Evidence base metabolic bariatric surgery – Impossible dream?

Is MBS clinical practice currently driven by evidence or opinion?

Maurizio De Luca

Director Department of Surgery Rovigo,Trecenta and Adria Hospitals– Italy
President Elect Italian Society of Bariatric Surgery and Metabolic Disorders (SICOB)
Treasurer International Federation for Surgery of Obesity and Metabolic Disorders European Chapter (IFSO EC)
Co-chair Scientific Committee International Federation for Surgery of Obesity and Metabolic Disorders (IFSO EC)
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)

4th of September, 2024

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I have no potential conflict of interest to report

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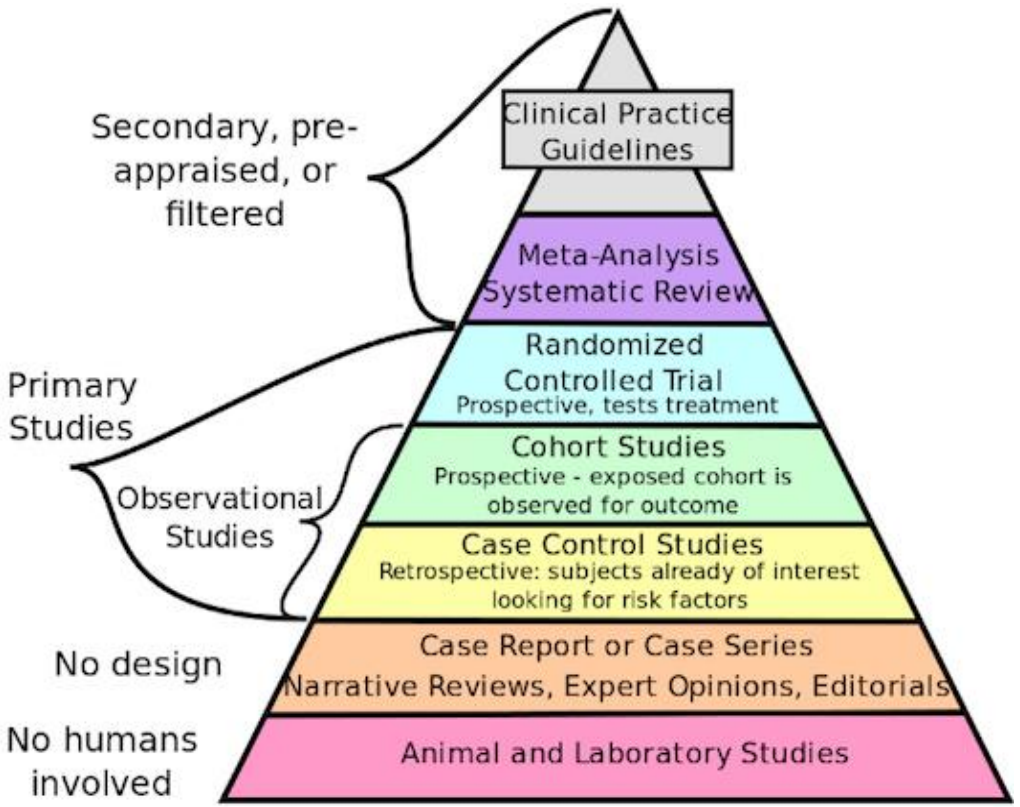

Centre for Evidence-Based Medicine. Study Designs. 2016
https://www.cebm. net/2014/04/study-designs/.

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

DOMAIN 3: RIGOUR OF DEVELOPMENT

Systematic methods were used to search for evidence.

There is an explicit link between the recommendations and the supporting evidence.

The guideline has been externally reviewed by experts prior to its publication.

A procedure for **updating** the guideline is provided.

USER'S MANUAL page 7

DOMAINS		No. of Items
1	Scope & Purpose	3
2	Stakeholder Involvement	3
3	Rigour of Development	8
4	Clarity & Presentation	4
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Overview of Different Study Design

Systematic Review and Metanalysis

- **Systematic Reviews and meta-analysis are epidemiological types of studies which do not provide new data but have great importance.**
- They **allow to have a summary picture of the scientific evidence present on a particular topic.**
- They are therefore **defined as updated summaries on the state of art of scientific research in each sector, conducted by experts in the field**, from which us you can get an idea of a certain topic.

Cochrane Handbook for Systematic Reviews of Interventions.
Retrieved from www.cochrane.org/resources/handbook/index.htm

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Overview of Different Study Design

Systematic Review

- **The systematic review is a common type of research used in the assessment of literature and studies,** which addresses a particular health-related issue .
- **Systematic reviews can be used *"to summarize", "to collect"* the results of all available medical studies and controlled trials**.
- Systematic reviews **can provide vital information about the effectiveness of an intervention.**
- One of the main disadvantages is that failing to collect and research complicated data may lead to erroneous conclusions.

Cochrane Handbook for Systematic Reviews of Interventions. Retrieved from www.cochrane.org/resources/handbook/index.htm

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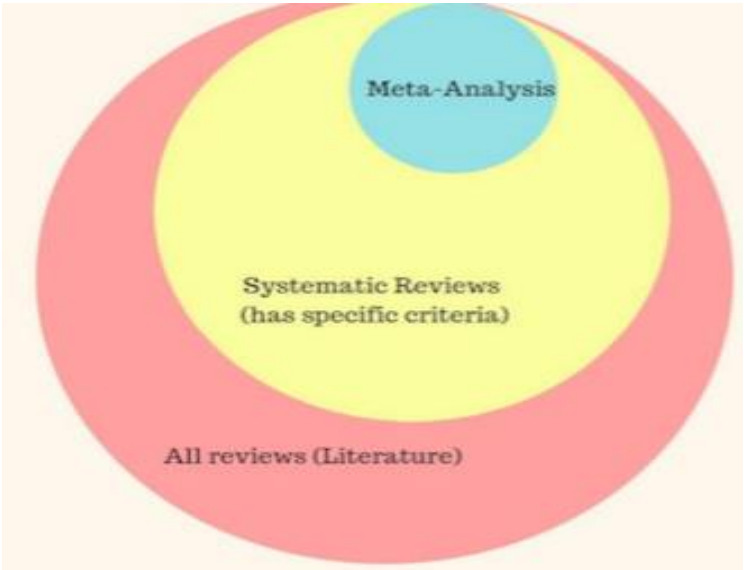
Overview of Different Study Design

