624 Postmenopausal Women^a

Model ^b	HR (95% CI)					
	Normal Weight		Overweight		Obesity	
	Normal WC	High WC	Normal WC	High WC	Normal WC	High WC
Participants, No. (%)	52 735 (33.7)	1390 (0.9)	36 337 (23.2)	18 572 (11.9)	4957 (3.2)	42 633 (27.2)
Any Cause Mortality						
No.	13 718	562	8722	6348	1093	13 395
Model 1	1 [Reference]	1.43 (1.31-1.55)	0.92 (0.90-0.95)	1.25 (1.21-1.28)	0.93 (0.87-0.99)	1.40 (1.36-1.43)
Model 2	1 [Reference]	1.39 (1.28-1.51)	0.91 (0.88-0.93)	1.20 (1.17-1.24)	0.90 (0.85-0.96)	1.32 (1.29-1.35)
Model 3	1 [Reference]	1.31 (1.20-1.42)	0.91 (0.89-0.94)	1.16 (1.13-1.20)	0.93 (0.87-0.99)	1.30 (1.27-1.34)

Sun Y et al. JAMA
2019;2:e197337.

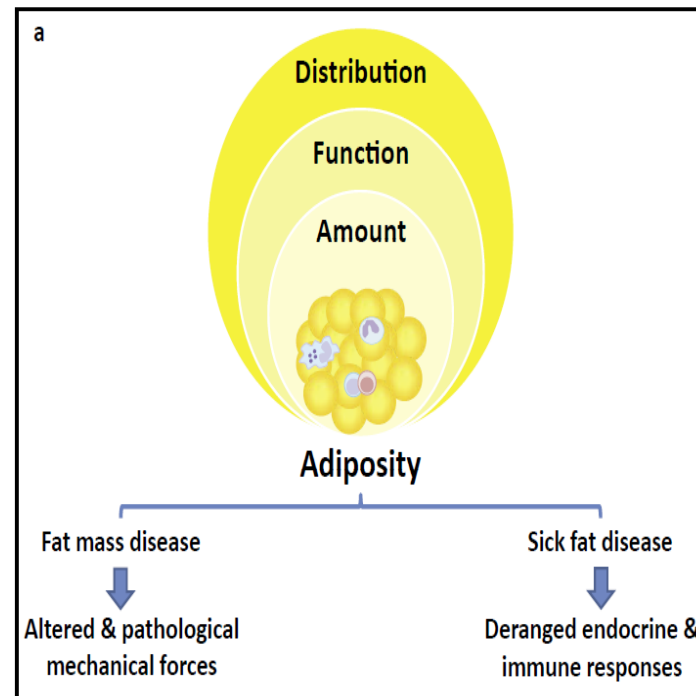
Clinical presentation of obesity is complex

The ABCD of Obesity: An EASO Position Statement on a Diagnostic Term with Clinical and Scientific Implications

Gema Frühbeck^{a,b} Luca Busetto^{a,c} Dror Dicker^{a,d} Volkan Yumuk^{a,e}
Gijs H. Goossens^{a,f} Johannes Hebebrand^{a,g} Jason G.C. Halford^{a,h}
Nathalie J. Farpour-Lambert^{a,i} Ellen E. Blaak^{a,f} Euan Woodward^{a,j}
Hermann Toplak^{a,k}

Obesity Facts
The European Journal of Obesity

Obes Facts 2019;12:131–136



Management strategies in obesity

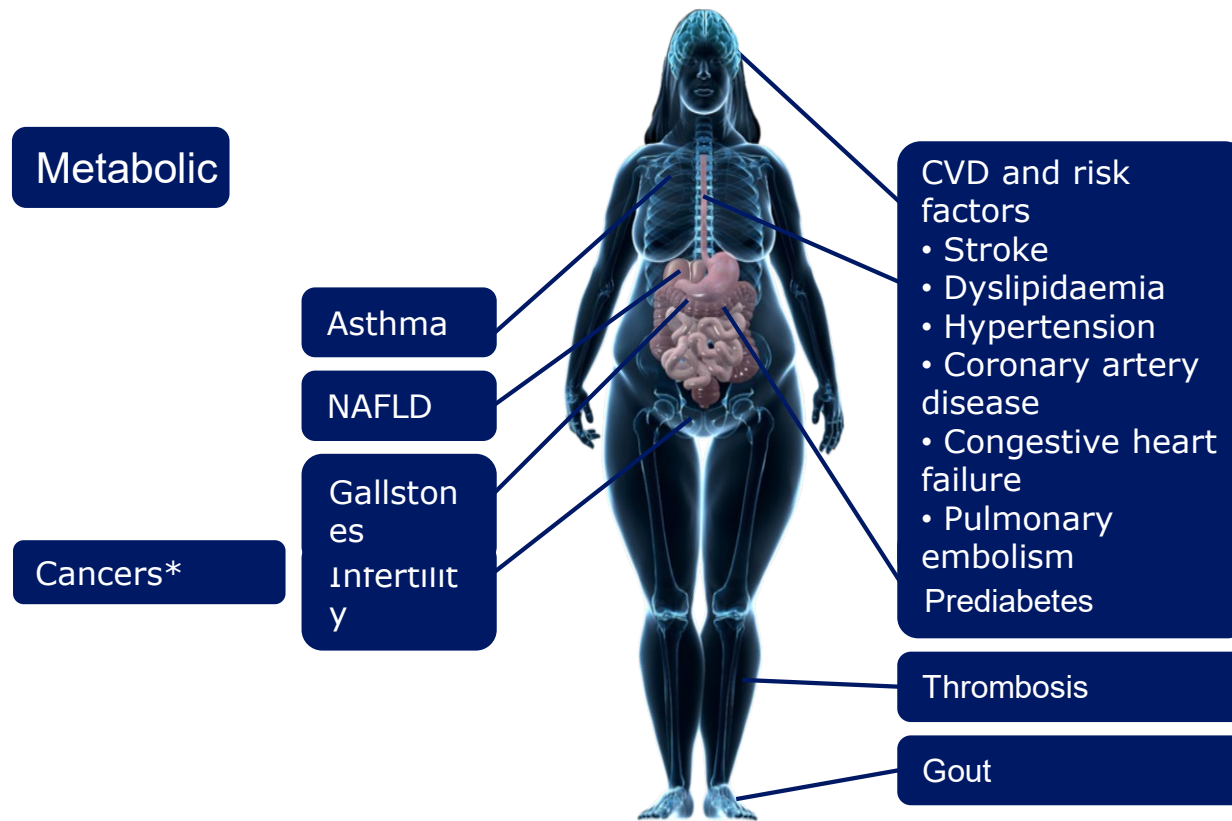
Statement 2. *Cardio-metabolic risk stratification in patients with obesity* should be based on systematic measurement of adipose tissue distribution in addition to BMI.

(Expert panel median consensus estimate: 8)

Updating obesity management strategies: an audit of Italian specialists

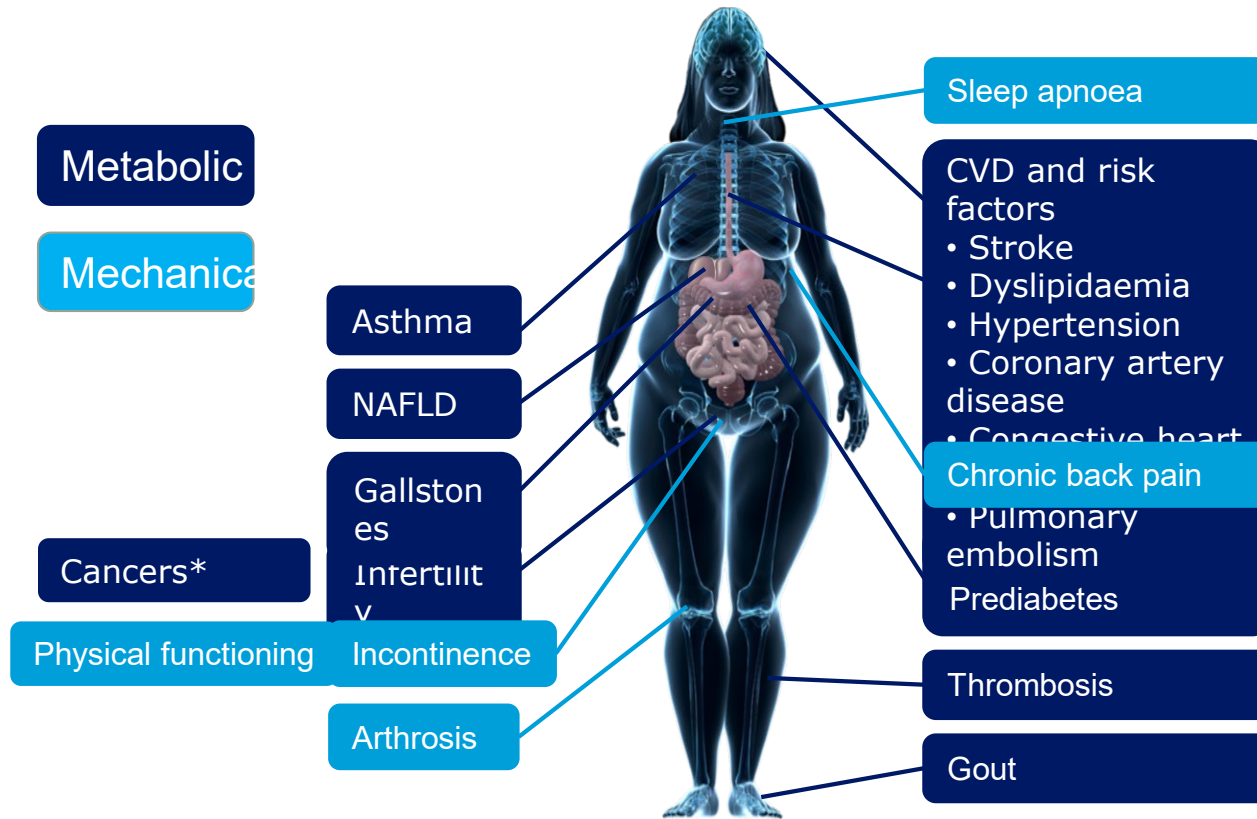
Luca Busetto, Maria Grazia Carbonelli, Antonio Caretto, Annamaria Coalo, Claudio Cricelli, Maurizio De Luca, Francesco Giorgino, Lucio Gnessi, Gerardo Medea, Giovanni Pappagallo, Ferruccio Santini, Paolo Sbraccia, Marco Antonio Zappa
Eating and Weight Disorders – Study on Anorexia, Bulimia and Obesity, 2022 <https://doi.org/10.1007/s40519-022-01402->

