



**CORSO SICOB III EDIZIONE
MILANO 11-12 APRILE 2024**

IL MANAGEMENT DELL'OBESITÀ

DIRETTORI DEL CORSO: MAURIZIO DE LUCA, GIUSEPPE NAVARRA

Corso sul management nutrizionale, psicologico-psichiatrico, motorio, farmacologico, endoscopico e chirurgico per i pazienti affetti da obesità.

**PROVIDER SICOB
EVENTO ACCREDITATO ECM 401500
15 CREDITI FORMATIVI**

Linee guida e ISS

**MATTEO MONAMI
AOU-CAREGGI- FIRENZE**

Conflitti di interessi

Negli ultimi due anni, M. Monami ha ricevuto:
compensi per relazioni a corsi/convegni da **Sanofi e Zuccato srl**
compensi da agenzie in simposi sponsorizzati da **Boehringer Ingelheim, Eli Lilly, Mundipharma, Novo Nordisk, Sanofi e Takeda**

Legge n. 24/2017

Criteri di inclusione

1. Essere elaborate da **gruppi multidisciplinari e multiprofessionali di esperti**;
2. Essere basate su un **processo esplicito e sistematico di ricerca** della letteratura biomedica;
3. Dimostrare un legame esplicito e oggettivo fra **rilevanza e validità delle evidenze trovate** e forza relativa delle raccomandazioni;
4. Offrire **raccomandazioni di comportamento clinico assistenziale** su questioni cliniche o clinico-organizzative specifiche.

Criteri di esclusione

1. ***Position statements, consensus statements, consensus papers***, cioè prese di posizione di gruppi di esperti
2. ***LG basate su consenso di esperti***
3. ***Percorsi clinico assistenziali (PDTA)***

Legge n. 24/2017

Le LG devono superare il processo di valutazione da parte del **CNEC** (Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure):

1. Valutazione della qualità del reporting della LG (AGREE-based)
2. Valutazione della qualità metodologica (AGREE-based)

AGREE (Appraisal of Guidelines for Research and Evaluation) - II

DOMAIN 1: SCOPE AND PURPOSE

DOMAIN 2: STAKEHOLDER INVOLVEMENT

DOMAIN 3: RIGOUR OF DEVELOPMENT

DOMAIN 4: CLARITY OF PRESENTATION

DOMAIN 5: APPLICABILITY

DOMAIN 6: EDITORIAL INDEPENDENCE

AGREE (Appraisal of Guidelines for Research and Evaluation) - II

DOMAIN 1: SCOPE AND PURPOSE



Article

Development of the Italian Clinical Practice Guidelines on Bariatric and Metabolic Surgery: Design and Methodological Aspects

Maurizio De Luca ¹, Marco Antonio Zappa ², Monica Zese ¹ , Ugo Bardi ³, Maria Grazia Carbonelli ⁴, Francesco Maria Carrano ⁵ , Giovanni Casella ⁶ , Marco Chianelli ⁷, Sonja Chiappetta ⁸ , Angelo Iossa ⁹, Alessandro Martinino ¹⁰ , Fausta Micanti ¹¹, Giuseppe Navarra ¹², Giacomo Piatto ¹³, Marco Raffaelli ¹⁴ , Eugenia Romano ¹⁵, Simone Rugolotto ¹, Roberto Serra ¹⁶, Emanuele Soricelli ¹⁷, Antonio Vitiello ¹⁸ , Luigi Schiavo ¹⁹, Iris Caterina Maria Zani ²⁰, Giulia Bandini ²¹, Edoardo Mannucci ²¹, Benedetta Raggianti ²¹ and Matteo Monami ^{21,*}  on behalf of the Panel and Evidence Review Team for the Italian Guidelines on Surgical Treatment of Obesity