Meta-analysis

- **Meta-analysis is a study design, which is a powerful research method.**
- **A meta-analysis is the statistical process which "analyzes" and "compares" results from several similar studies.**
- **It's based on data collected from different studies.** Meta-analysis is described as quantitative and epidemiological study design.
- **A rigorous meta-analysis is a great approach to evidence-based medicine**.
- Since this design involves the profound analysis of previous studies, **meta-analysis may have the potential to reveal hidden insights and relationships, such as possible health risks related to a new treatment and medical interventions. This particular aspect is one of the main advantages of meta-analyses.**



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Need for and EVIDENCE-BASED MBS clinical practice: WHEN & WHY

- **Pre-operative stage**: choose the right procedure for the right patient according to his BMI, obesity-medical conditions, preferences and anatomy
- **Peri-operative stage**: clinical-making in the management of possible complications (i.e., malabsorption, Venous Thromboembolism, pain control)
- **Post-operative stage**: nutritional assessment, need for revisional/conversion surgery

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Check for updates

SYSTEMATIC REVIEW

Bariatric Surgery

Assessment of guidelines for bariatric and metabolic surgery: a systematic review and evaluation using appraisal of guidelines for research and evaluation II (AGREE II)

Yung Lee[1], Caroline Hircock[1], Jerry Dang[2], James Jung[3], Boris Zevin[4], Ahmad Elnahas[5], Jigish Khamar[1], Ashley Vergis[6], Umair Tahir[1], Krista Hardy[6], Yasith Samarasinghe[1], Richdeep Gill[7], Jeffrey Gu[8], Tyler McKechnie[1], Radu Pescarus[9], Laurent Biertho[10], Elaine Lam[11], Amy Neville[12], James Ellsmere[13], Shahzeer Karmali[7], Timothy Jackson[3], Allan Okrainec[3], Aristithes Doumouras[1], Matthew Kroh[2] and Dennis Hong[1]✉

Commentary

AGREE II: Advancing guideline development, reporting, and evaluation in health care☆

Melissa C. Brouwers [a,b,*,1], Michelle E. Kho [a], George P. Browman [c], Jako S. Burgers [d], Francoise Cluzeau [e], Gene Feder [f], Béatrice Fervers [g], Ian D. Graham [h], Jeremy Grimshaw [i], Steven E. Hanna [a], Peter Littlejohns [j], Julie Makarski [a], Louise Zitzelsberger [k]
for the AGREE Next Steps Consortium [2]

[a] *McMaster University, Hamilton, Ontario, Canada*
[b] *Program in Evidence-based Care, Cancer Care Ontario, Hamilton, Ontario, Canada*
[c] *British Columbia Cancer Agency, Victoria, British Columbia, Canada*
[d] *Dutch Institute for Healthcare Improvement CBO and IQ Healthcare Radboud University Nijmegen Medical Centre, The Netherlands*
[e] *St. George's University of London, London, UK*
[f] *University of Bristol, Bristol, UK*
[g] *Unité Cancer et Environement, Université de Lyon – Centre Léon Bérard, Université Lyon 1, EA 4129, Lyon, France*
[h] *Canadian Institutes of Health Research, Ottawa, Ontario, Canada*
[i] *Ottawa Hospital Research Institute, Ottawa, Ontario, Canada*
[j] *National Institute for Health and Clinical Excellence, London, UK*
[k] *Canadian Partnership Against Cancer, Ottawa, Ontario, Canada*

2010

- Comprehensive search of MEDLINE and EMBASE conducted **from January 2010 to October 2022** for **bariatric clinical practice guidelines.**
- **Guideline evaluation** carried out adopting the **Appraisal of Guidelines for Research and Evaluation II (AGREE II) framework.**

- Lee Y, Hircock C et al. Assessment of guidelines for bariatric and metabolic surgery: a systematic review and evaluation using appraisal of guidelines for research and evaluation II (AGREE II) Int J Obes (Lond). 2024 Jun 18
- Brouwers MC et al; AGREE Next Steps Consortium. AGREE II: advancing guideline development, reporting, and evaluation in health care. Prev Med. 2010 Nov;51(5):421-4.

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- **Quality appraisal of guidelines evaluated using the AGREE II instrument : 23 items** across **six domains**

- Additionally, **2 global rating items:**
  - **overall quality of the guideline (domain 7)**
  - **potential recommendation for use of the guideline in clinical practice (domain 8)**

- **Each item rated using a Likert scale from 1 (strong disagreement) to 7 (strong agreement**). The quality score for each domain is represented as a scaled domain score, as described in the AGREE II User Manual. The **scaled domain score** is calculated by standardizing the obtained score (total summed appraiser score) for each domain: **(obtained score – minimum possible score)/(maximum possible score – minimum possible score)**

- A guideline with **an overall assessment score ≥70%** was considered to be of **high quality**

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2024

Table 1. Characteristics of the identified guidelines on bariatric surgery.