Clinical presentation of obesity is complex



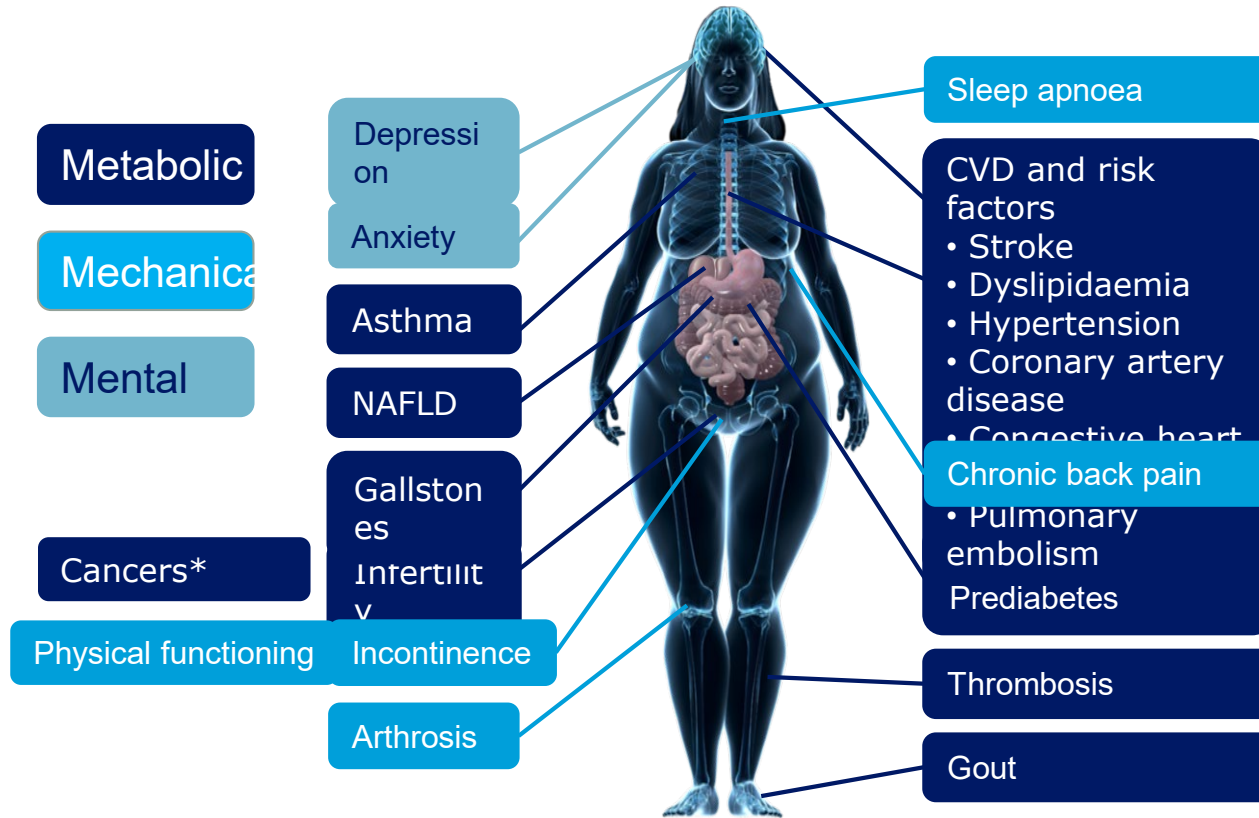
*Including breast, colorectal, endometrial, esophageal, kidney, ovarian, pancreatic and prostate

Clinical presentation of obesity is complex



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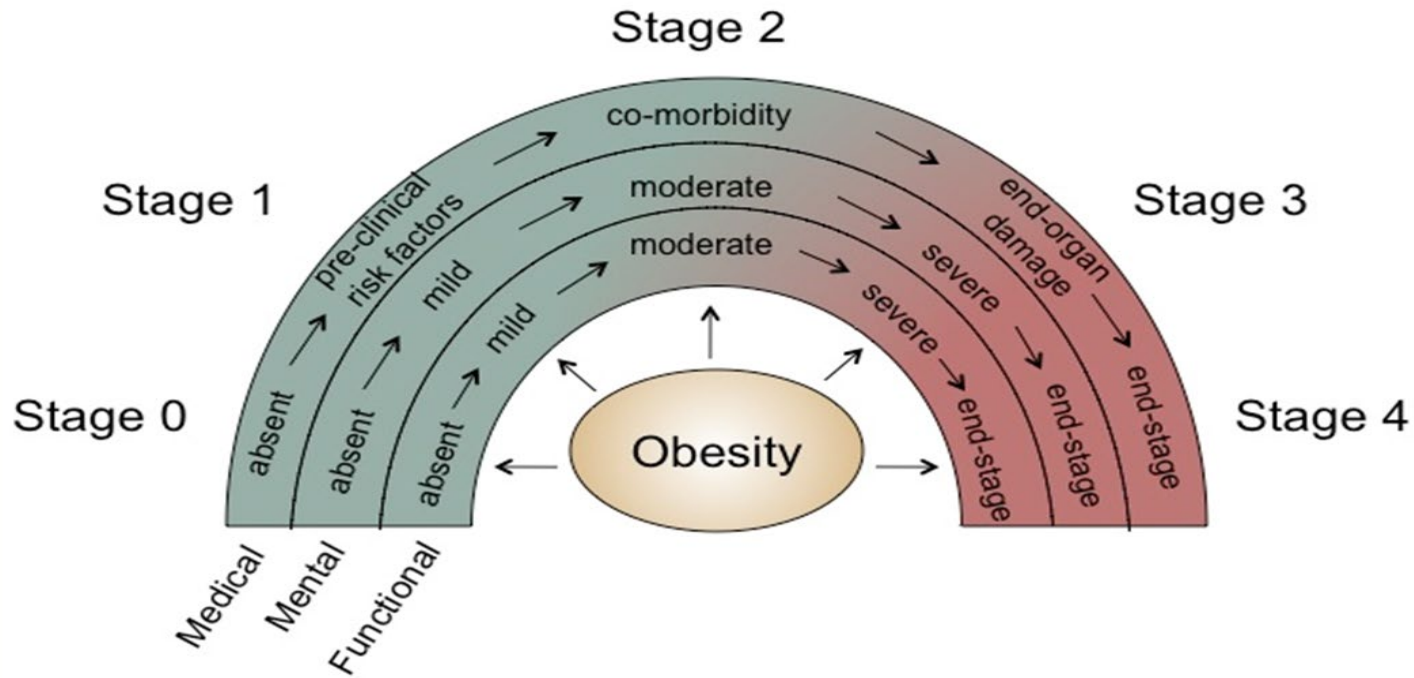
Clinical presentation of obesity is complex



*Including breast, colorectal, endometrial, esophageal, kidney, ovarian, pancreatic and prostate

Clinical presentation of obesity is complex

Edmonton Obesity Staging System (EOSS)



Clinical presentation of obesity is complex

STAGE 0

- **NO** sign of obesity-related risk factors
- **NO** physical symptoms
- **NO** psychological symptoms
- **NO** functional limitations

Case Example:

Physically active female with a BMI of 32 kg/m², no risk factors, no physical symptoms, no self-esteem issues, and no functional limitations.

Class I, Stage 0 Obesity

EOSS Score

WHO Obesity Classification

STAGE 1

- Patient has obesity-related **SUBCLINICAL** risk factors (borderline hypertension, impaired fasting glucose, elevated liver enzymes, etc.) - *OR* -
- **MILD** physical symptoms - patient currently not requiring medical treatment for comorbidities (dyspnea on moderate exertion, occasional aches/pains, fatigue, etc.) - *OR* -
- **MILD** obesity-related psychological symptoms and/or mild impairment of well-being (quality of life not impacted)

Case Example:

38 year old female with a BMI of 59.2 kg/m², borderline hypertension, mild lower back pain, and knee pain. Patient does not require any medical intervention.

Class III, Stage 1 Obesity

STAGE 2

- Patient has **ESTABLISHED** obesity-related comorbidities requiring medical intervention (HTN, Type 2 Diabetes, sleep apnea, PCOS, osteoarthritis, reflux disease) - *OR* -
- **MODERATE** obesity-related psychological symptoms (depression, eating disorders, anxiety disorder) - *OR* -
- **MODERATE** functional limitations in daily activities (quality of life is beginning to be impacted)

Case Example:

32 year old male with a BMI of 36 kg/m² who has primary hypertension and obstructive sleep apnea.

Class II, Stage 2 Obesity

STAGE 3

- Patient has **significant** obesity-related end-organ damage (myocardial infarction, heart failure, diabetic complications, incapacitating osteoarthritis) - *OR* -
- **SIGNIFICANT** obesity-related psychological symptoms (major depression, suicide ideation) - *OR* -
- **SIGNIFICANT** functional limitations (eg. unable to work or complete routine activities, reduced mobility)
- **SIGNIFICANT** impairment of well-being (quality of life is significantly impacted)

Case Example:

49 year old female with a BMI of 67 kg/m² diagnosed with sleep apnea, CV disease, GERD, and suffered from stroke. Patient's mobility is significantly limited due to osteoarthritis and gout.

Class III, Stage 3 Obesity

STAGE 4

- **SEVERE** (potential end stage) from obesity-related comorbidities - *OR* -
- **SEVERELY** disabling psychological symptoms - *OR* -
- **SEVERE** functional limitations

Case Example:

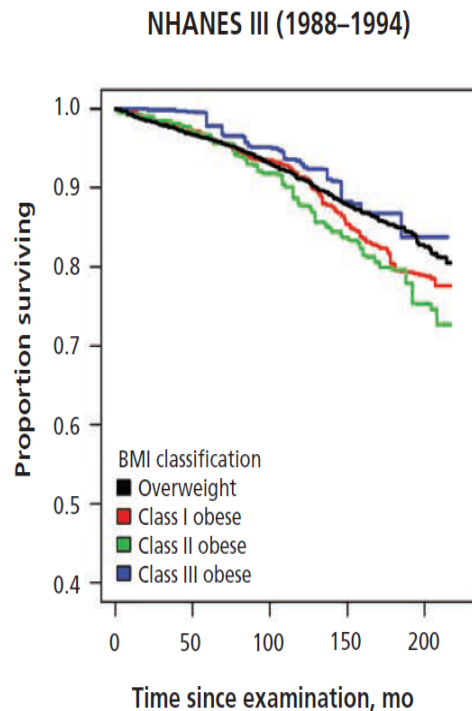
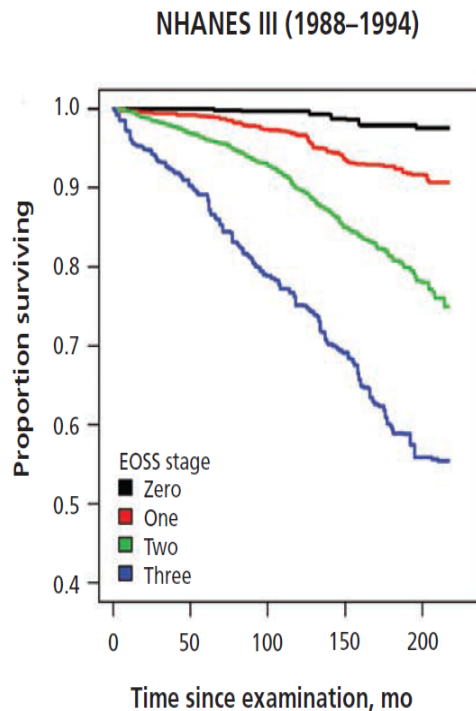
45 year old female with a BMI of 54 kg/m² who is in a wheel chair because of disabling arthritis, severe hyperpnea, and anxiety disorder.

