Linee guida endoscopiche

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***

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

DOMAIN 1: SCOPE AND PURPOSE

Upcoming Italian Clinical Practice Guidelines on Endobariatric Treatment of Overweight and Obesity: Design and Methodological Aspects.

Maurizio de Luca[1], Antonio Silverii[2], Rosario Bellini[3], Maria Grazia Carbonelli[4], Rita Cataldo[5], Maria Rosaria Cerbone[6], Marco Chianelli[7], Francesca Clemente Gregoris[8], Rita Conigliaro[9], Carla Micaela Cuttica[10], Carlo de Werra[11], Massimo Di Simone[12], Ludovico Docimo[13], Giuseppe Gagliardi[14], Giovanni Galasso[15], Giuseppe Galloro[16], Arianna Goracci[17], Valentina Lorenzoni[18], Raffaele Manta[19], Paolo Marzullo[20], Gerardo Medea[21], Giuseppe Navarra[22], Monica Ortenzi[23], Barbara Paolini[24], Luigi Piazza[25], Debora Porri[26], Farnaz Rahimi[27], Simone Rugolotto[28], Giovanni Sarnelli[29], Luca Sessa[30], Iris Zani[31], Marco Antonio Zappa[32], Giulia Bandini[33], Benedetta Ragghianti[2], Matteo Monami[2], and the Panel of the Italian Guidelines for the Endobariatric Treatment of Obesity.

de Luca et al., Updates in Surgery, ahead-of print, 2024

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

DOMAIN 2: STAKEHOLDER INVOLVEMENT

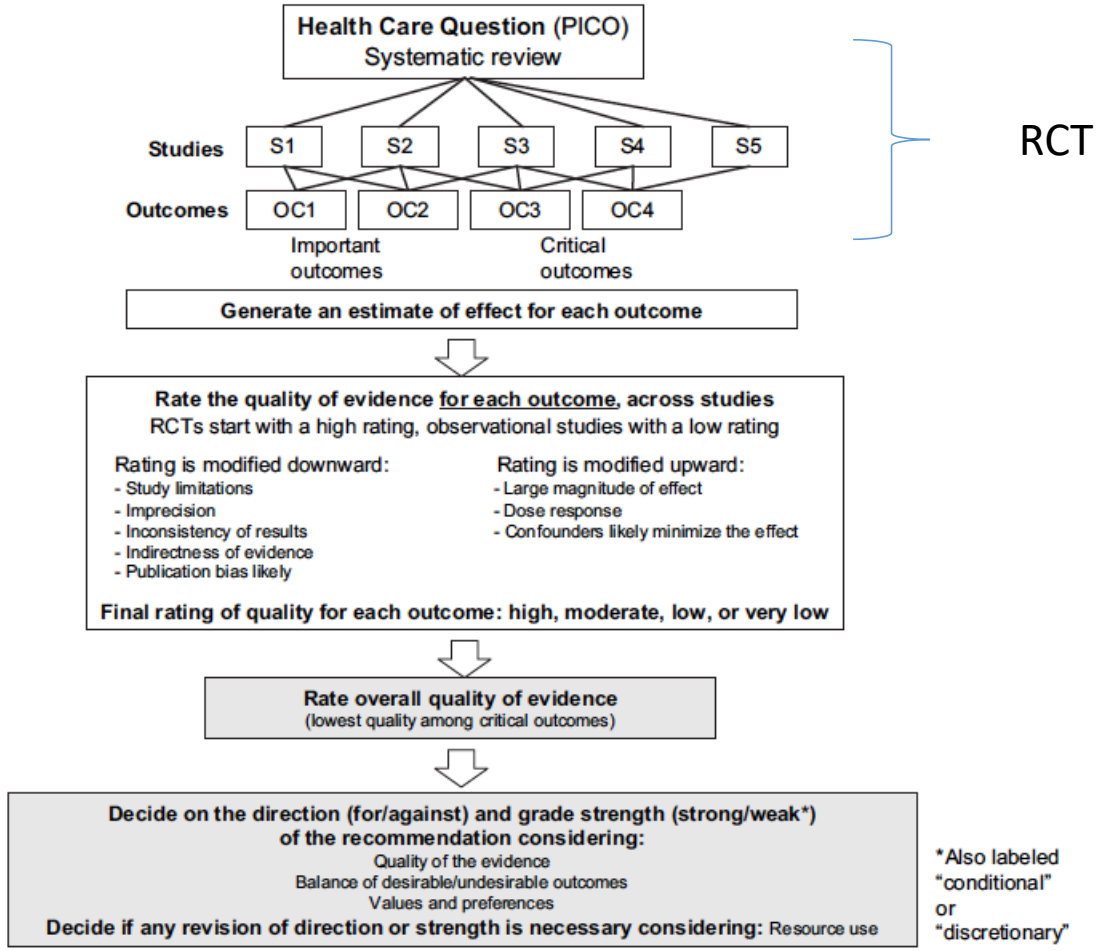
SICOB: Società Italiana di Chirurgia dell'Obesità; **SID**: Società Italiana di Diabetologia; **AME**: Associazione Medici Endocrinologi; **SIMG**: Società Italiana di Medicina Generale e delle Cure Primarie; **ADI**: Associazione Italiana di dietetica e Nutrizione Clinica; **SIS**: Società Italiana di Statistica; **SIAARTI**: Società Italiana Anestesia, Analgesia, Rianimazione e Terapia Intensiva; **AIAMC**: Associazione Italiana Analisi e Modificazione del Comportamento; **ASAND**: Associazione Scientifica Alimentazione, Nutrizione e Dietetica; **SIED**: Società Italiana Endoscopia Digestiva; **AME**: Associazione Medici Endocrinologi; **SIPAD**: Società Italiana di Patologia dell'Apparato Digerente; **SICE**: Società Italiana di Endoscopia di Area chirurgica; **SIC**: Società Italiana di Chirurgia; **ACOI**: Associazione Chirurghi Ospedalieri; **SIED**: Società Italiana Endoscopia Digestiva; **SOPSI**: Società Italiana di Psicopatologia; **AIGO**: Associazione Italiana Gastroenterologi ed endoscopisti digestivi Ospedalieri; **SIE**: Società Italiana Endocrinologia; **ADI**: Associazione italiana di dietetica e nutrizione clinica; **ANSISA**: Associazione Nazionale Specialisti In Scienze dell'Alimentazione; **SIO**: Società Italiana dell'Obesità; **SIUEC**: Società Italiana Unitaria di Endocrinochirurgia; **SIGE**: Società Italiana di Gastroenterologia ed Endoscopia Digestiva; **SIP**: Società Italiana di Pediatria.