AGREE (Appraisal of Guidelines for Research and Evaluation) - II

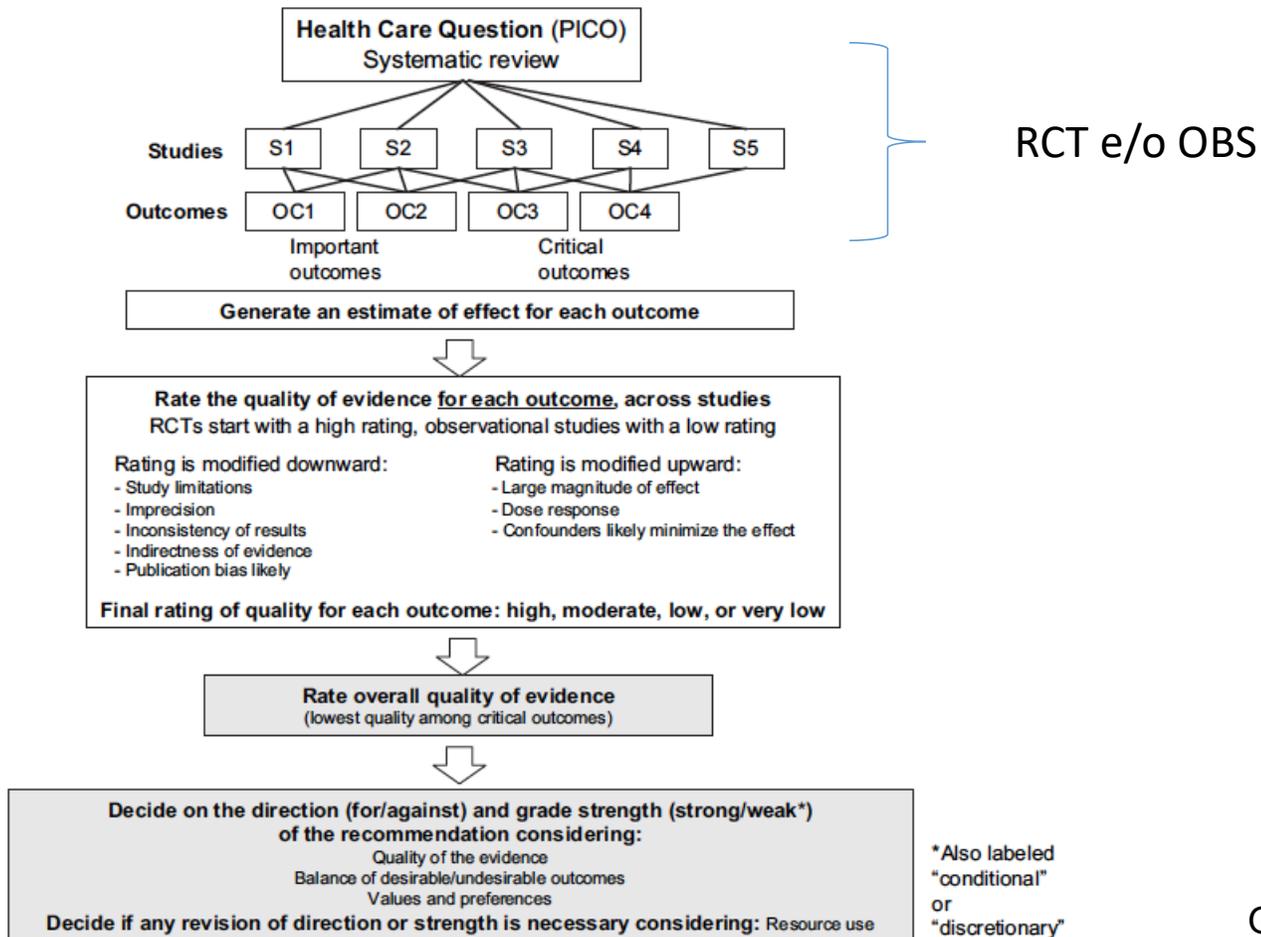
DOMAIN 2: STAKEHOLDER INVOLVEMENT

SICOB: Società Italiana di Chirurgia dell'Obesità (Italian Society of Obesity Surgery); ACOI: Associazione Chirurghi Ospedalieri (Hospital Surgeons Association); IFSO: International Federation for the Surgery of Obesity and Metabolic Disorders; SID: Società Italiana di Diabetologia (*Italian Society for the Study of Diabetes*); AME: Associazione Medici Endocrinologi (Endocrinologist Association); SIO: Società Italiana dell'Obesità (Italian Society of Obesity); SIMG: Società Italiana di Medicina Generale e delle Cure Primarie (Italian Society of General Medicine and Primary Care); SIP: Società Italiana di Pediatria (Italian Society of Pediatrics); ADI: Associazione Italiana di dietetica e Nutrizione Clinica (Italian Association of Dietetics and Clinical Nutrition); SIS: Società Italiana di Statistica (Italian Society of Statistics).