Class III, Stage 4 Obesity

Edmonton Obesity Scoring System

Clinical presentation of obesity is complex

Using the Edmonton obesity staging system to predict mortality in a population-representative cohort of people with overweight and obesity.



**Padwal R et al. CMAJ
2011;183:E1059-66.**



Obesity Surgery 2016, 8, 26: 1659-1696

2016 IFSO Statement on indications for surgery for obesity and weight related diseases

A Position Statement from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)



Maurizio De Luca, Luigi Angrisani, Jacques Himpens, Luca Busetto, Nicola Scopinaro, Rudolf Weiner, Alberto Sartori, Christine Stier, Muffazal Lakdawala, Aparna G Bhasker, Henry Buchwald, John Dixon, Sonja Chiappetta, Hans-Christian Kolberg, Gema Frühbeck, Michel Suter, Emanuele Soricelli, Mattias Blüher, Ramon Vilallonga, Arya Sharma and Scott Shikora



Bariatric Surgery Literature in Class I Obesity Beyond BMI

2015 IFSO Statement on indications for surgery for obesity and weight related diseases

A Position Statement from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)

Statement 2

BMI and anthropometric measures, although useful, have important limitations when applied to individuals for indication to surgery (Level of Evidence 2, grade of recommendation B)

26.Ko GT, Tang JS. Waist circumference and BMI cut-off based on 10-year cardiovascular risk: evidence for "central pre-obesity". *Obesity (Silver Spring)*. 2007;15(11):2832-9.

27.Neel JV. Diabetes mellitus: a "thrifty" genotype rendered detrimental by "progress"? *Am J Hum Genet*. 1962;14:353-62.

28.Saydah SH, Fradkin J, Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA*. 2004;291(3):335-42.

29.Summary of revisions for the 2009 Clinical Practice recommendations. *Diabetes Care*. 2009;32 Suppl 1:S3-5.

30.Dixon JB, Zimmet P, Alberti KG, Rubino F; International Diabetes Federation Taskforce on Epidemiology and Prevention. Bariatric surgery: an IDF statement for obese type 2 diabetes. *Surg Obes Relat Dis*. 2011;7(4):433-47.

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Bariatric Surgery Literature in Class I Obesity Beyond BMI

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Statement 2

BMI and anthropometric measures, although useful, have important limitations when applied to individuals for indication to surgery

The indication for surgery for obesity and weight related disease should be based on the overall assessment of the current health status of the patient with obesity and on the identification of disease risk factors that are not addressed by the only calculation of BMI.

These factors include:

- **distribution of adipose tissue** as an important cardiovascular and metabolic risk factor; a high amount of visceral fat is often associated with an increased liver fat and muscle fat, and pancreatic fat and represent an significant BMI independent risk factor with a causal relationship with the metabolic syndrome.
- **different body composition related to gender**; at equal BMI the percentage of adipose tissue is greater in the female sex.
- **individual fat distribution**; at equal BMI, distribution between adipose tissue and non-adipose tissue may vary; body composition related to age; a positive correlation between age, visceral fat and abnormal lipid and glucose metabolism has been demonstrated.
- **body composition linked to race**; at equal BMI, the risk of developing T2DM and metabolic syndrome is greater in individuals originating from Asian countries; in fact, for these populations and other ethnic groups that are considered at high risk a reduction of the threshold value of 2.5 kg/m² compared to Western standards is recommended for obesity classification, [18, 26-31].
- **psychological and psychiatric symptoms**
- **limitation of functional aspects** [32-34].



Bariatric Surgery Literature in Class I Obesity Beyond BMI

Sub-chapter 4.5 Low BMI

Statement 4.5.1

Surgery for obesity and weight related diseases is effective in patients with class I obesity (BMI 30-35 kg/m²) and comorbidity.
(Level of evidence 1, grade of recommendation A)

60. ASMBS Clinical Issues Committee. Bariatric surgery in class I obesity (body mass index 30-35 kg/m²). *Surg Obes Relat Dis*. 2013;9(1):e1-10.

61. Busetto L, Dixon J, De Luca M, Shikora S, Pories W, Angrisani L. Bariatric surgery in class I obesity: a Position Statement from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO). *Obes Surg*. 2014;24(4):487-519.

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LINEE GUIDA 2016

*** Commissioni

INDICAZIONI ALLA CHIRURGIA BARIATRICA

Maurizio De Luca, Marina Biglia, Maria Grazia Carbonelli, Clemente Nicola, Ludovico Docimo, Cesare Lunardi, Emilio Manno, Fausta Micanti, Natale Pellicano, Antonio Pontiroli, Alberto Sartori, Paolo Sbraccia, Vittorio Sepe, Carlo Sollai, Emanuele Soricelli

INDICAZIONI ALLA CHIRURGIA NEL PAZIENTE DIABETICO (DMT2)

Giuliano Sarro, Luca Busetto, Mario Musella, Ferruccio Santini, Fabrizio Bellini

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Mirto Foletto, Giuseppe Marinari, Pietro Maida, Giuseppe Nanni, Alba Calderone, Maria Laura Chiozza

TRATTAMENTO PERIOPERATORIO

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CHIRURGIA DI REVISIONE

Roberto Moroni, Marco Anselmino, Gianfranco Silecchia, Mauro Toppino

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******* SEGRETARIO GENERALE**

Vincenzo Bruni

LINEE GUIDA SICOB 2016

Indicazioni

ENUNCIATO 2

Il BMI non è l'unico parametro nella selezione dei pazienti candidati alla chirurgia bariatrica e metabolica.

Livello di evidenza 2; grado di raccomandazione A

LINEE GUIDA SICOB 2016

Indicazioni



Le **indicazioni** alla chirurgia bariatrica nel paziente obeso si fondano su diversi parametri:

- 1) **B.M.I. (anche solo > 30 se presenti comorbidità specifiche)** (Liv. 1, RA)
- 2) **Età (anche < 18 anni o > 60 anni, ma con limitazioni specifiche)** (Liv. 2, RB)
- 3) **Presenza di comorbidità specifiche** (Liv. 1 RA)
anche in pazienti candidati al trapianto d'organo (Liv. 3 RC)

In relazione alla capacità della chirurgia bariatrica di:

- 4) **determinare una significativa perdita di peso a lungo termine** (Liv. 1 RA)
- 5) **migliorare la qualità di vita dei pazienti** (Liv. 1, RA)
- 6) **aumentare l'aspettativa di vita** (Liv. 1, RA)

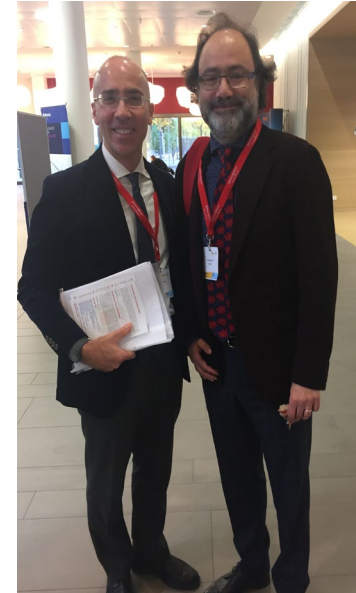
risolvere le comorbidità associate e in particolare:

- 7) **la sindrome delle apnee notturne** (Liv. 1, RA)
- 8) **la patologia articolare** (Liv. 1, RA)
- 9) **la malattia da reflusso gastro-esofageo** (Liv. 2 RB)
- 10) **le endocrinopatie ginecologiche** (Liv. 2 RC)
- 11) **Riduzione dell'insorgenza di (alcune) neoplasie maligne** (Liv. 3 RC)

Algoritmo di cura dei pazienti con sovrappeso o obesità

EOSS	BMI < 30	BMI 30-35	BMI 35-40	BMI >40	Età
STADIO 0					> 60
					< 60
STADIO 1	●			●	> 60
	●				< 60
STADIO 2	●			●	> 60
		●			< 60
STADIO 3			● ●	● ●	> 60
			●	●	< 60
STADIO 4					> 60
		●	●	●	< 60

- interventi sullo stile di vita
- interventi sullo stile di vita e terapia farmacologica (In pazienti con diabete T2, è indicato l'uso preferenziale di farmaci con effetto sul peso come gli analoghi del GLP1RA)
- chirurgia bariatrica + interventi sullo stile di vita e, se indicata, terapia farmacologica
- riabilitazione (motoria, nutrizionale, psichiatrica, cardiopolmonare)
- farmaci: in casi selezionati e se sovrappeso con BMI >27
- chirurgia: in casi selezionati con profilo rischio/beneficio favorevole
- riabilitazione: nei casi nei quali la chirurgia sia controindicata



Standard Italiani per la cura dell'Obesità
SIO- ADI 2016-2017
<http://www.sio-obesita.org/wp-content/uploads/2017/09/STANDARD-OBESITA-SIO-ADI.pdf>

Management strategies in obesity

Statement 3. *Assessment of the presence of medical comorbidities, psychological status, and severity of disability should be performed systematically, using clinical, biochemical, and instrumental parameters with an advantageous cost-effectiveness ratio.*

(Expert panel median consensus estimate: 9)

Updating obesity management strategies: an audit of Italian specialists

Luca Busetto, Maria Grazia Carbonelli, Antonio Caretto, Annamaria Coalo, Claudio Cricelli, Maurizio De Luca, Francesco Giorgino, Lucio Gnessi, Gerardo Medea, Giovanni Pappagallo, Ferruccio Santini, Paolo Sbraccia, Marco Antonio Zappa
Eating and Weight Disorders – Study on Anorexia, Bulimia and Obesity, 2022 <https://doi.org/10.1007/s40519-022-01402->

The patient with prediabetes

STAGE 1

- Patient has obesity-related **SUBCLINICAL** risk factors
(borderline hypertension, impaired fasting glucose, elevated liver enzymes, etc.)
- *OR* -
- **MILD** physical symptoms - patient currently not
requiring medical treatment for comorbidities
(dyspnea on moderate exertion, occasional aches/pains, fatigue, etc.) - *OR* -
- **MILD** obesity-related psychological symptoms
and/or mild impairment of well-being
(quality of life not impacted)

Case Example:

38 year old female with a BMI of 59.2 kg/m², borderline hypertension, mild lower back pain, and knee pain. Patient does not require any medical intervention.