de Luca et al., Updates in Surgery, ahead-of print, 2024

DOMAIN 3: RIGOUR OF DEVELOPMENT

GRADE

(Grading of Recommendations Assessment, Development and Evaluation)



RCT e/o OBS

*Also labeled "conditional" or "discretionary"

Guyatt G et al. *J Clin Epidemiol* 64:383-94, 2011

PICO

N	PICO	Disagreement (score 1–2)	Agreement (score3–5)	Outcome (median)	Approval
	A. INDICATION FOR ENDOBARIATRIC SURGERY				
1	***In patients with at least one uncontrolled obesity-related comorbid condition (diabetes, hypertension, dyslipidemia, obstructive sleep apnea, metabolic-associated fatty liver disease, and polycystic ovary syndrome) and BMI 27-29.9 kg/m², is endobariatric surgery preferable to life-style/pharmacological interventions, for the treatment of overweight?***	0%	100%	-	✓

	Outcomes (efficacy)			*Outcomes* (safety)		
1.1	Obesity-related comorbid conditions remission	8	✓	1.9 Perioperative mortality	7.5	✓
1.2	Improvement of glycometabolic control (HbA1c; FPG; lipid profile; blood pressure)	8	✓	1.10 Perioperative surgical complications	7.5	✓
1.3	Decrease of body weight (BMI; percentage of weigh loss and excess of weight loss)	9	✓	1.11 Vitamin/other nutrients deficiency	7	✓
1.4	Reduction of macrovascular complications	7.5	✓	1.12 Serious adverse events (surgical and non-surgical)	8.5	✓
1.5	Reduction of all-cause mortality	7	✓			
1.6	Improvement of quality of life	8	✓			
1.7	Reduced incidence of weight regain	7	✓			
1.8	Reduced incidence of insufficient weight loss	7	✓			