Practice guideline	Year	Society Affiliation	Funding/ Conflicts of Interest	Grading system	Overall recommendations (4 reviewers)		
					R	RM	NR
Endocrine and nutritional management of the post-bariatric surgery patient: an Endocrine Society Clinical Practice Guideline	2010	The Endocrine Society	Reported	GRADE	0	1	3
Recommendations for bariatric surgery in adolescents in Australia and New Zealand	2010	Australian and New Zealand Association of Paediatric Surgeons Obesity Surgery Society of Australia and New Zealand Paediatrics & Child Health Division of The Royal Australasian College of Physicians	Not reported	None	0	0	4
Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient-2013 update: cosponsored by American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery	2013	American Association of Clinical Endocrinologists (AACE) The Obesity Society (TOS) ASMBS	Reported	AACE protocol	4	0	0
Interdisciplinary European guidelines on metabolic and bariatric surgery	2013	IFSO—European Chapter European Association for the Study of Obesity (EASO)	None	OCEMC system	1	3	0
Bariatric Nutrition Guidelines for the Indian Population	2016	Centre for Obesity and Digestive Surgery	None	Used but not specified	0	0	4
Guidelines for the follow-up of patients undergoing bariatric surgery	2016	NHS England Obesity Clinical Reference Group	None	GRADE	0	4	0
Practical Recommendations of the Obesity Management Task Force of the European Association for the Study of Obesity for the Post-Bariatric Surgery Medical Management	2017	EASO	None	EASO protocol	0	4	0
Nordic guidelines for dietary supplements and follow-up after bariatric surgery	2018	Scandinavian obesity surgery registry Swedish Association for Bariatric Surgery Norwegian Association for Bariatric Surgery	Reported	None	0	0	4
ASMBS pediatric metabolic and bariatric surgery guidelines, 2018	2018	ASMBS	Reported	None	0	3	1
American Society for Metabolic and Bariatric Surgery and American Hernia Society consensus guideline on bariatric surgery and hernia surgery	2018	ASMBS	None	None	0	2	2
Obesity Surgery and the Treatment of Metabolic Diseases	2018	German Society of General and Visceral Surgery	Reported	None	1	3	0
Clinical Practice Guidelines for Childbearing Female Candidates for Bariatric Surgery, Pregnancy, and Post-partum Management After Bariatric Surgery	2019	Association Française d'Etude et de Recherche sur l'Obésité (AERO) SOFFCO-MM Collège National des Gynécologues et Obstétriciens Français (CNGOF) Société Francophone de Nutrition Clinique et Métabolisme (SFNCM) Société Française de Néonatalogie; SFP, Société Française de Pédiatrie (SFN) Société Francophone du Diabète (SFD)	Reported	Used but not specified	2	2	0
British Obesity Metabolic Surgery Society endorsed guidelines for psychological support pre- and post-bariatric surgery	2019	British Obesity Metabolic Surgery Society (BOMSS)	None	None	0	4	0

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Practice guideline	Year	Society Affiliation	Funding/ Conflicts of Interest	Grading system	Overall recommendations (4 reviewers)		
					R	RM	NR
Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures - 2019 Update: Cosponsored by American Association of Clinical Endocrinologists/American College of Endocrinology, The Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists	2020	AACE TOS ASMBS Obesity Medicine Association American Society of Anesthesiologists	Reported	AACE protocol	0	4	0
OSSI (Obesity and Metabolic Surgery Society of India) Guidelines for Patient and Procedure Selection for Bariatric and Metabolic Surgery	2020	Obesity and Metabolic Surgery Society of India	None	None	0	2	2
Recommendations for Metabolic and Bariatric Surgery During the COVID-19 Pandemic from IFSO	2020	IFSO	None	None	0	0	4
Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP	2020	European Association for Endoscopic Surgery (EAES) IFSO – European Chapter EASO European Society for the Peri-operative Care of the Obese Patient	Reported	GRADE	4	0	0
The recommendations of the Brazilian College of Surgeons and the Brazilian Bariatric and Metabolic Surgery Societies on the return of bariatric and metabolic operations in geographic regions of the country where the procedures have been allowed by local policies, in the period of COVID-19 pandemic	2020	Brazilian College of Surgeons Brazilian Bariatric and Metabolic Surgery Societies	None	None	0	1	3
SOFFCO-MM guidelines for the resumption of bariatric and metabolic surgery during and after the Covid-19 pandemic	2020	French and Francophone Society for the Surgery of Obesity and Metabolic Diseases (SOFFCO-MM)	None	None	0	3	1
British Obesity and Metabolic Surgery Society Guidelines on perioperative and postoperative biochemical monitoring and micronutrient replacement for patients undergoing bariatric surgery-2020 update	2020	BOMSS	Reported	SIGN	4	0	0
EAES rapid guideline: systematic review, network meta-analysis, CINeMA and GRADE assessment, and European consensus on bariatric surgery-extension 2022	2022	EAES	Reported	GRADE	4	0	0
Guidelines for Canadian bariatric surgical and medical centres: a statement from the Canadian Association of Bariatric Physicians and Surgeons	2022	Canadian Association of Bariatric Physicians and Surgeons	None	None	0	4	0
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	2022	ASMBS IFSO	None	None	0	0	4
Guidelines for Perioperative Care in Bariatric Surgery: Enhanced Recovery After Surgery (ERAS) Society Recommendations	2016	Enhanced Recovery After Surgery (ERAS) Society	Reported	GRADE	1	3	0
Evidence-based German guidelines for surgery for obesity	2011	German Society for General and Visceral Surgery (DGAV)	Not Reported	Used but not specified	0	4	0
Perioperative management of obstructive sleep apnea in bariatric surgery: a consensus guideline	2017	IFSO	Reported	GRADE	3	1	0

R recommended, *RM* recommended with modification, *NR* not recommended, *GRADE* grading of recommendations, assessment, development and evaluations, *SIGN* Scottish intercollegiate guidelines network, *OCEMC* Oxford Centre for evidence-based medicine classification.

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Surgical Endoscopy (2022) 36:1709–1725
https://doi.org/10.1007/s00464-022-09008-0

2022

GUIDELINES

EAES rapid guideline: systematic review, network meta-analysis, CINeMA and GRADE assessment, and European consensus on bariatric surgery–extension 2022

Francesco M. Carrano[1] · Angelo Iossa[2] · Nicola Di Lorenzo[3] · Gianfranco Silecchia[2] · Katerina-Maria Kontouli[4] · Dimitris Mavridis[4,5] · Isaias Alarçon[6] · Daniel M. Felsenreich[7] · Sergi Sanchez-Cordero[8] · Angelo Di Vincenzo[9] · M. Carmen Balagué-Ponz[10] · Rachel L. Batterham[11,12] · Nicole Bouvy[13] · Catalin Copaescu[14] · Dror Dicker[15] · Martin Fried[16] · Daniela Godoroja[17] · David Goitein[18,19] · Jason C. G. Halford[20] · Marina Kalogridaki[21] · Maurizio De Luca[22] · Salvador Morales-Conde[6] · Gerhard Prager[7] · Andrea Pucci[11,12] · Ramon Vilallonga[23] · Iris Zani[24] · Per Olav Vandvik[25] · Stavros A. Antoniou[26,27] · The EAES Bariatric Surgery Guidelines Group

- The guideline with the **highest overall assessment** was created by the **EAES**, receiving an **overall score of 94%** and was **recommended by all four evaluators**. Five other articles achieved an overall score of 70% or higher.