DOMAIN 3: RIGOUR OF DEVELOPMENT

GRADE

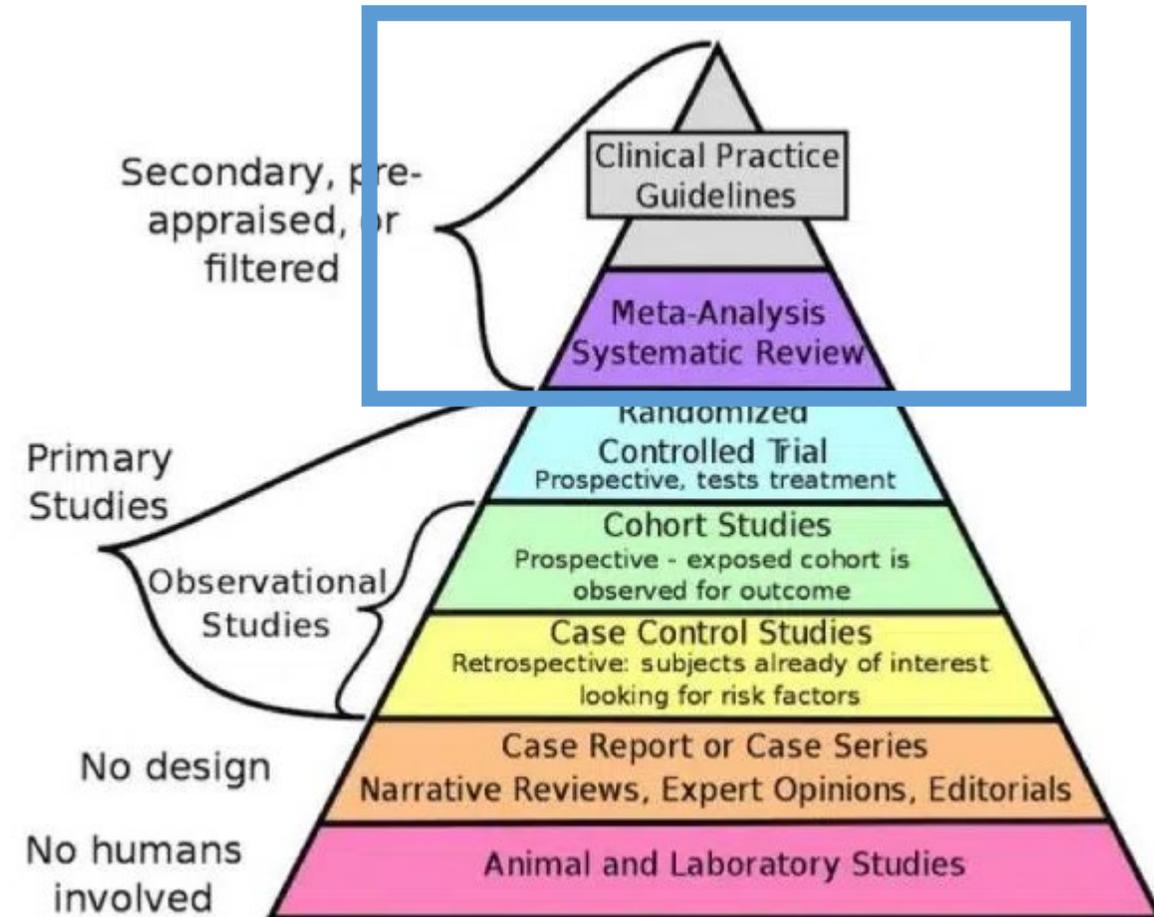
(Grading of Recommendations Assessment, Development and Evaluation)



AGREE (Appraisal of Guidelines for Research and Evaluation) - II

DOMAIN 3: RIGOUR OF DEVELOPMENT

1. **Systematic methods** were used to search for evidence.
2. **There is an explicit link between the recommendations and the supporting evidence.**
3. The guideline has been externally reviewed by experts prior to its publication.
4. A procedure for **updating** the guideline is provided.



Esempio di LG

5.2.1 GRADO DI RACCOMANDAZIONE PER PAZIENTI CON PREGRESSO EVENTO CARDIOVASCOLARE, SENZA SCOMPENSO CARDIACO

Raccomandazione forte a favore dell'intervento, con qualità delle prove moderata.

Si raccomanda l'uso di metformina, inibitori di SGLT-2 e GLP-1 RA come farmaci di prima scelta per il trattamento a lungo termine in pazienti con diabete di tipo 2 con pregressi eventi cardiovascolari e senza scompenso cardiaco. Pioglitazone, DPP-4i, acarbosio ed insulina dovrebbero essere considerati farmaci di seconda scelta. *(Le sulfaniluree non sono più raccomandate per il trattamento del DM tipo 2)*