Class III, Stage 1 Obesity

Progression to diabetes

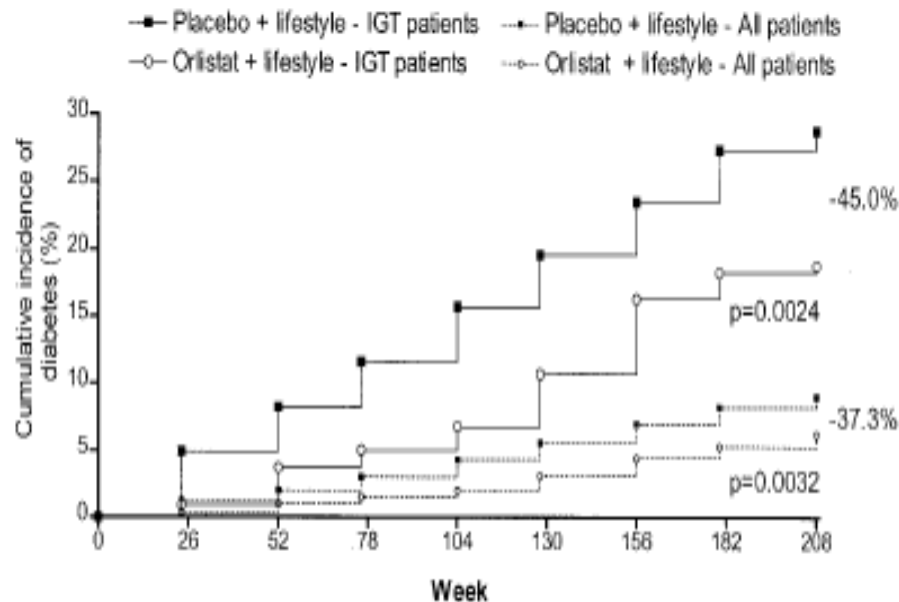
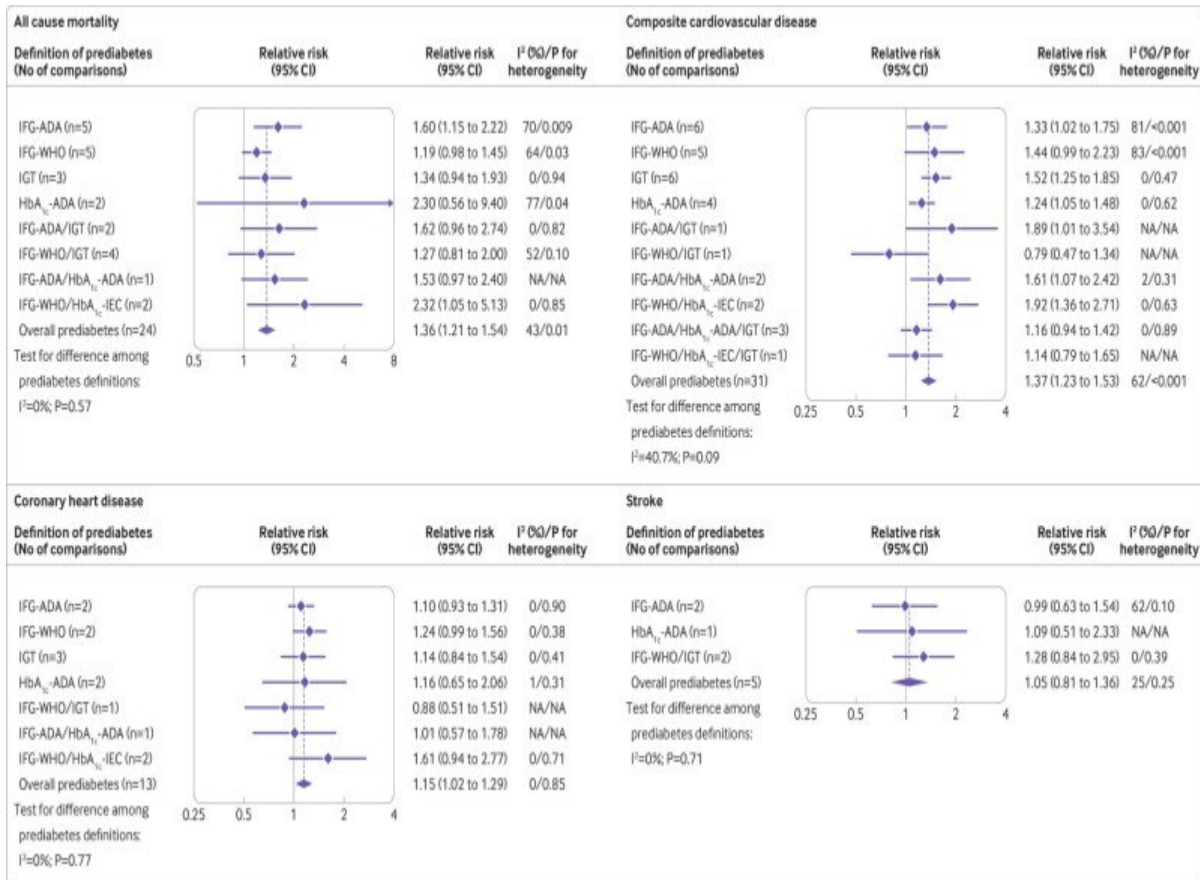
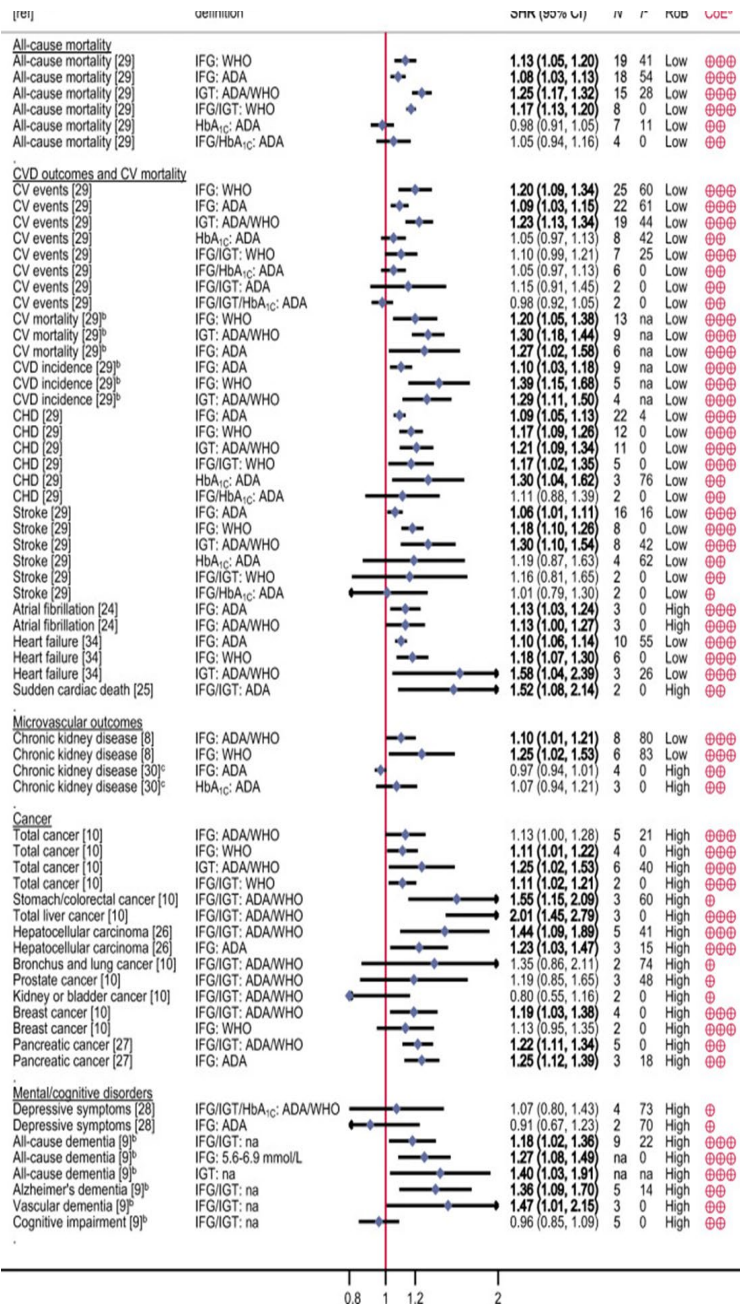


Figure 1—Cumulative incidence of diabetes by study group in all obese patients (IGT or NGT at baseline) and only in obese patients with IGT at baseline. The decrease in the risk of developing diabetes with orlistat plus lifestyle compared with placebo plus lifestyle is indicated. P values shown are for the log-rank test.

Prediabetes, mortality and CVD



Updating Obesity Management Strategies: an Audit of Italian Specialists



Prediabetes, mortality and diabetes-related complications

Schlesinger S et al. Diabetologia. 2022;65:275-285.