- The **applicability domain** was the **lowest-scoring domain** with a **median of 6%**, which was **33% lower than the next lowest score, rigor of development.**

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- Carrano FM et al EAES Bariatric Surgery Guidelines Group. EAES rapid guideline: systematic review, network meta-analysis, CINeMA and GRADE assessment, and European consensus on bariatric surgery-extension 2022. Surg Endosc. 2022 Mar;36(3):1709-1725.

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2022

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Table 3. Subgroup analysis of guidelines conducted by major societies.

Society	Number of Guidelines	Scope and Purpose (%, SD)	Stakeholder Involvement (%, SD)	Rigour of Development (%, SD)	Clarity of Presentation (%, SD)	Applicability (%, SD)	Editorial Independence (%, SD)	Overall assessment (%, SD)
American Society of Metabolic and Bariatric Surgery (ASMBS)	5	77 (23.41)	50 (11.47)	38 (14.64)	91 (6.62)	12 (11.59)	48 (29.77)	49 (20.54)
International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)	5	76 (23.27)	56 (26.48)	52 (35.45)	80 (15.66)	19 (32.34)	54 (43.27)	58 (31.62)
European Association for the Study of Obesity (EASO)	3	90 (9.00)	69 (26.27)	65 (30.66)	90 (7.00)	30 (41.04)	58 (38.42)	67 (26.10)
American Association of Clinical Endocrinologists (AACE)	2	95 (4.95)	58 (9.90)	46 (16.97)	95 (1.41)	25 (1.41)	65 (21.92)	66 (23.33)
The Obesity Society (TOS)	2	95 (4.95)	58 (9.90)	46 (16.97)	95 (1.41)	25 (1.41)	65 (21.92)	66 (23.33)
British Obesity Metabolic Surgery Society (BOMSS)	2	91 (7.78)	77 (23.33)	65 (22.63)	88 (2.83)	21 (9.90)	75 (35.36)	75 (24.04)
European Association for Endoscopic Surgery (EAES)	2	97 (2.12)	98 (1.41)	94 (6.36)	95 (2.83)	73 (5.66)	100 (0)	94 (2.83)

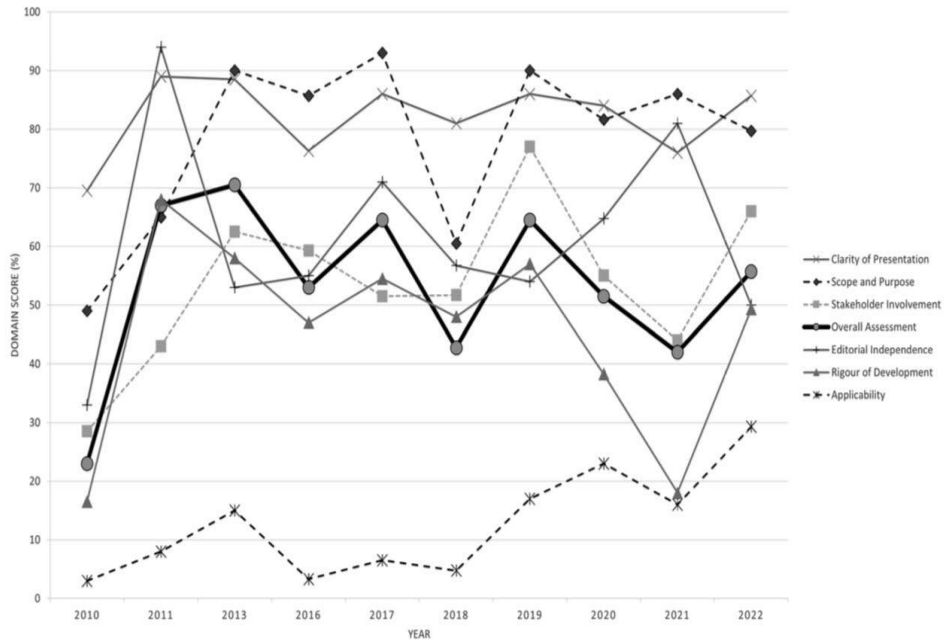

Fig. 3 Change in domain scores for bariatric and metabolic surgery guidelines over time.

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Obesity Facts

Research Article

Obes Facts
DOI: 10.1159/000536320

Received: July 22, 2023
Accepted: January 14, 2024
Published online: January 22, 2024

2024

Systematic Development of National Guidelines for Obesity Care: The Swedish Approach

Paulina Nowicka[a] Lovisa Sjögren[b, c, d] Ann-Sofie Bertilsson[e]
Kajsa Järvholm[f, g] Fanny Sellberg[h] Magnus Sundbom[i, j] Liv Thalén[h]
Ylva Trolle Lagerros[k, l]

Fig. 1. A schematic overview of the process to develop national guidelines from start to first publication, and the experts involved according to the Swedish National Board of Health and Welfare's government documents.

- **PICOS** (**P**opulation, **I**ntervention, **C**omparison, **O**utcomes, and **S**tudy Design) model was used. **22 PICOS** were constructed.
- The certainty of the evidence was graded for each outcome using the **GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) system.**

Nowicka P, Sjögren L, Bertilsson AS, Järvholm K, Sellberg F, Sundbom M, Thalén L, Trolle Lagerros Y.
Systematic Development of National Guidelines for Obesity Care: The Swedish Approach. Obes Facts. 2024;17(2):183-190.