PICO

2	***In patients with at least one obesity-related comorbid condition (diabetes, hypertension, dyslipidemia, obstructive sleep apnea, metabolic-associated fatty liver disease, and polycystic ovary syndrome) and class I obesity (BMI 30-34.9 kg/m^2), is endobariatric surgery preferable to life-style/pharmacological interventions, for the treatment of obesity?***	0%	100%	-

	Outcomes (efficacy)				*Outcomes* (safety)		
1.1	Obesity-related comorbid conditions remission	8	✓	1.9	Perioperative mortality	7.5	✓
1.2	Improvement of glycometabolic control (HbA1c; FPG; lipid profile; blood pressure)	8	✓	1.10	Perioperative surgical complications	7.5	✓
1.3	Decrease of body weight (BMI; percentage of weigh loss and excess of weight loss)	9	✓	1.11	Vitamin/other nutrients deficiency	7	✓
1.4	Reduction of macrovascular complications	7.5	✓	1.12	Serious adverse events (surgical and non-surgical)	8.5	✓
1.5	Reduction of all-cause mortality	7	✓				
1.6	Improvement of quality of life	8	✓				
1.7	Reduced incidence of weight regain	7	✓				
1.8	Reduced incidence of insufficient weight loss	7	✓				

PICO

3	***In patients with at least one obesity-related comorbid condition (diabetes, hypertension, dyslipidemia, obstructive sleep apnea, metabolic-associated fatty liver disease, and polycystic ovary syndrome) and class II obesity (BMI 35-39.9 kg/m^2), is endobariatric surgery preferable to life-style/pharmacological interventions, for the treatment of obesity?***	0%	100%	-

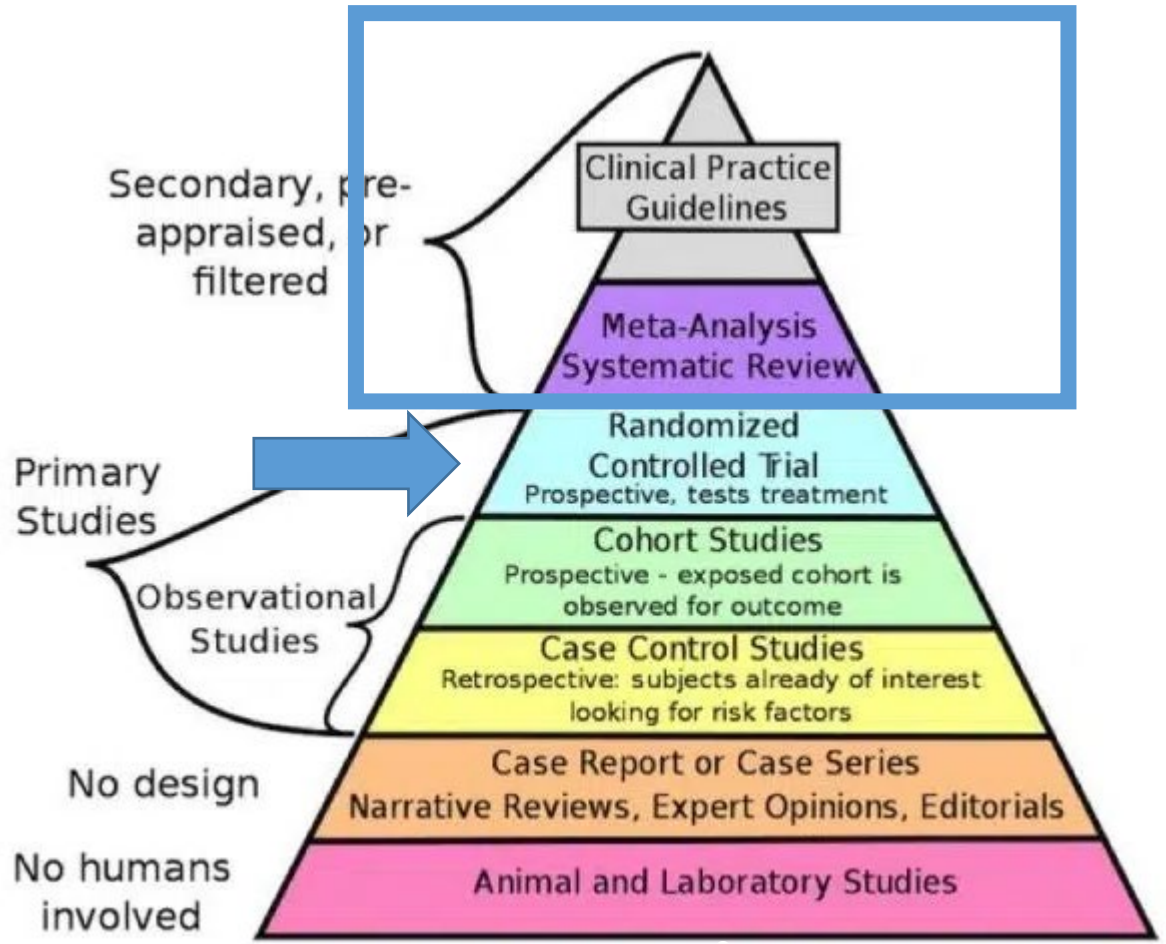
	Outcomes (efficacy)		
1.1	Obesity-related comorbid conditions remission	8	✓
1.2	Improvement of glycometabolic control (HbA1c; FPG; lipid profile; blood pressure)	8	✓
1.3	Decrease of body weight (BMI; percentage of weigh loss and excess of weight loss)	9	✓
1.4	Reduction of macrovascular complications	7.5	✓
1.5	Reduction of all-cause mortality	7	✓
1.6	Improvement of quality of life	8	✓
1.7	Reduced incidence of weight regain	7	✓
1.8	Reduced incidence of insufficient weight loss	7	✓