RCT vs observational studies: DPP-4i and mortality

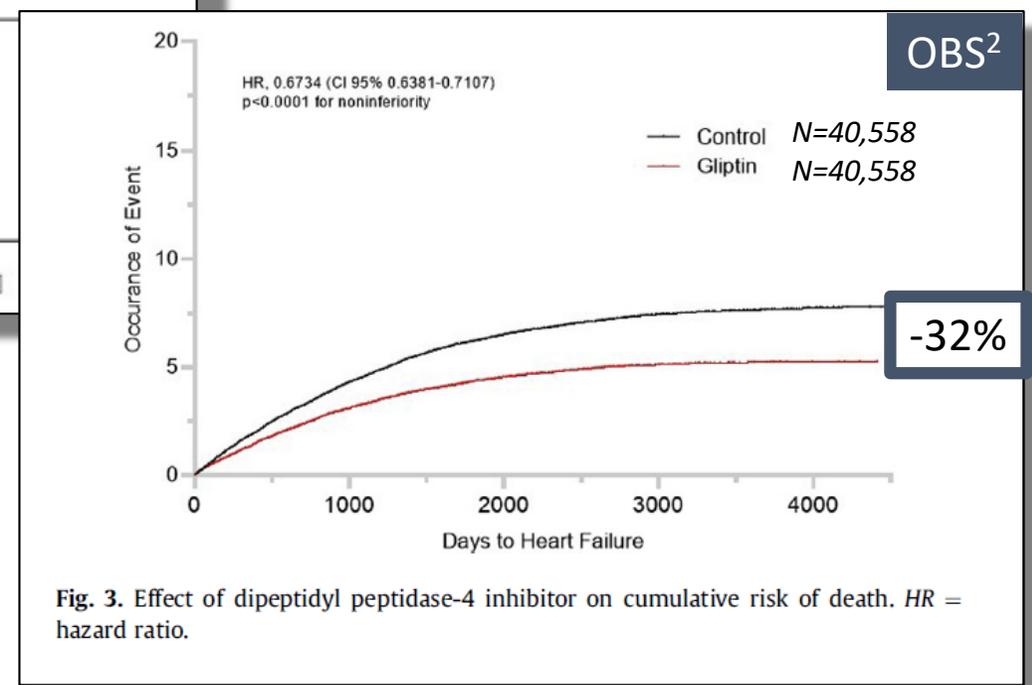
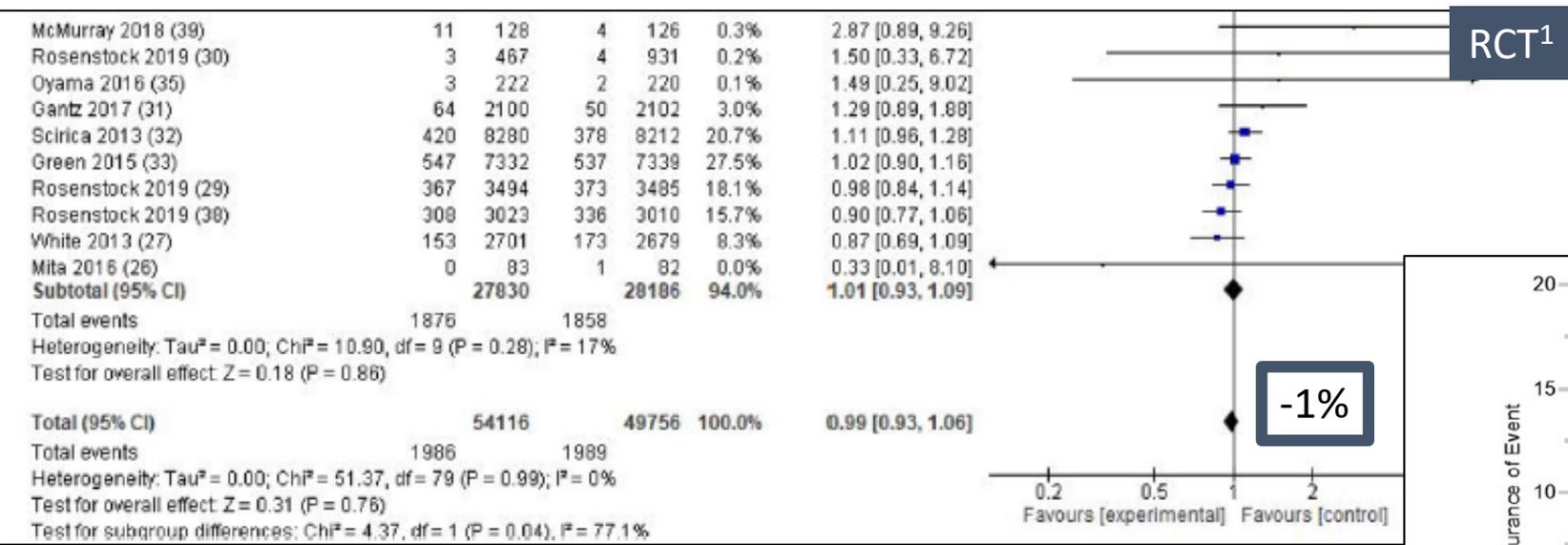
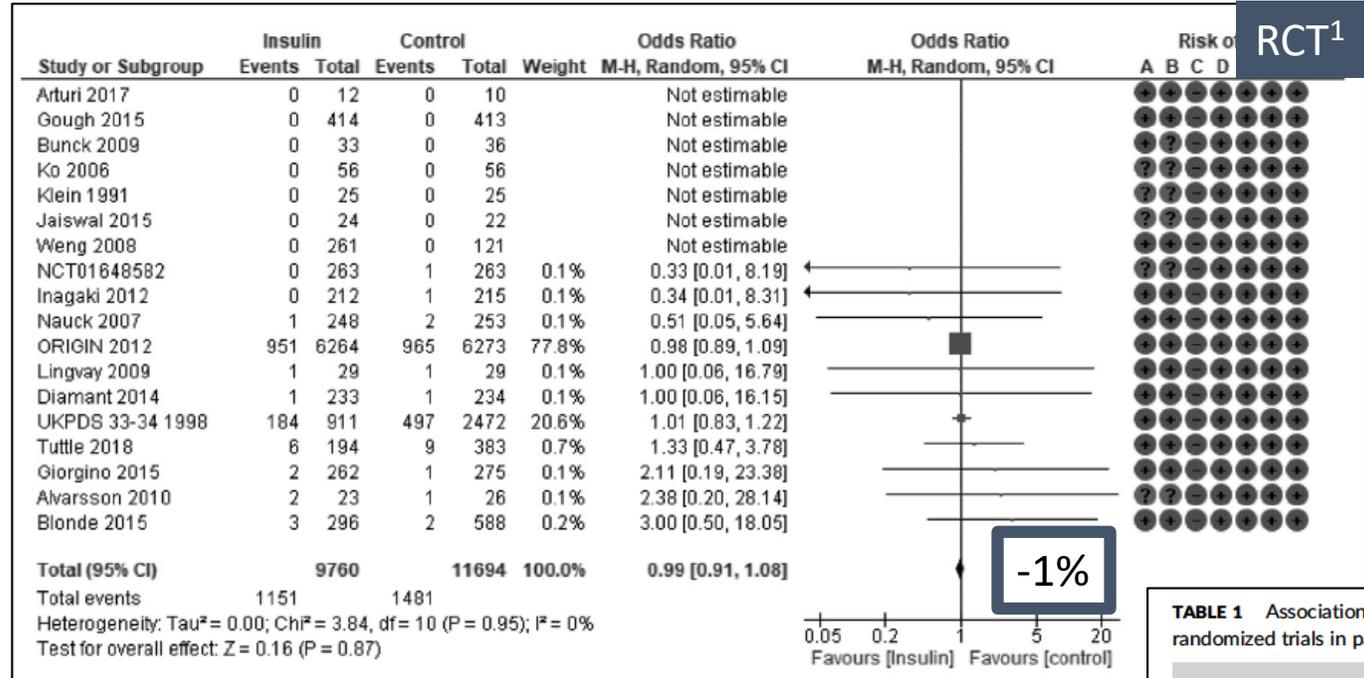