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

Obesity Facts

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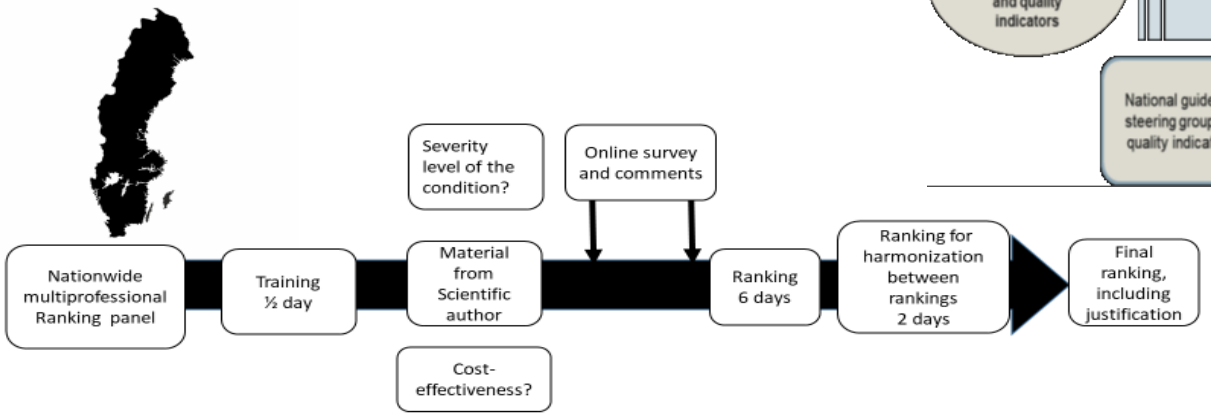

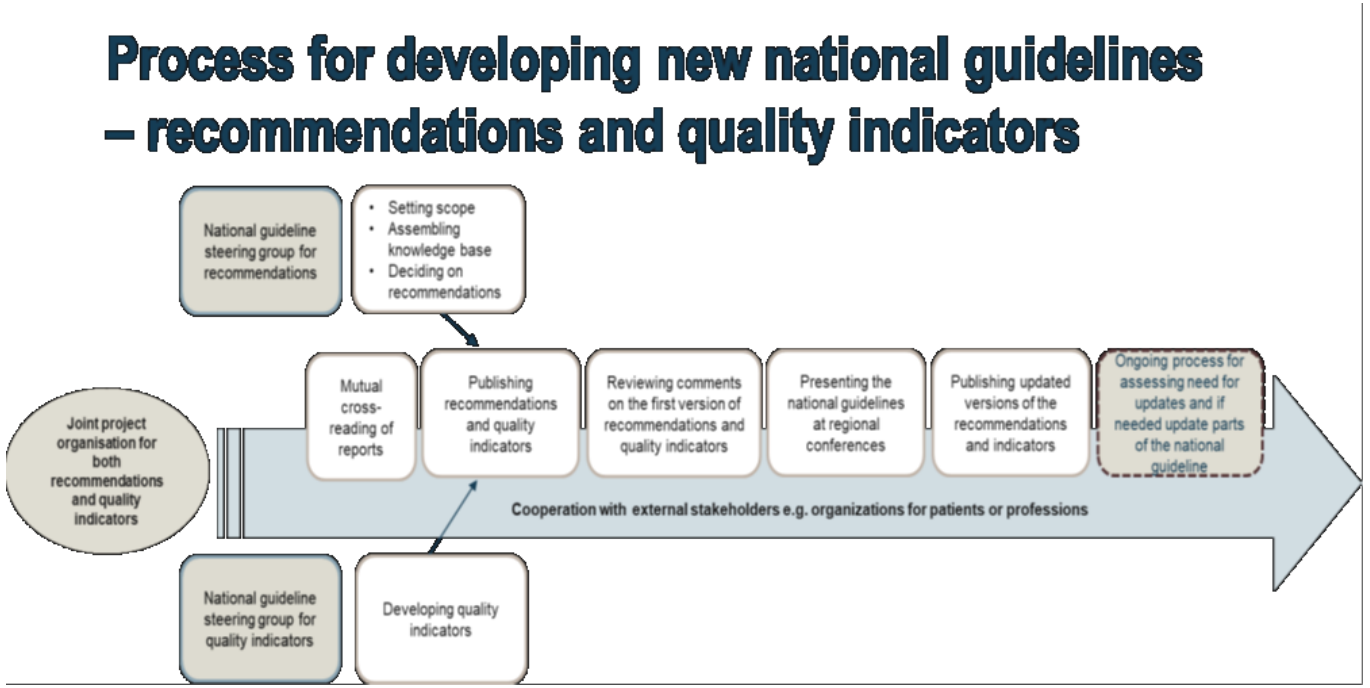

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Quality evaluation of metabolic and bariatric surgical guidelines

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Zi-Han Qin[1], Xin Yang[2], Ya-Qi Zheng[1], Li-Ya An[3], Ting Yang[3], Yu-Lu Du[3], Xiao Wang[3], Shu-Han Zhao[1], Hao-Han Li[1], Cheng-Kai Sun[1], Da-Li Sun[4*] and Yue-Ying Lin[3*]

[1]The First Affiliated Hospital of Kunming Medical University, Kunming, Yunnan, China, [2]Zhujiang Hospital, Southern Medical University, Guangzhou, Guangdong, China, [3]The Second Affiliated Hospital of Kunming Medical University, Kunming, Yunnan, China, [4]Department of Gastrointestinal Surgery, The Second Affiliated Hospital of Kunming Medical University, Kunming, China

Commentary

AGREE II: Advancing guideline development, reporting, and evaluation in health care☆

2010

Melissa C. Brouwers [a,b,*,1], Michelle E. Kho [a], George P. Browman [c], Jako S. Burgers [d], Francoise Cluzeau [e], Gene Feder [f], Béatrice Fervers [g], Ian D. Graham [h], Jeremy Grimshaw [i], Steven E. Hanna [a], Peter Littlejohns [j], Julie Makarski [a], Louise Zitzelsberger [k]
for the AGREE Next Steps Consortium [2]