Management strategies in obesity

Statement 4. *Impaired fasting glucose and especially impaired glucose tolerance are risk factors for developing type 2 diabetes. These conditions can therefore make a patient eligible for a level of therapy that requires the presence of at least one comorbidity, in addition to a given BMI value.*

(Expert panel median consensus estimate: 8)

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Eating and Weight Disorders – Study on Anorexia, Bulimia and Obesity, 2022 <https://doi.org/10.1007/s40519-022-01402->

Statement 5. In patients *with BMI 27–30 kg/m²* who cannot control body weight with lifestyle modifications only, the presence of *prediabetes is a sufficient criterion to consider anti-obesity pharmacologic therapy.*

(Expert panel median consensus estimate: 8)

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Farmaci autorizzati per il trattamento dell'obesità da parte della FDA e da parte dell'EMA

	Autorizzato FDA	Autorizzato EMA	Regime fornitura AIFA
Fentermina	SI	NO	
Bupropione-naltrexone Approvato FDA settembre 2014 Approvato EMA 2015	si	si	RRL
Fendimetrazina	SI	NO	
rimonabant	No. Mai approvato	no	
Orlistat	SI	SI	RR
Sibutramina	NO	NO	
Lorcaserina Approvato FDA luglio 2012 e ritirato nel 2020	no	No mai approvato	
Fentermina/Topiramato Approvato FDA luglio 2012	SI	Nel 2013 non Autorizzata da parte di EMA	
Liraglutide 3 mg Approvato FDA settembre 2014 e EMA 2015	si	si	RR

Management strategies in obesity

Statement 6. *In patients with BMI 35–40 kg/m² who cannot control their body weight with maximal medical therapy, a prediabetes condition should be considered as a sufficient criterion for proposing bariatric surgery, also based on the age and overall cardio-metabolic risk profile of the patient.*

(Expert panel median consensus estimate: 8)

Updating obesity management strategies: an audit of Italian specialists

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Eating and Weight Disorders – Study on Anorexia, Bulimia and Obesity, 2022 <https://doi.org/10.1007/s40519-022-01402->

Management strategies in obesity

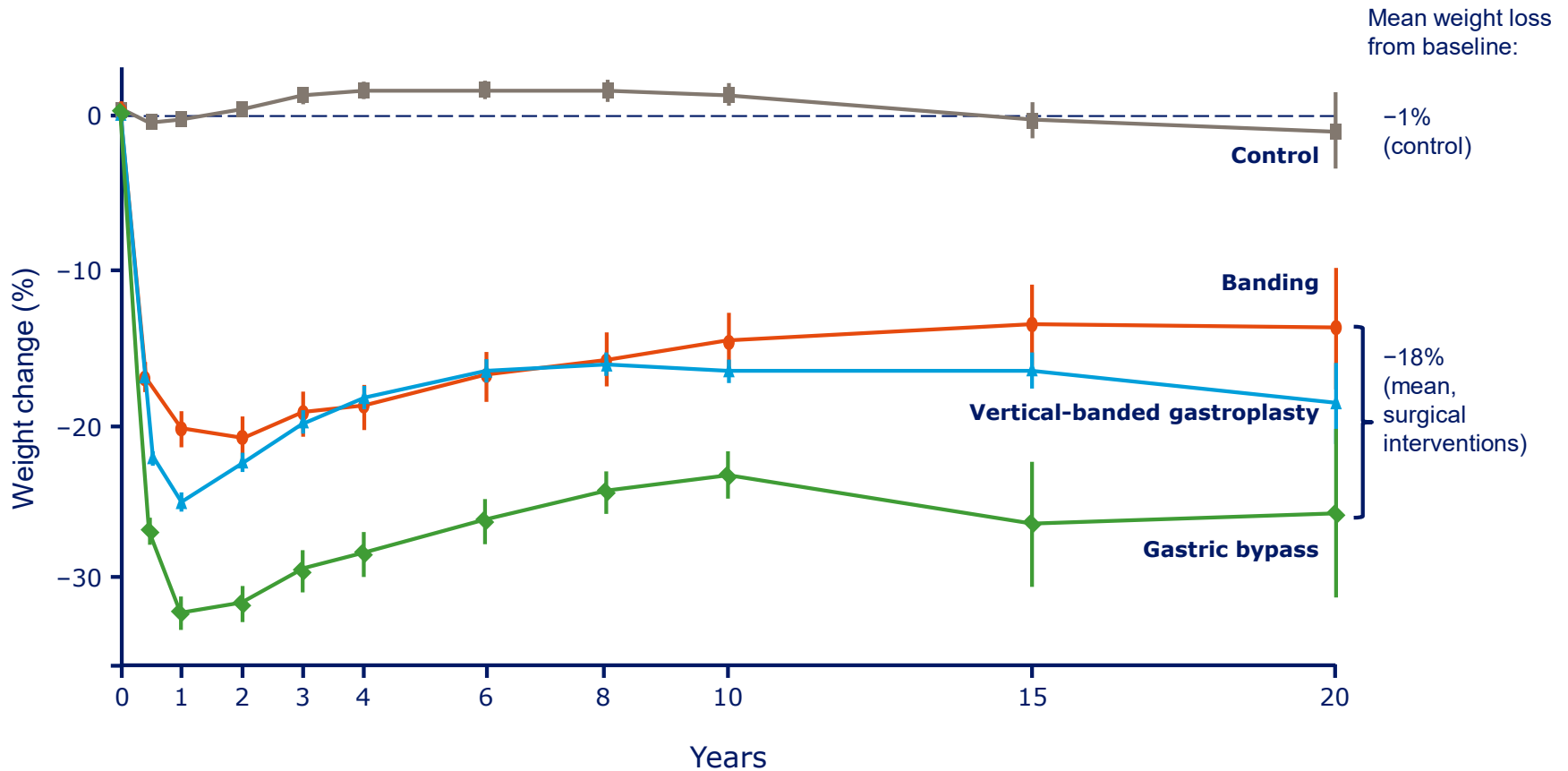
Statement 7. Weight loss is only one of the aspects involved in the entire psycho-physical complexity of patients with obesity. In line with the principles of precision medicine, the therapeutic goal must be *individualized, realistic, shared with the patient, and should take into account the complexity of the clinical situation associated with obesity, as well as the history of the patient's weight and dietary attempts made.* The extent of weight loss should be commensurate with the specific medical comorbidities, psychological status and severity of disability.

(Expert panel median consensus estimate: 9)

Updating obesity management strategies: an audit of Italian specialists

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Eating and Weight Disorders – Study on Anorexia, Bulimia and Obesity, 2022 <https://doi.org/10.1007/s40519-022-01402->

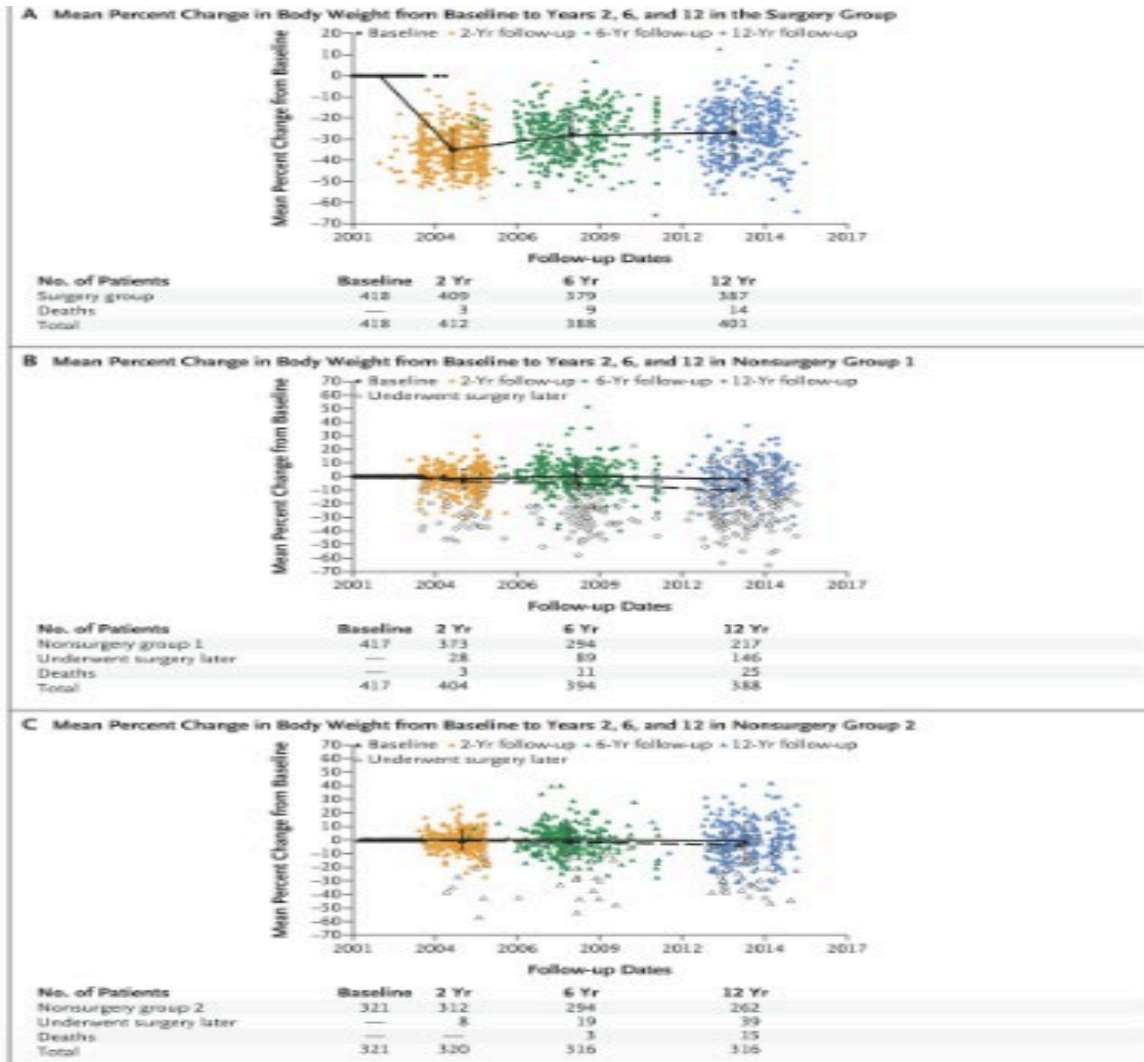
Benefits of bariatric surgery: sustained weight loss over 20 years