Fig. 3. Effect of dipeptidyl peptidase-4 inhibitor on cumulative risk of death. HR = hazard ratio.

¹Mannucci E et al. on behalf of the SID AMD Italian Guideline Panel. *Nutr Metab Cardiovasc Dis* 31:2745-55, 2021

²Cristiano EA, *Endocr. Pract.*, Epub ahead of print, 2022

RCT vs observational studies: insulin and mortality



RCT¹

TABLE 1 Association of insulin therapy with major cardiovascular events and all-cause mortality in selected observational studies and randomized trials in patients with type 2 diabetes

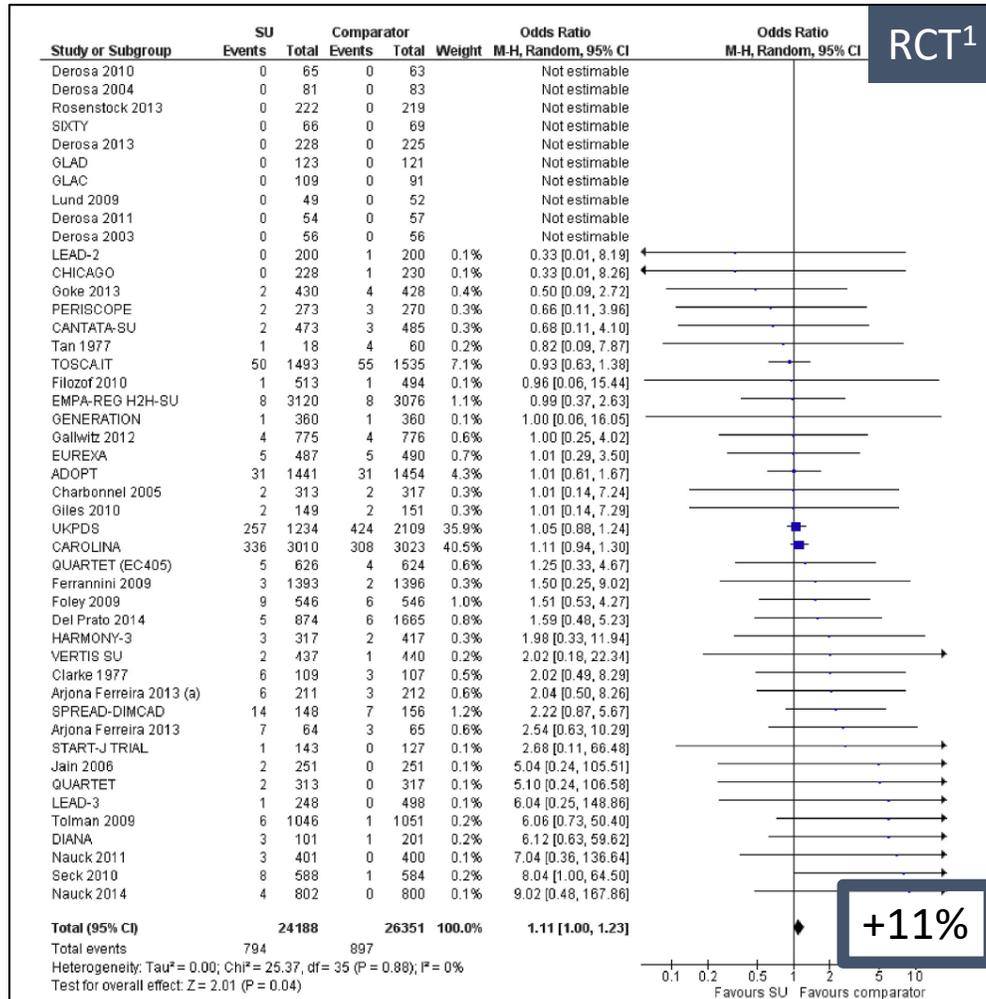
Study [Ref.]	Comparator/Reference	HR [95% CI] ^a	
		Major CV events	All-cause mortality
Observational studies			
Currie et al. 2010 ¹	Oral agents	1.31 [1.22-1.42]	1.46 [1.34-1.59]
Vallarino et al. 2013 ²	Pioglitazone	2.27 [2.00-2.56]	NR
Roumie et al. 2014 ³	Sulfonylureas	1.30 [1.07-1.58]	1.44 [1.15-1.79]
Nijjar et al. 2014 ⁴	No treatment	1.25 [1.13-1.39]	1.31 [1.17-1.42]
Paul et al. 2015 ⁵	Exenatide BID	2.00 [1.26-3.12]	NR