	Outcomes (safety)		
1.9	Perioperative mortality	7.5	✓
1.10	Perioperative surgical complications	7.5	✓
1.11	Vitamin/other nutrients deficiency	7	✓
1.12	Serious adverse events (surgical and non-surgical)	8.5	✓

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.



Indication to endoscopic bariatric surgery: BMI 27-29.9 Kg/m2

Outcome 1: BMI, reduction

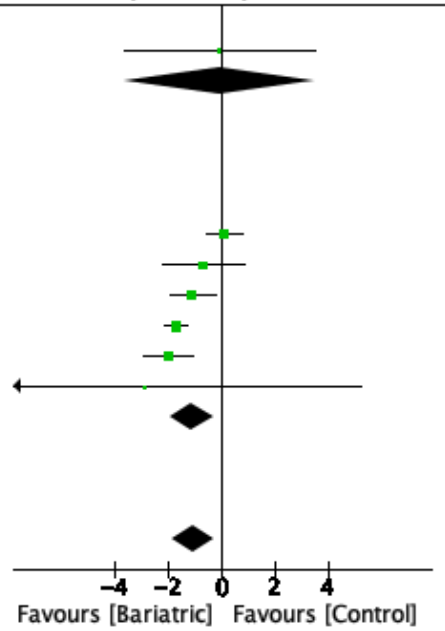
No trials retrieved

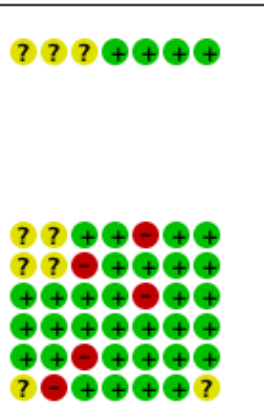
Unpublished data

Indication to endoscopic bariatric surgery: BMI 30-34.9 Kg/m2

Outcome 1: BMI, reduction

Study or Subgroup	Bariatric surgery Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
30.18.1 BTA								
Mittemair 2007	32.5	2.8	5	32.6	3	5	4.0%	−0.10 [−3.70, 3.50]
Subtotal (95% CI)			5			5	4.0%	−0.10 [−3.70, 3.50]
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.05 (P = 0.96)								
30.18.2 IGB								
Ng 2009	28.9	1.6	50	28.8	1.8	49	21.3%	0.10 [−0.57, 0.77]
Dargent 2015	30.7	3.7	68	31.4	3.7	32	12.7%	−0.70 [−2.25, 0.85]
Chan 2021	27.4	2.3	50	28.5	2.1	49	19.3%	−1.10 [−1.97, −0.23]
Ponce 2015	32.7	2	187	34.4	2	139	23.4%	−1.70 [−2.14, −1.26]
Courcoulas 2017	32	4	135	34	4	136	18.4%	−2.00 [−2.95, −1.05]
Lee 2012	28.7	8.1	8	31.6	9.5	10	0.9%	−2.90 [−11.03, 5.23]
Subtotal (95% CI)			498			415	96.0%	−1.12 [−1.93, −0.30]
Heterogeneity: $Tau^2 = 0.67$; $Chi^2 = 22.69$, df = 5 (P = 0.0004); $I^2 = 78\%$								
Test for overall effect: Z = 2.67 (P = 0.007)								
Total (95% CI)			503			420	100.0%	−1.08 [−1.86, −0.29]
Heterogeneity: $Tau^2 = 0.64$; $Chi^2 = 23.06$, df = 6 (P = 0.0008); $I^2 = 74\%$								
Test for overall effect: Z = 2.68 (P = 0.007)								