[a] *McMaster University, Hamilton, Ontario, Canada*
[b] *Program in Evidence-based Care, Cancer Care Ontario, Hamilton, Ontario, Canada*
[c] *British Columbia Cancer Agency, Victoria, British Columbia, Canada*
[d] *Dutch Institute for Healthcare Improvement CBO and IQ Healthcare Radboud University Nijmegen Medical Centre, The Netherlands*
[e] *St. George's University of London, London, UK*
[f] *University of Bristol, Bristol, UK*
[g] *Unité Cancer et Environement, Université de Lyon – Centre Léon Bérard, Université Lyon 1, EA 4129, Lyon, France*
[h] *Canadian Institutes of Health Research, Ottawa, Ontario, Canada*
[i] *Ottawa Hospital Research Institute, Ottawa, Ontario, Canada*
[j] *National Institute for Health and Clinical Excellence, London, UK*
[k] *Canadian Partnership Against Cancer, Ottawa, Ontario, Canada*

- **9 surgical guidelines included** in this study. **5 articles with AGREE II scores over 60%** are worthy of clinical recommendation.
- The field of **rigor of development** was relatively **low**, with an **average score of 50.82%.**
- Among 15 key recommendations and the corresponding best evidence in the guidelines, **only 3 key recommendations** were **grade A recommendations**.

- Qin ZH et al. Quality evaluation of metabolic and bariatric surgical guidelines. Front Endocrinol (Lausanne). 2023 Mar 9;14:1118564
- Brouwers MC et al; AGREE Next Steps Consortium. AGREE II: advancing guideline development, reporting, and evaluation in health care. Prev Med. 2010 Nov;51(5):421-4

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TABLE 1 Characteristics of included guidelines.

Title	Authors	Organization	Short name	Country Applied	Grading system	Subjects	Version	Target population	Development Method
Reoperative surgery for nonresponders and complicated sleeve gastrectomy operations in patients with severe obesity. An international expert panel consensus statement to define best practice guideline	Kichler K, et al.,2018	ASMBS	Ki (9)	International	Not specified	Providing a clinical consensus guideline regarding standardization of indications, contraindications, surgical options, and surgical techniques when reoperating on patients who underwent a failed or complicated SG.	Original version	Adults	CB
ASMBS pediatric metabolic and bariatric surgery guidelines	Pratt JSA, et al.,2018	ASMBS	Pr (10)	International	Not specified	Removing the stigma against the surgical treatment of childhood obesity and educate paediatric physicians and providers about the need for early referral of patients suffering from severe obesity to a MBS program.	Original version	Children & Adolescents	EB
The first consensus statement on revisional bariatric surgery using a modified Delphi approach	Mahawar KK, et al.,2019	IFSO	Ma (11)	International	Not specified	Developing consensus amongst a group of international RBS experts on a range of practices and principles concerning this procedure following a Modified Delphi protocol.	Original version	Adults	CB
Bariatric surgery in class I obesity: a Position Statement from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)	Busetto L, et al.,2014	IFSO	Bu (12)	International	Not specified	Examining the use of bariatric surgery in the class I obesity range (BMI 30 - 35 kg/m^2).	Original version	Adults	EB & CB
Duodenal switch in revisional bariatric surgery: conclusions from an expert consensus panel	Merz AE, et al.,2019	ASMBS	Me (13)	International	Not specified	Generating expert consensus points on the appropriate use of BPD/DS in the revisional bariatric surgical setting	Original version	Adults	EB & CB
ASMBS Updated Position Statement on Bariatric Surgery in Class I Obesity (BMI 30-35 kg/m^2)	Aminian A, et al.,2018	ASMBS	Am (14)	International	Not specified	Assessing the evidence regarding the benefits and risks of bariatric surgery in patients with class I obesity (BMI of 30.0 – 34.9 kg/m^2), which accounts for more than 20% of the United States population	Original version	Adults	EB
Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP	Lorenzo ND, et al.,2020	EAES	Lo (15)	Europe	GRADE	Aiming to increase health care knowledge among bariatric patients. Summarizing the latest evidence on bariatric surgery through state-of-the art guideline development, aiming to facilitate evidence-based clinical decisions	Updated version	Adults	EB & CB
IFSO (International Federation for Surgery of Obesity and Metabolic Disorders) Consensus Conference Statement on One-Anastomosis Gastric Bypass (OAGB-MGB): Results of a Modified Delphi Study	Ramos AC, et al.,2020	IFSO	Ra (16)	International	Not specified	Validating the results of the previous exercise as well as to expand into areas not previously covered.	original version	Adults	EB & CB
OSSI (Obesity and Metabolic Surgery Society of India) Guidelines for Patient and Procedure Selection for Bariatric and Metabolic Surgery	Bhasker AG, et al.,2020	OSSI	Bh (17)	India	Not specified	Enlisting the OSSI guidelines for patient and procedure selection for surgeons and allied health practitioners practising bariatric and metabolic surgery. Intending to guide Insurance Regulatory and Development Authority of India and multiple other stake-holders.	original version	Adults	EB & CB

EB, Guidelines based on evidence-based medicine; CB, Develop guidelines based on expert consensus; ASMBS, American Society for Metabolic and Bariatric Surgery; IFSO, International Federation for Surgery of Obesity and Metabolic Diseases; EAES, European Association of Endoscopic Surgery; EASO, European Association for the Study of Obesity; ESPCOP, European Society for the Peri-operative Care of the Obese Patient; OSSI, Obesity and Metabolic Surgery Society of India; SG, Sleeve gastrectomy; MBS, Metabolic and bariatric surgery; RBS, Revisional bariatric surgery; BMI, Body mass index; BPD/DS, Biliopancreatic diversion with duodenal switch; GRADE, Grade of recommendations assessment, development and evaluation.

Qin ZH et al. Quality evaluation of metabolic and bariatric surgical guidelines. Front Endocrinol (Lausanne). 2023 Mar 9;14:1118564

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TABLE 2 AGREE II domain score and ICC of the included guidelines.