OBS²

¹Mannucci E et al. on behalf of the SID AMD Italian Guideline Panel. *Nutr Metab Cardiovasc Dis* 32:1353-60, 2022

²Mannucci E, Ferrannini E. *Diabetes Obes Metab* 19:1201-1204, 2017

RCT vs observational studies: sulfonylureas and mortality



SU vs	Observational HR (95% CI)	I ² (95% CI)
All-cause mortality		
No active treatment/placebo	1.13 (1.07-1.19)	63.5 (14.2-79.3) ¹
Biguanide	1.57 (1.48-1.66)	0.00 (0.00-64.1)
DPP-4 inhibitor	1.58 (1.36-1.83)	0.00 (0.00-72.9)
GLP-1 agonist	-	-
SGLT-2 inhibitor	-	-
Thiazolidinedione	1.50 (1.32-1.71)	96.6 (93.9-97.8) ²
Insulin	0.82 (0.77-0.89)	92.4 (86.7-95.0) ²
Combined	1.22 (1.18-1.26)	92.4 (90.6-93.7) ²

¹Mannucci E et al. on behalf of the SID AMD Italian Guideline Panel. *Nutr Metab Cardiovasc Dis* 30:1601-08, 2020

²Bain S., et al. *Diabetes Obes Metab* 19(3):329-335, 2017.

Esempio di LG

5.2.1 GRADO DI RACCOMANDAZIONE PER PAZIENTI CON PREGRESSO EVENTO CARDIOVASCOLARE, SENZA SCOMPENSO CARDIACO

Raccomandazione forte a favore dell'intervento, con qualità delle prove moderata.

Si raccomanda l'uso di metformina, inibitori di SGLT-2 e GLP-1 RA come farmaci di prima scelta per il trattamento a lungo termine in pazienti con diabete di tipo 2 con pregressi eventi cardiovascolari e senza scompenso cardiaco. Pioglitazone, DPP-4i, acarbosio ed insulina dovrebbero essere considerati farmaci di seconda scelta. *(Le sulfaniluree non sono più raccomandate per il trattamento del DM tipo 2)*

*Si raccomanda l'uso di metformina, ~~SGLT-2i~~, ~~GLP-1 RA~~ e **DPP-4i** (meno costoso) come farmaci di prima scelta per il trattamento a lungo termine in pazienti con diabete di tipo 2 con pregressi eventi cardiovascolari e senza scompenso cardiaco. ~~SGLT-2i~~ e ~~GLP-1 RA~~ dovrebbero essere considerati come farmaci di seconda scelta, mentre pioglitazone e acarbosio di terza scelta.*

*(**Insulina** e sulfaniluree non sono più raccomandate per il trattamento del DM tipo 2)*



Surgical Endoscopy (2020) 34:2332–2358
<https://doi.org/10.1007/s00464-020-07555-y>



GUIDELINES



Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP

Nicola Di Lorenzo¹ · Stavros A. Antoniou^{2,3} · Rachel L. Batterham^{4,5} · Luca Busetto⁶ · Daniela Godoroja⁷ · Angelo Iossa⁸ · Francesco M. Carrano⁹ · Ferdinando Agresta¹⁰ · Isaias Alarçon¹¹ · Carmil Azran¹² · Nicole Bouvy¹³ · Carmen Balaguè Ponz¹⁴ · Maura Buza¹⁵ · Catalin Copaescu¹⁵ · Maurizio De Luca¹⁶ · Dror Dicker¹⁷ · Angelo Di Vincenzo⁶ · Daniel M. Felsenreich¹⁸ · Nader K. Francis¹⁹ · Martin Fried²⁰ · Berta Gonzalo Prats¹⁴ · David Goitein^{21,22} · Jason C. G. Halford²³ · Jitka Herlesova²⁰ · Marina Kalogridaki²⁴ · Hans Ket²⁵ · Salvador Morales-Conde¹¹ · Giacomo Piatto¹⁶ · Gerhard Prager¹⁸ · Suzanne Pruijssers¹³ · Andrea Pucci^{4,5} · Shlomi Rayman^{21,22} · Eugenia Romano²³ · Sergi Sanchez-Cordero²⁶ · Ramon Vilallonga²⁷ · Gianfranco Silecchia⁸