Test for subgroup differences: $Chi^2 = 0.29$, df = 1 (P = 0.59), $I^2 = 0\%$								





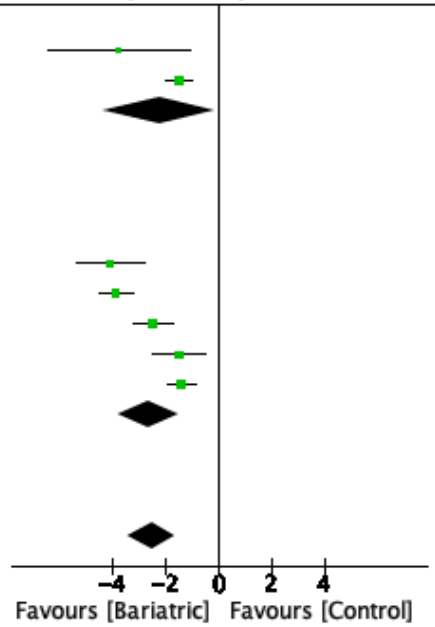
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

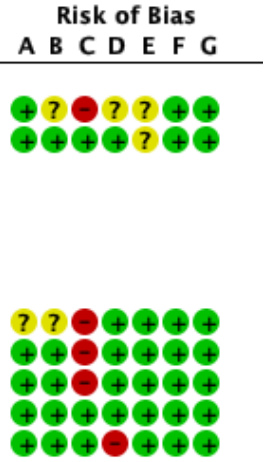
Unpublished data

Indication to endoscopic bariatric surgery: BMI 35-39.9 Kg/m2

Outcome 1: BMI, reduction

Study or Subgroup	Bariatric surgery Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
31.1.1 Interventi di suturing								
Miller 2017	31.5	3.3	30	35.3	3.7	9	7.0%	−3.80 [−6.49, −1.11]
Sullivan 2017	34.3	2.4	221	35.8	2.2	111	16.7%	−1.50 [−2.02, −0.98]
Subtotal (95% CI)			251			120	23.7%	−2.26 [−4.37, −0.14]
Heterogeneity: $Tau^2 = 1.67$; $Chi^2 = 2.71$, df = 1 (P = 0.10); $I^2 = 63\%$								
Test for overall effect: Z = 2.09 (P = 0.04)								
31.1.2 Device occupanti spazio								
Fuller 2013	30.9	2.7	37	35	2.9	37	13.1%	−4.10 [−5.38, −2.82]
Abu Dayyeh 2021	30.8	2.7	187	34.7	2.6	101	16.3%	−3.90 [−4.54, −3.26]
Abu Dayyeh 2022	32.7	2.6	77	35.2	2.6	110	15.8%	−2.50 [−3.26, −1.74]
Ponce 2015	32.6	5.5	187	34.1	3.9	139	14.5%	−1.50 [−2.52, −0.48]
Sullivan 2018	32.9	2.7	198	34.3	2.7	189	16.6%	−1.40 [−1.94, −0.86]
Subtotal (95% CI)			686			576	76.3%	−2.65 [−3.80, −1.50]
Heterogeneity: $Tau^2 = 1.54$; $Chi^2 = 44.23$, df = 4 (P < 0.00001); $I^2 = 91\%$								
Test for overall effect: Z = 4.50 (P < 0.00001)								
Total (95% CI)			937			696	100.0%	−2.53 [−3.45, −1.62]
Heterogeneity: $Tau^2 = 1.24$; $Chi^2 = 55.08$, df = 6 (P < 0.00001); $I^2 = 89\%$								
Test for overall effect: Z = 5.42 (P < 0.00001)								
Test for subgroup differences: $Chi^2 = 0.10$, df = 1 (P = 0.75), $I^2 = 0\%$								