Guidelines				Scope and Purpose	Stakeholder Involvement	Rigour of Development	Clarity and Presentation	Applicability	Editorial independence	Overall assessment	ICC
complicated sleeve gastrectomy operations in patients with severe obesity. An international expert panel consensus statement to define best practice guideline	Kichler K, et al.,2018	ASMBS	Ki (9)	77.78%	50.00%	20.83%	79.17%	27.08%	0.00%	37.85%	0.947
ASMBS pediatric metabolic and bariatric surgery guidelines	Pratt JSA, et al.,2018	ASMBS	Pr (10)	91.67%	86.11%	70.83%	77.78%	77.08%	47.92%	74.91%	0.881
The first consensus statement on revisional bariatric surgery using a modified Delphi approach	Mahawar KK, et al.,2019	IFSO	Ma (11)	77.79%	52.78%	48.44%	77.78%	54.17%	93.75%	63.42%	0.892
Bariatric surgery in class I obesity: a Position Statement from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)	Busetto L, et al.,2014	IFSO	Bu (12)	87.50%	52.78%	77.08%	66.67%	78.13%	0.00%	64.67%	0.905
Duodenal switch in revisional bariatric surgery: conclusions from an expert consensus panel	Merz AE, et al.,2019	ASMBS	Me (13)	83.33%	47.22%	56.25%	87.50%	46.88%	50.00%	59.29%	0.915
ASMBS Updated Position Statement on Bariatric Surgery in Class I Obesity (BMI 30-35 kg/m^2)	Aminian A, et al.,2018	ASMBS	Am (14)	80.56%	79.17%	55.21%	84.72%	33.33%	100.00%	65.19%	0.837
Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP	Lorenzo ND, et al.,2020	EAES	Lo (15)	91.67%	69.44%	68.32%	91.67%	55.21%	50.00%	68.73%	0.913
IFSO (International Federation for Surgery of Obesity and Metabolic Disorders) Consensus Conference Statement on One-Anastomosis Gastric Bypass (OAGB-MGB): Results of a Modified Delphi Study	Ramos AC, et al.,2020	IFSO	Ra (16)	83.22%	51.39%	30.21%	62.50%	20.83%	50.00%	43.65%	0.897
OSSI (Obesity and Metabolic Surgery Society of India) Guidelines for Patient and Procedure Selection for Bariatric and Metabolic Surgery	Bhasker AG, et al.,2020	OSSI	Bh (17)	83.33%	51.39%	30.21%	62.50%	20.83%	50.00%	43.66%	0.922
Median score (range)				84.09% (77.78%-91.67%)	60.03% (47.22%-86.11%)	50.82% (20.83%-77.08%)	76.70% (62.5%-91.67%)	45.95% (27.08%-78.13%)	49.07% (0%-100%)	57.93% (37.85%-68.73%)	

ICC, Intraclass correlation coefficient.

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TABLE 3 The key recommendations and the best evidence to support the recommendations at present.

	The key recommendations	The best evidence to support the recommendations at present	Strength of recommendation	Quality of evidence	Ki (9)	Pr (10)	Ma (11)	Bu (12)	Me (13)	Am (14)	Lo (15)	Ra (16)	Bh (17)
Indications of bariatric/metabolic surgery	Bariatric/metabolic surgery should be considered for patients with BMI≥ 35 kg/m2 with associated comorbidities	A RCT including 57 patients (20).	B	2b	1	1	1	1	1	1	3	1	3
	Bariatric/metabolic surgery should be considered for patients with BMI≥ 30 kg/m2 and type 2 diabetes with poor control despite optimal medical therapy	A systematic review of 11 RCTs (21)	A	1a	1	1	1	1	1	3	3	3	3
	Bariatric/metabolic surgery should be considered for patients with BMI≥ 30 kg/m2 and obesity-related comorbidities that cannot lose enough weight through nonsurgical treatment	A RCT including 80 patients (22).	B	2b	1	1	1	3	1	3	1	1	1
Operative methods of bariatric/metabolic surgery	SG should be preferred over AGB	A cohort study including 71 patients (23).	B	2b	3	2	1	1	1	1	2	1	1
	RYGB should be preferred over AGB	A cohort study including 1295 patients (24).	B	2b	1	2	1	1	1	1	3	1	1
	OAGB may offer greater short-term weight loss than SG	A cohort study including 123 patients (25).	B	2b	1	1	1	1	1	1	3	3	1
	OAGB may offer greater short-term weight loss than RYGB	A RCT including 253 patients (26).	A	1b	1	1	1	1	1	1	3	3	1
	RYGB is an acceptable revisional bariatric surgery option after AGB	A case series analysis including 58 patients (27).	C	4	1	2	3	1	1	1	1	1	1
	BPD/DS is an acceptable revisional bariatric surgery option after SG	A case series analysis including 33 patients (28).	C	4	3	1	3	1	3	1	1	1	1
	SADIs is an acceptable revisional bariatric surgery option after SG	A case series analysis including 63 patients (29).	C	4	3	1	3	1	3	1	1	1	1
	BPD/DS is a more acceptable revisional bariatric surgery option than RYGB after SG	A cohort study including 74 patients (28).	C	4	3	1	1	1	3	1	1	1	1
	RYGB is an acceptable surgery option for patients with gastroesophageal reflux disease after SG	A case series analysis including 10 patients(30)	C	4	3	1	1	1	3	1	1	1	1
Preoperative work-up	Preoperative nutritional assessment can be considered before bariatric/metabolic surgery	A RCT including 120 patients (31).	A	1b	1	2	3	1	1	1	3	1	1
	Psychological evaluation can be considered before bariatric/metabolic surgery	A cohort study including 2458 patients (32).	B	2b	1	1	3	1	1	1	2	1	1
Postoperative care	Micro and/or macronutrients supplementation is recommended after bariatric/metabolic surgery	A systematic review of 5 RCTs and 7 observational studies (33).	B	2a	1	2	1	1	1	3	3	1	1