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

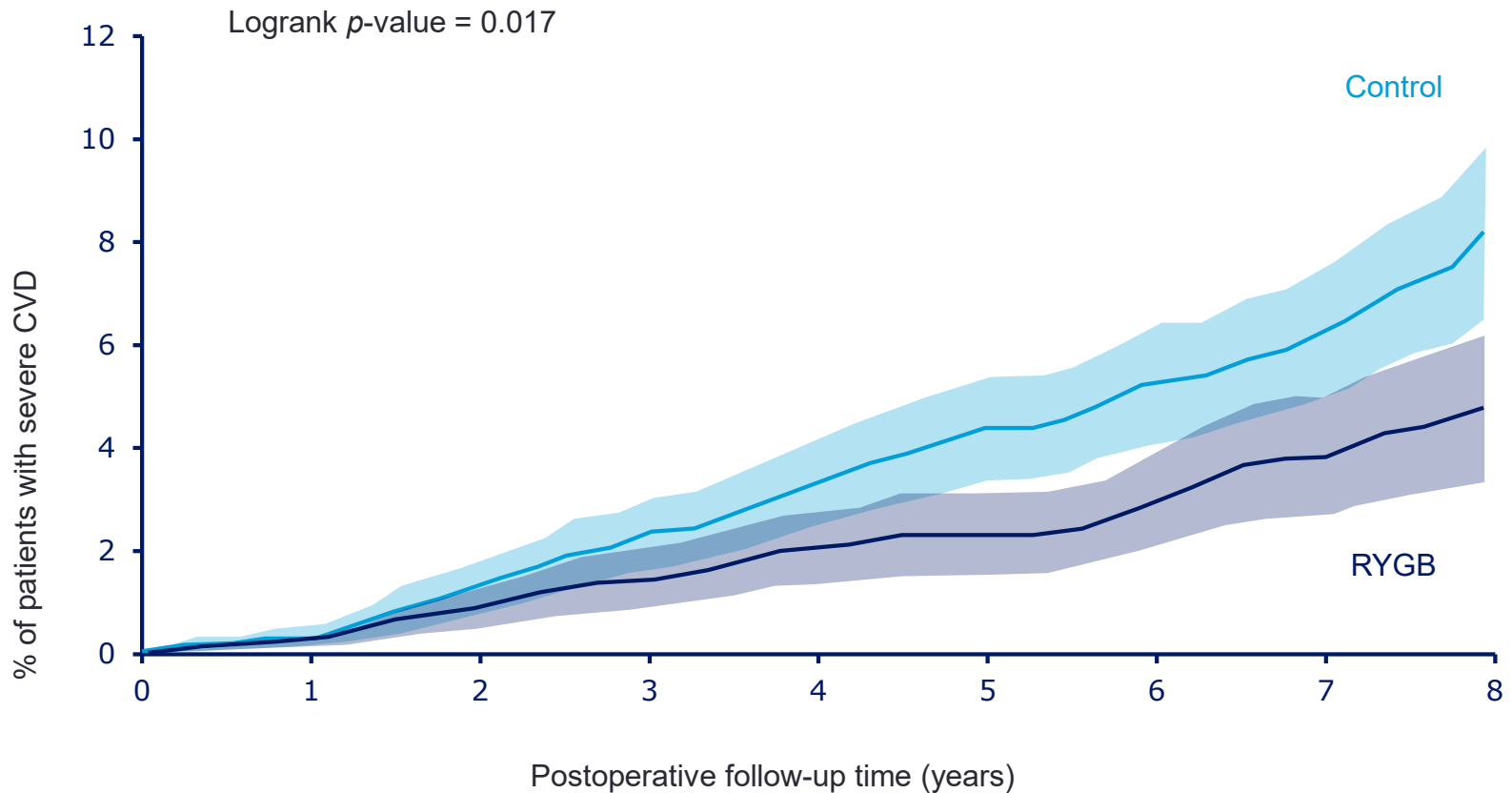
Updating Obesity Management Strategies: an Audit of Italian Specialists

Bariatric surgery is associated with variable weight loss outcomes



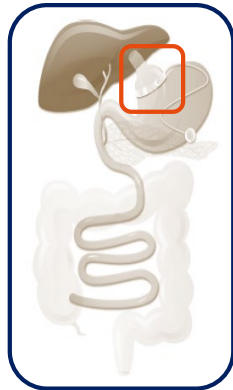
- Observational prospective controlled study
- 1156 pts
- **12 years follow up**
- 418 pts RYGB
- 417 non surgical group 1 (followed up to obesity clinic)
- 321 non surgical group 2 (followed up to obesity clinic)

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

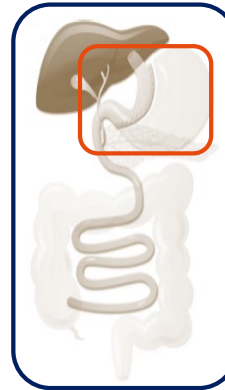
Types of bariatric surgery



Adjustable gastric band

An inflatable band is used to create a small pouch, which limits food consumption

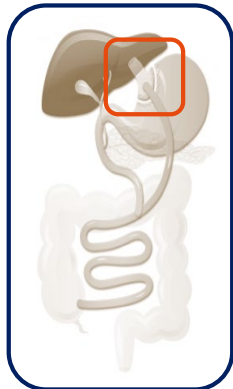
- 1-year weight loss: **14–30%**
- **3%** of total procedures



Vertical sleeve gastrectomy

Permanently removes most of the stomach, leaving a sleeve-shaped pouch; results in ↓ ghrelin (hunger hormone)

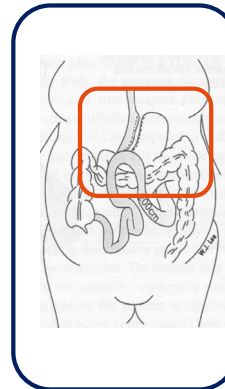
- 1-year weight loss: **20–28%**
- **59%** of total procedures



Roux-en-Y gastric bypass

Creates a smaller stomach and bypasses part of the intestine; results in ↑ GLP-1 (satiety hormone)

- 1-year weight loss: **23–43%**
- **18%** of total procedures



One anastomosis gastric bypass

Similar to Roux-en-Y. Single anastomosis, long bilopancreatic limb

- 1-year weight loss: **38–52%**
- **8–10%** of total procedures

Bariatric metabolic surgery: 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	2.5 days	2.5 days	1–2 days	2.1 days*
Mortality risk	0.5%	0.5%	0.2%	0.4%*
Deficiencies	Vitamin/mineral	Vitamin	Vitamin/mineral (lowest risk of all procedures)	Protein + vitamin/mineral
Other complications	Vomiting, dumping syndrome, ulcers	Non-reversible	Band slippage, erosion, or mechanical problems	Vitamin supplementation required

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

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

Updating Obesity Management Strategies: an Audit of Italian Specialists



- **Trattamento farmacologico pre-operatorio**
- **Trattamento farmacologico post-operatorio**

The rationale of medications for preoperative bariatric surgery preparation

For patients class III obesity (BMI >40 kg/m²) or more, pre-surgical weight loss is suggested to reduce intra-abdominal volume and achieve operability in laparoscopic technique



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



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

Preoperative WL using pharmacological treatment

Study	Year	Study type	Intervention
Modi	2018	Case studies	Liraglutide 3.0 mg
Shah	2017	RCT	Liraglutide 1.8 mg
Morton	2016	Retrospective	Various AOM**
Wang	2015	Retrospective	Lorcaserin
Iglesias	2015	Prospective	Exenatide
Stier	2015	Retrospective	Liraglutide 1.8 mg
Malone	2012	Prospective	Orlistat

**AOM = bupropion/naltrexone, phentermine/topiramate, liraglutide, phentermine or a combination of the aforementioned medications
AOM, anti-obesity medication

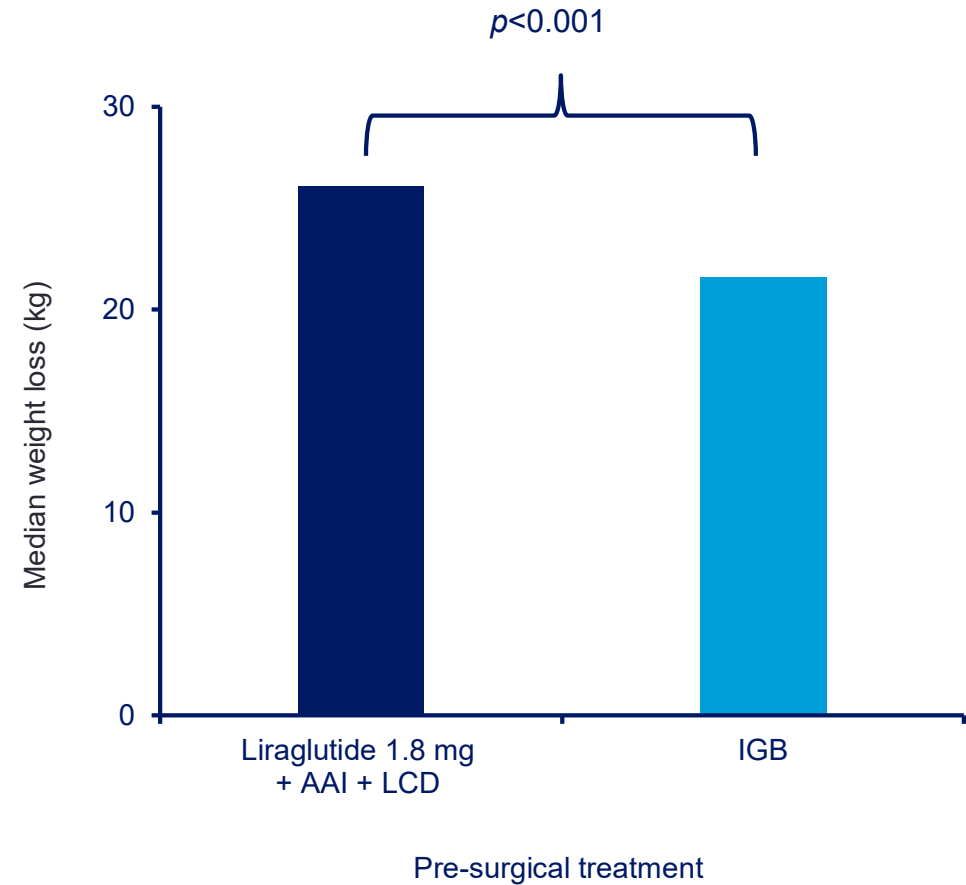
1. Modi *et al. Obes Surg* 2018;28:2113-6;
2. Shah *et al. Obes Surg* 2017;27:137;
3. Morton *et al. Surg Obes Relat Dis* 2016;12:S126;
4. Wang *et al. Value in Health* 2015;18:A295;
5. Iglesias *et al. Obes Surg* 2015;25:575-8;
6. Stier *et al. Diabetes* 2015;64:A43;
7. Malone *et al. Ann Pharmacother*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

Updating Obesity Management Strategies: an Audit of Italian Specialists

Liraglutide is effective for preoperative weight loss compared to intragastric balloon

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/m²) 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

Updating Obesity Management Strategies: an Audit of Italian Specialists



- Trattamento farmacologico pre-operatorio
- Trattamento farmacologico post-operatorio