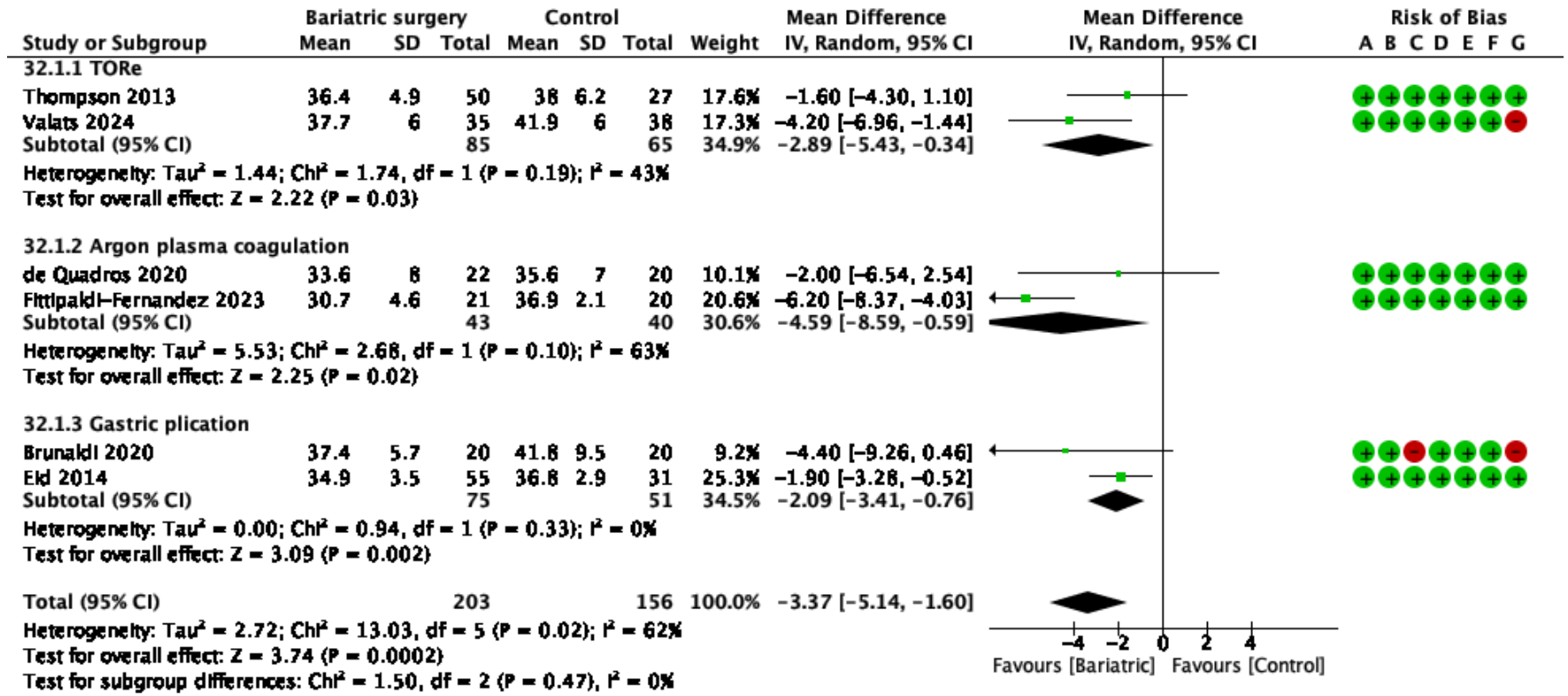


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Unpublished data

Indication to endoscopic bariatric surgery: insufficient weight loss/regain

Outcome 1: BMI, reduction