GUIDELINES



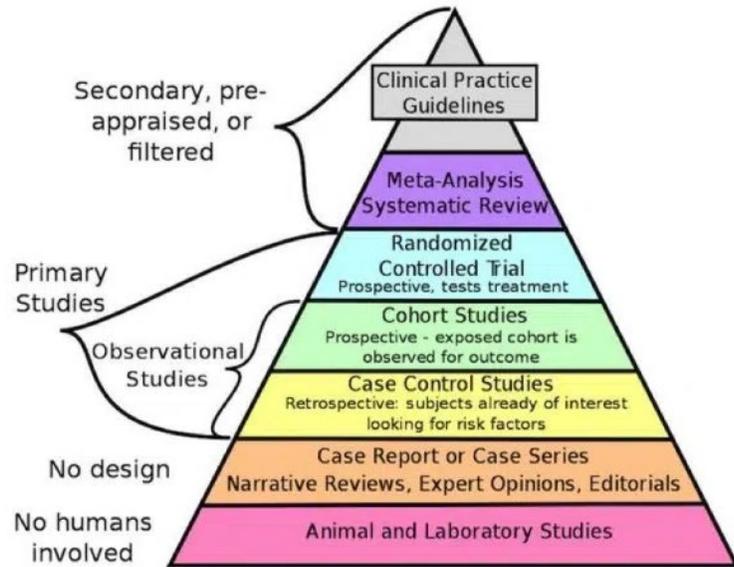
Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP

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Proton-pump inhibitor (PPI) therapy after bariatric surgery for the prevention of marginal ulcers

PPI therapy should be given to patients undergoing bypass procedures for the prevention of marginal ulcers

Strong recommendation



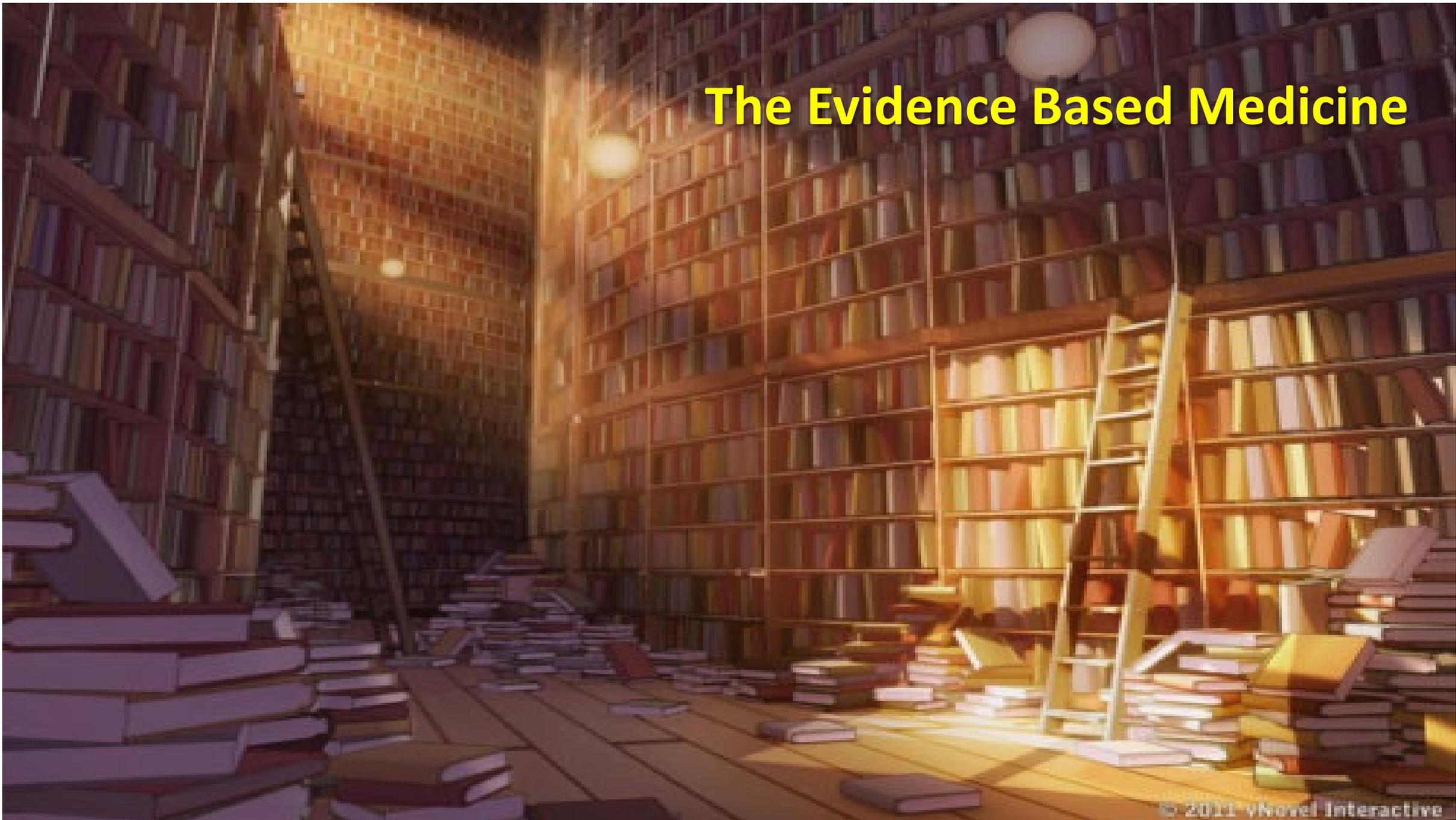
Justification

A meta-analysis of three cohort studies that compared the comparative effect of PPIs on marginal ulcers suggested beneficial effect of PPI treatment (OR 0.50, 95% CI 0.29 to 0.90, moderate certainty) (Supplementary Table S34) [131]. Under consideration of the risk/benefit ratio, the low cost and acceptability of the intervention, the panel provided a strong recommendation.