Aetiology of 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

Updating Obesity Management Strategies: an Audit of Italian Specialists



Conversione: procedura chirurgica diversa dalla precedente

Correzione: modifica delle precedente procedura

Restaurazione: ripristino della condizione pre-intervento (può essere anatomica o funzionale)

ASMBS Revision Task Force, 2014

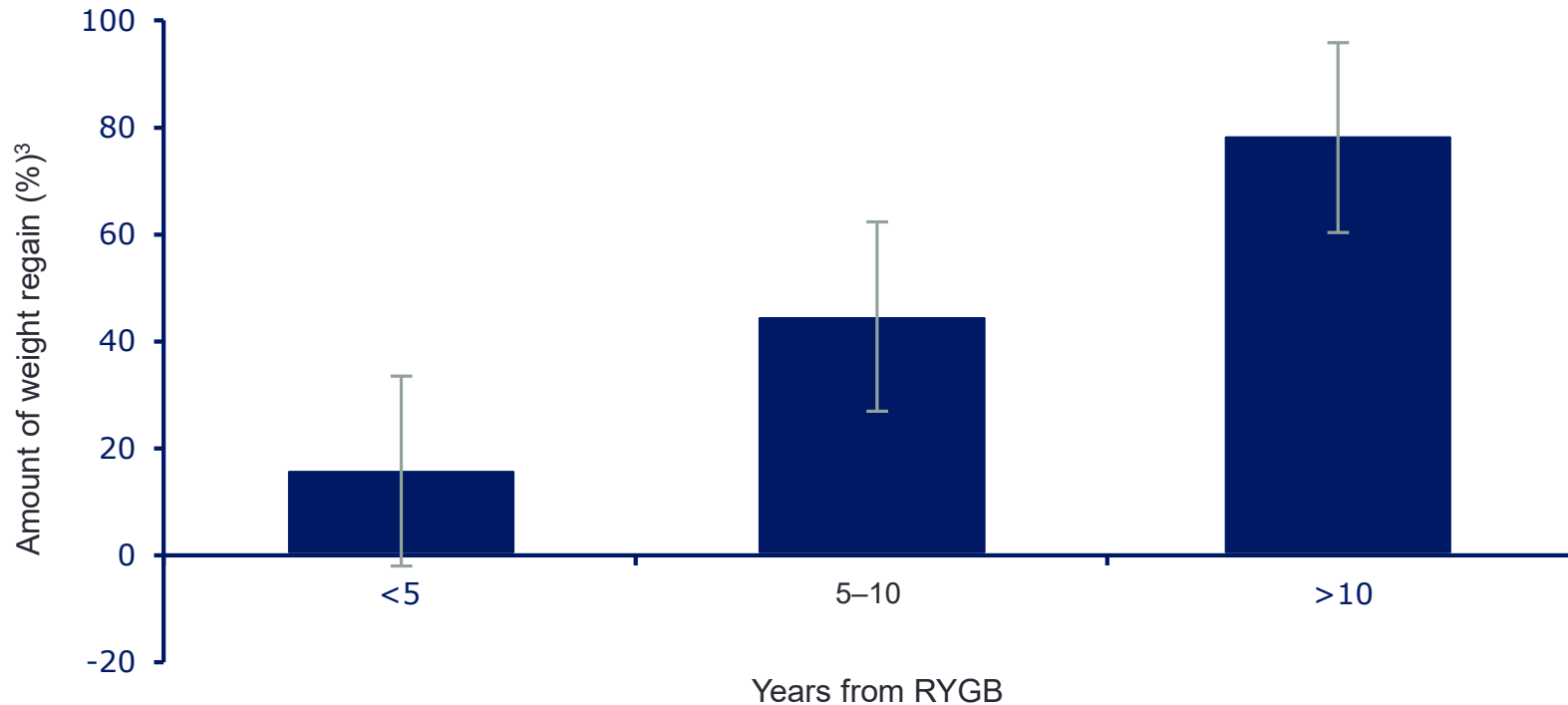
Redo after metabolic-bariatric surgery - Definition

- **Conversion:** surgical procedure different from the previous one
- **Revisional surgery:** modification or revision of the previous procedure
(replace “correction”)
- **Reversal surgery:** reestablish normal anatomy
(replace “restoration”)

IFSO Consensus on Definitions and Clinical Practice Guidelines
Hamburg, March 2023

Weight regain after bariatric surgery

- Significant WR ($\geq 15\%$) occurs in **25–35%** of patients 2–5 years after surgery¹
- However, there is no generally accepted definition for WR. Most are based on kg, BMI units or %EWL²

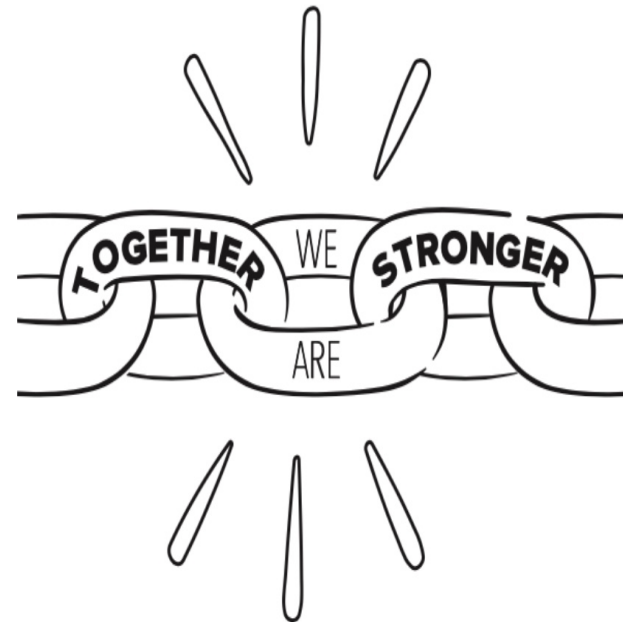
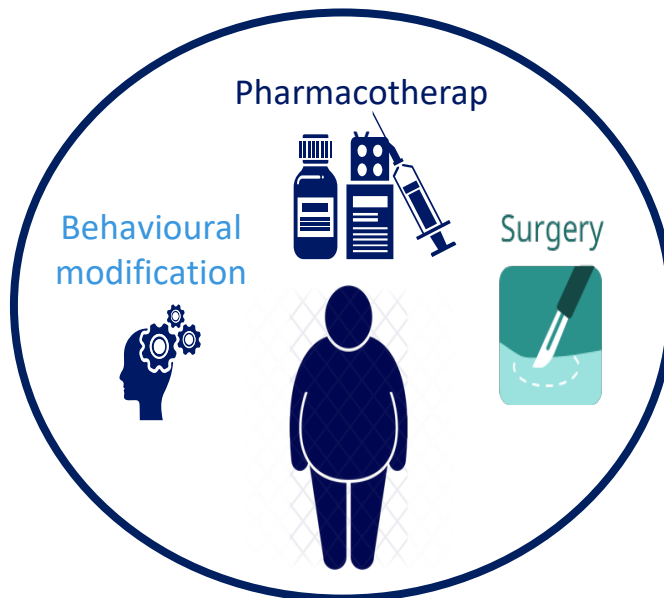


BMI, body mass index; EWL, excess weight loss; RYGB, Roux-en-Y gastric bypass; WR, weight regain

1. Cooper *et al. Obes Surg* 2015;25:1474–81
2. Karmali *et al. Obes Surg* 2013;23:1922–33
3. Jirapinyo *et al. BMJ Open Gastroenterol* 2017;4:e000153

Post-operative Pharmacotherapy

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



Bariatric and metabolic surgery during and after the COVID-19 pandemic: DSS recommendations for management of surgical candidates and postoperative patients and prioritisation of access to surgery



Francesco Rubino, Ricardo V Cohen, Geltrude Mingrone, Carel W le Roux, Jeffrey I Mechanick, David E Arterburn, Josep Vidal, George Alberti, Stephanie A Amiel, Rachel L Batterham, Stefan Bornstein, Ghassan Chamseddine, Stefano Del Prato, John B Dixon, Robert H Eckel, David Hopkins, Barbara M McGowan, An Par, Ameet Patel, François Pattou, Philip R Schauer, Paul Z Zimmet, David E Cummings

Non-surgical options to mitigate harm from delaying surgery

- For patients with multiple weight-responsive comorbidities who face prolonged waiting times for surgery, dietary or pharmacological interventions for weight control might become necessary
- Diets with higher protein content and lower glycaemic index can be effective and should be considered
- Among patients already taking weight-loss medications, efforts should be made to continue the drug(s) until surgery is scheduled, since rapid weight regain is predictable when they are discontinued
- In countries where weight-loss medications (eg, phentermine, orlistat, GLP-1RAs, naltrexone–bupropion, and phentermine–topiramate) are accessible, clinicians could consider their use when weight loss or weight maintenance is important, such as for patients with multiple weight-responsive comorbidities

Anti obesity medications after bariatric surgery

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, pramlintide, 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. Pajeci *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



Efficacy of High-Dose Liraglutide as an Adjunct for Weight Loss in Patients with Prior Bariatric Surgery

Peter Rye¹ • Renuca Modi^{2,3} • Sarah Cawsey^{3,4} • Arya M. Sharma^{3,4}

Median weight change was:

126.25 (presurgery)
92.45 kg (nadir),
109.55 kg (prior to starting liraglutide)
99.4 kg (after 16 weeks of liraglutide)
95.9 kg (after 28 weeks of liraglutide)

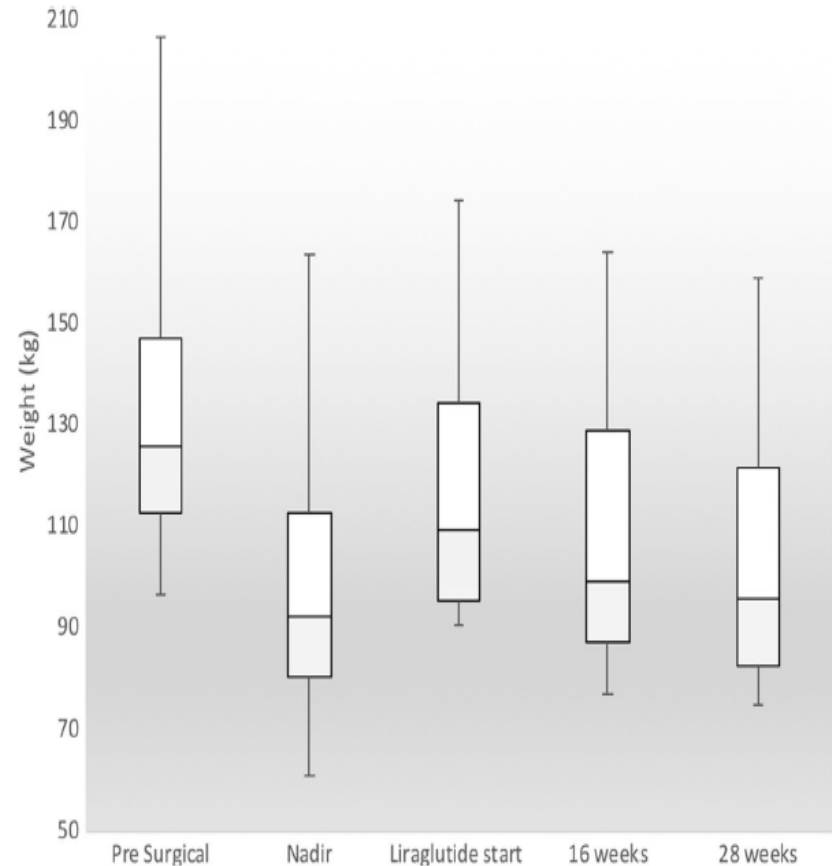
Median percentage weight loss was:

7.1% 16 weeks
9.7% at 28 weeks

Median BMI change was:

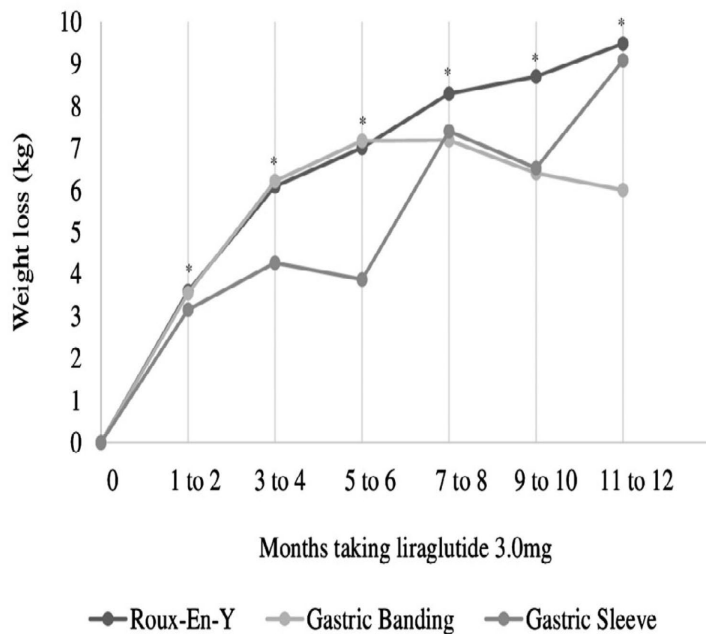
3.5 kg/m² at 16 weeks
4.7 kg/m² at 28 weeks

Liraglutide 3.0 mg in post bariatric-surgery weight regain



Liraglutide 3.0 mg for the management of insufficient weight loss or excessive weight regain post-bariatric surgery

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*Significantly different from baseline regardless of surgical group ($P < 0.05$)

FIGURE 1 Weight loss while taking liraglutide 3.0 mg over time by type of bariatric surgery

Summary

To assess the effectiveness of liraglutide 3.0 mg in post-bariatric surgery patients, and to determine whether this would differ based on the type of bariatric surgery. One hundred seventeen post-bariatric surgery patients from the Wharton Medical Clinic were analysed. Changes in weight while taking liraglutide 3.0 mg were examined for all patients, and by three types of bariatric surgery—Roux-en-Y gastric bypass, gastric banding and gastric sleeve. Patients primarily underwent Roux-en-Y gastric bypass ($n = 53$, 45.3%) or gastric banding ($n = 50$, 42.7%). Over 7.6 ± 7.1 months taking liraglutide 3.0 mg, patients lost a statistically significant amount of weight (-6.3 ± 7.7 kg, $P < .05$) regardless of the type of surgery they had ($P > .05$). This decrease in weight remained significant after 1-year of taking liraglutide 3.0 mg ($P < .05$). Nausea was the most prevalent side effect, reported by 29.1% patients. While options for excess weight management in post-bariatric surgery patients are limited, results of this study suggest that 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. Further, similar to non-surgical populations, 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.

KEYWORDS

bariatric surgery, liraglutide 3.0 mg, pharmacologic therapy, weight loss

ORIGINAL CONTRIBUTIONS



Reversal of Long-Term Weight Regain After Roux-en-Y Gastric Bypass Using Liraglutide or Surgical Revision. A Prospective Study

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- Liraglutide-treated bariatric patients lost a similar amount of weight (13 ± 8 kg or BMI 4.7 ± 2.9 kg/m²) as did surgically revised patients (17 ± 7 kg or BMI 5.5 ± 2.9 , NS vs liraglutide) during the 24 months of study.
- Treatment of weight regain after RYGB surgery should primarily be treated with liraglutide

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

Group	N	BMI-0 [†] kg/m ²	BMI-24 [‡] kg/m ²	delta BMI-lost kg/m ²	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 ± 4.4	-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 ± 3.3	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 ± 4.4	5.5 ± 2.9 [£]	96 ± 12 [#]	90 ± 12	88 ± 12	85 ± 12	83 ± 11	82 ± 12	79 ± 10 [£]

Values are given as mean ± standard deviation (SD)

[†] BMI-0 depicts BMI at the beginning of liraglutide therapy, endosurgery, or Fobi-ring implantation, respectively

[‡] BMI-24 depicts BMI after 24 months of liraglutide therapy or after Fobi-ring implantation and 12 months after endosurgery, respectively

[&] Daily dose of subcutaneous liraglutide at 24 months (m): 2.0 ± 0.9 mg (range 0.6 to 3.0 mg)

[#] $p < 0.01$ controls vs other groups before treatment (ANOVA)

[§] All patients demanded additional drug therapy after 12 months of treatment

[§] Laparoscopic pouch revision with Fobi-ring [11, 17]

[£] $p < 0.001$, ANOVA for repeated measures 0 vs 24 months of treatment

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Demographic Data and Baseline Characteristics for Patients ≤30 Years Old.

Preoperative Characteristics			
Mean BMI (kg/m ²)	50.6 (SD = 10.2)	47.1 (SD = 5.8)	51.7 (SD = 11.1)
Obesity Class			
Class I (BMI 30–34.9)	0	0	0
Class II (BMI 35–39.9)	5 (13.5%)	1 (11.1%)	4 (14.3%)
Class III (BMI ≥ 40)	32 (86.5%)	8 (88.9%)	24 (85.7%)
Comorbid Conditions (Individual)			
Hypertension	10 (27%)	2 (22.2%)	8 (28.6%)
Type II Diabetes	2 (5.4%)	0	2 (7.1%)
OSA	10 (27%)	2 (22.2%)	8 (28.6%)
Dyslipidemia	10 (27%)	3 (33.3%)	7 (25%)
NAFLD	28 (74.3%)	4 (44.4%)	24 (85.7%)
Number of Comorbid Conditions			
None	4	2	2
1	16	4	12
2	10	2	8
3	4	1	3
4	3	0	3

	All Patients	Sleeve Gastrectomy	Roux-En-Y Gastric Bypass
Post-Op Nadir Before Medication	n = 37	n = 9 (24.3%)	n = 28 (75.7%)
Mean BMI (kg/m ²)	33.9 (SD = 7.8)	34.6 (SD = 4.9)	33.7 (SD = 8.6)
Mean Time to Achieve Nadir (months)	17.3 (SD = 11.2)	15.9 (SD = 10.8)	17.7 (SD = 11.4)
At Start of Medication			
Mean BMI (kg/m ²)	38.5 (SD = 8.3)	37.3 (SD = 5.7)	38.9 (SD = 9.1)
Time elapsed between surgery and start of medication (months)			
Mean (SD)	52.2 (SD = 38.7)	20.1 (SD = 5.2)	62.6 (SD = 39.1)
Min	6.6	9.8	6.6
Max	164.8	28.1	164.8
Post-Medication Treatment—At Nadir Weight			
Mean BMI (kg/m ²)	34.0 (SD = 6.4)	35.9 (SD = 5.6)	33.4 (SD = 6.6)

- Retrospective cohort study
- Postoperative use of topiramate, phentermine, and/or metformin
- 21-30 years old patients
- RYGB, SG

- 54.1% of pts lost >5% of post-surgical WL
- 34.3% of pts lost >10% of post surgical WL
- 22.9 % of pts lost >15% of post surgical WL
- RYGB > median %EWL than SG (-8.1% vs -3.3%)

AT. Toth et al. Weight Loss Medications in Young Adults after Bariatric Surgery for Weight Regain or Inadequate Weight Loss: A Multi-Center Study. Children Basel, 2018, 5,9, 116

Management strategies in obesity

Statement 8. *Intensification of therapy in patients with obesity should be started early* if the patient is at risk of comorbidities and/or when there is evidence for a preventive role of weight loss in the occurrence of specific comorbidities.

(Expert panel median consensus estimate: 9)

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Eating and Weight Disorders – Study on Anorexia, Bulimia and Obesity, 2022 <https://doi.org/10.1007/s40519-022-01402->

Management strategies in obesity

Statement 9. In patients with obesity, *the main guiding criteria for the choice of therapy level (lifestyle modification/anti-obesity pharmacologic therapy/bariatric surgery) should be not only the BMI value but also the disease stage, based on assessment of the medical comorbidities, psychological status, and severity of disability.*

(Expert panel median consensus estimate: 9)

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Statement 10. In patients with *severe obesity* and/or advanced stage, it is advisable to immediately consider *the pharmacologic or surgical therapy* according to specific indications/contraindications, in addition to lifestyle modifications.

(Expert panel median consensus estimate: 9)

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Conclusions

- 1 Obesity is a chronic disease linked to a disruption of the physiologic mechanisms regulating eating behaviour and energy balance.
- 2 Genetic, biological and environmental factors contribute to obesity.
- 3 *Comorbidities, particularly cardio-metabolic risks, should be based on systematic measurement of adipose tissue in addition to BMI.*
- 4 The efficacy of anti-obesity interventions based on patients' education and lifestyle change is overestimated and can delay more effective strategies.
- 5 *Clinicians should avoid therapeutic inertia and approach a more intensive therapeutic approach beyond the BMI.*
- 6 In patients with obesity the main guiding criteria for the choice of therapy level, *lifestyle modification vs anti-obesity pharmacologic therapy vs bariatric/metabolic surgery*, is the disease stage based on the assessment of medical comorbidities, psychological status, severity of disability.

Updating Obesity Management Strategies: an Audit of Italian Specialists



Thank you
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