Risk of bias legend

(A) Random sequence generation (selection bias)
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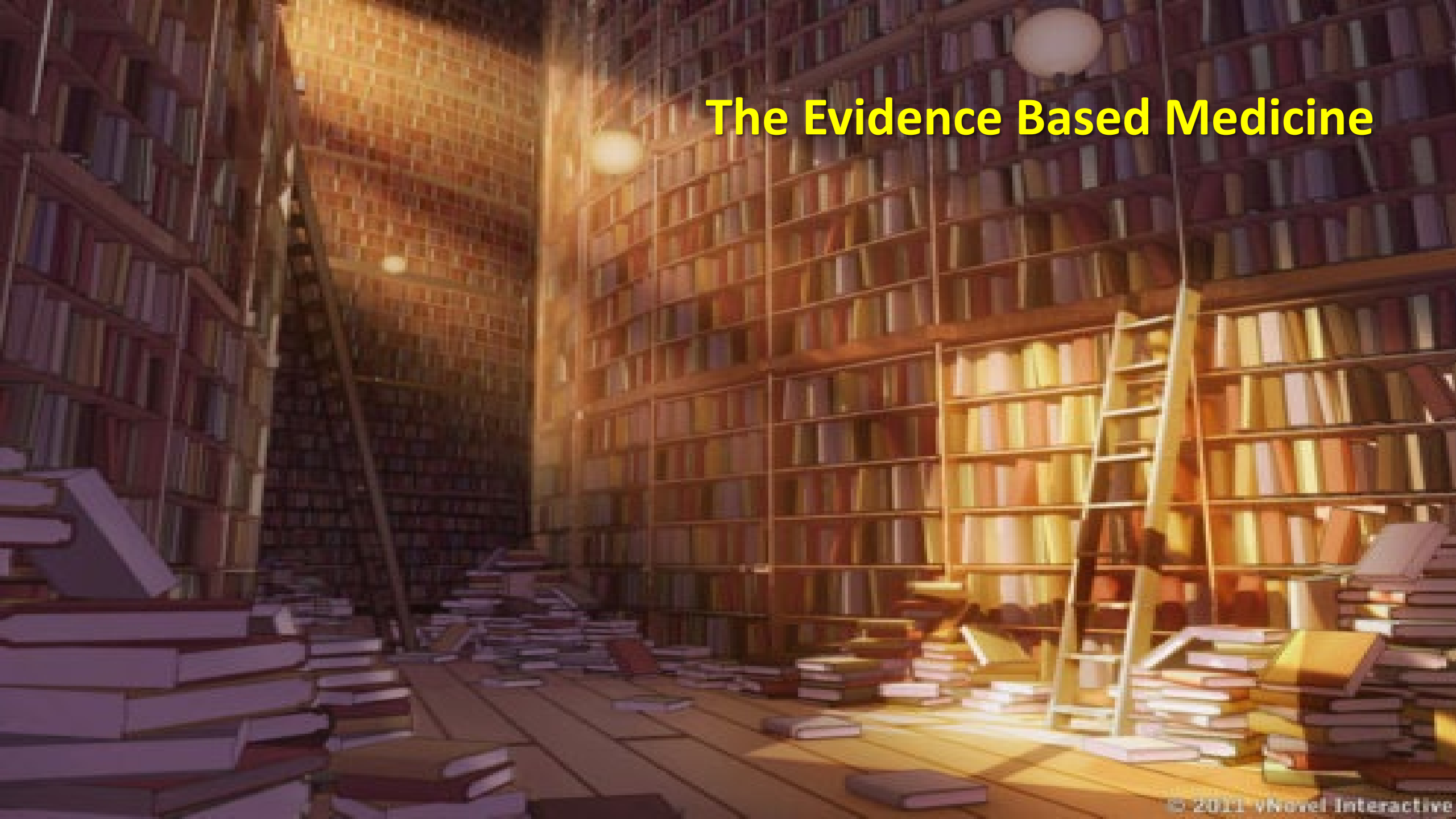
Unpublished data


The Eminence Based Medicine


The Evidence Based Medicine