The Eminence Based Medicine



The Evidence Based Medicine



Legge n. 24/2017: SNLG

Criteria di inclusione

1. Essere elaborate da **gruppi multidisciplinari e multiprofessionali di esperti**;
2. Essere basate su un **processo esplicito e sistematico di ricerca** della letteratura biomedica



nutrients



Article

Development of the Italian Clinical Practice Guidelines on Bariatric and Metabolic Surgery: Design and Methodological Aspects

Nutrients 2023, 15, 189. <https://doi.org/10.3390/nu15010189>

Article
**Development of the Italian Clinical Practice Guidelines on
 Bariatric and Metabolic Surgery: Design and
 Methodological Aspects**

N	PICO	Disagreement (Score 1–2)	Agreement (Score 3–5)	Outcome (Median)	Approval
A. Indication for surgery					
1	In patients with uncontrolled type 2 diabetes and BMI 30–34.9 kg/m ² , is bariatric/metabolic surgery preferable to non-bariatric and metabolic surgical treatments, for the treatment of diabetes?	4.2%	95.8%	-	✓
Outcomes (efficacy)					
1.1	Diabetes remission			8	✓
1.2	Improvement of glycometabolic control (HbA1c; FPG; lipid profile; blood pressure)			8	✓
1.3	Decrease of body weight (BMI; percentage of weight lost; percentage of fat mass)			8	✓
1.4	Reduction of macrovascular complications			8	✓
1.5	Reduction of all-cause mortality			8	✓
1.6	Improvement of quality of life			8	✓
Outcomes (safety)					
1.7	Perioperative mortality			7	✓
1.8	Perioperative surgical complications			7	✓
1.9	Serious adverse events (surgical and non-surgical)			7	✓

Criteria di inclusione

1. Essere elaborate da **gruppi multidisciplinari e multiprofessionali di esperti**;
2. **Processo esplicito e sistematico di ricerca della letteratura**

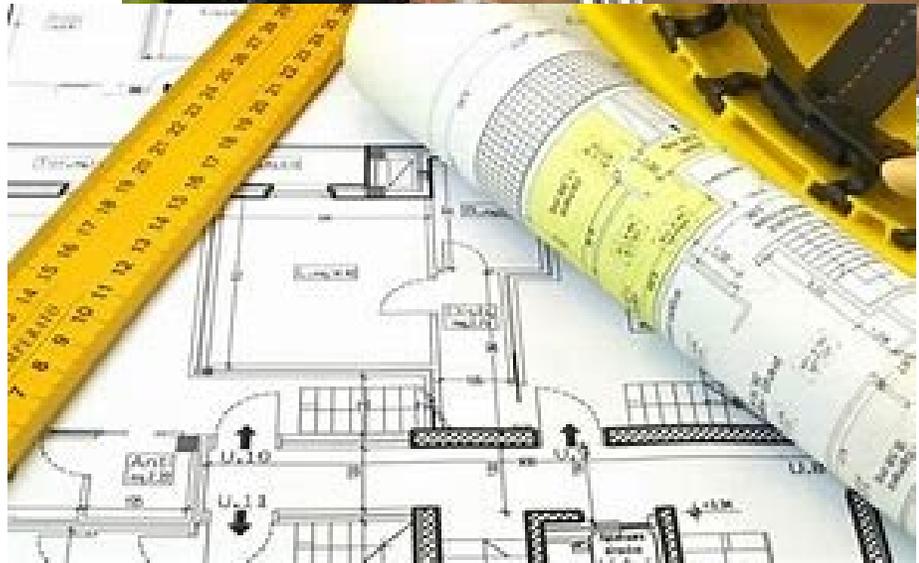
Article

Development of the Italian Clinical Practice Guidelines on Bariatric and Metabolic Surgery: Design and Methodological Aspects

N*	Outcome	Type of study	Main inclusion criteria
1.1, 2.1, 3.1, 4.1, 5.1	Diabetes remission	RCT	Patients aged 18+ years, with obesity and diabetes (or subgroups with diabetes); studies performed on patients with BMI 30/34.9, >35, and >40 Kg/m ² and duration ≥ 52 weeks ^{a,b,c} ; diabetes remission ¹ will be evaluated yearly whenever possible, and at endpoint.

b. Metaregression analyses will be performed on all trials, irrespective of BMI at entry, plotting the effect on outcome versus mean BMI at enrolment, in order to obtain a further estimate of the range of effect on outcome in patients with BMI within the defined range.

c. Subgroup analyses for studies with duration > 156 weeks and >260 weeks, and different comparators (active or placebo/none) will be performed for all clinical questions, whenever possible.



**LINEE GUIDA DELLA SICOB SOCIETÀ ITALIANA DI
CHIRURGIA DELL'OBESITÀ E DELLE MALATTIE
METABOLICHE**

*La terapia chirurgica dell'obesità e delle complicanze
associate*