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ASGE American Society for Gastrointestinal Endoscopy

GUIDELINE

ESGE

American Society for Gastrointestinal Endoscopy–European Society of Gastrointestinal Endoscopy guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity

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Pichamol Jirapinyo, MD, MPH,[1,*] Alia Hadefi, MD,[2,*] Christopher C. Thompson, MD, MSc,[1] Árpád V. Patai, MD, PhD,[3] Rahul Pannala, MD,[4] Stefan K. Goelder, MD, PhD,[5] Vladimir Kushnir, MD,[6] Marc Barthet, MD, PhD,[7] Caroline M. Apovian, MD,[8] Ivo Boskoski, MD, PhD,[9] Christopher G. Chapman, MD,[10] Paul Davidson, PhD,[11] Gianfranco Donatelli, MD,[12] Vivek Kumbhari, MBChB, PhD,[13] Bu Hayee, MD, PhD,[14] Janelle Esker, MS, RDN,[15] Tomas Hucl, MD, PhD,[16] Aurora D. Pryor, MD, MBA,[17] Roberta Maselli, MD, PhD,[18] Allison R. Schulman, MD, MPH,[19] Francois Pattou, MD,[20] Shira Zelber-Sagi, RD, PhD,[21] Paul A. Bain, PhD, MLIS,[22] Valérie Durieux, PhD,[23] Konstantinos Triantafyllou, MD, PhD,[24] Nirav Thosani, MD,[25] Vincent Huberty, MD, PhD,[2,†] Shelby Sullivan, MD[15,†]

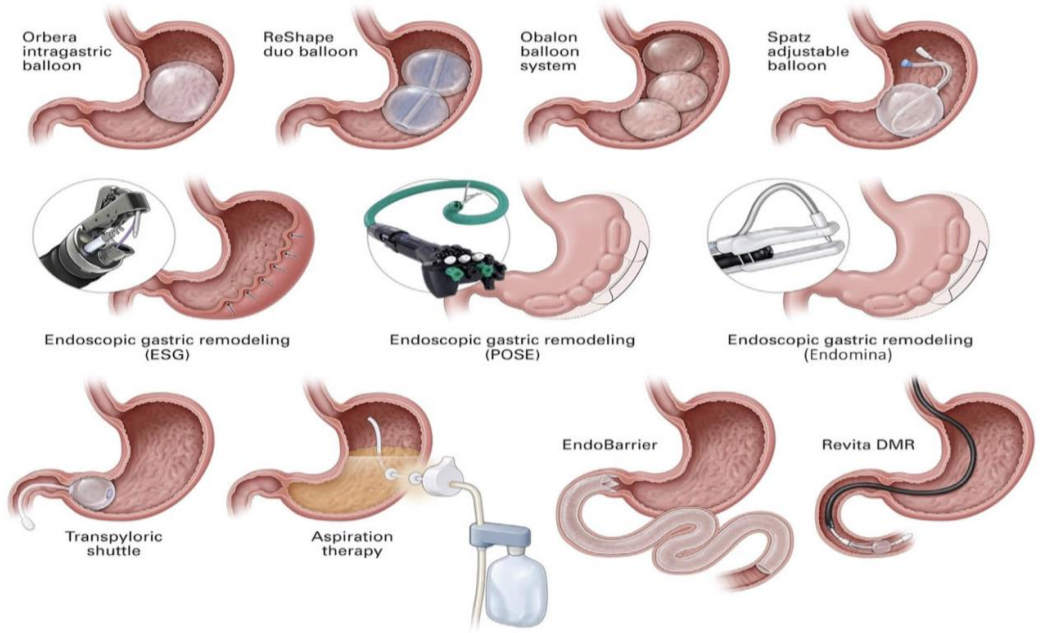

Figure 1. Gastric and small-bowel endoscopic bariatric and metabolic therapies. *ESG,* endoscopic sleeve gastroplasty; *POSE,* primary obesity surgery endoluminal; *DMR,* duodenal mucosal resurfacing.

- **PICOS** (**P**opulation, **I**ntervention, **C**omparison, **O**utcomes, and **S**tudy Design) model was used. **14 PICOS** were constructed
- The certainty of the evidence was graded for each outcome using the **GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) system**
- Evaluation of the efficacy and safety of EBMT devices and procedures with current CE mark or FDA-clearance/ approval, or approved within five years of document development.

Jirapinyo P et al. American Society for Gastrointestinal Endoscopy-European Society of Gastrointestinal Endoscopy guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity. Gastrointest Endosc. 2024 Jun;99(6):867-885.e64.

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SUPPLEMENTARY TABLE 1. PICO questions (population, intervention, comparator, outcome)

PICO question no.	Population	Intervention	Comparator	Outcomes
1	Adults with body mass indices of 27-29.9 kg/m^2 with at least 1 obesity-related comorbidity or body mass indices ≥30 kg/m^2	Endoscopic bariatric and metabolic therapy + lifestyle modification	Lifestyle modification	• %TWL • HbA1c reduction • SAE rate
2	Adults with obesity	Intragastric balloon + lifestyle modification	Lifestyle modification	• %TWL • SAE rate
3	Adults with obesity undergoing intragastric balloon placement	Antiemetics	No antiemetics	• Incidence of PONV • Rate of ED visit within 30 days for PONV
4	Adults with obesity undergoing intragastric balloon placement	Pain medications	No pain medications	• Rate of ED visit within 30 days for pain management
5	Adults with obesity undergoing intragastric balloon placement	PPIs	No PPIs	• Rate of gastric ulcer • Rate of bleeding SAE
6	Adults with obesity	Endoscopic gastric remodeling + lifestyle modification	Lifestyle modification	• %TWL • SAE rate
7	Adults with obesity undergoing endoscopic gastric remodeling	Antiemetics	No antiemetics	• Incidence of PONV • Rate of ED visit within 30 days for PONV
8	Adults with obesity undergoing endoscopic gastric remodeling	Pain medications	No pain medications	• Rate of ED visit within 30 days for pain management
9	Adults with obesity undergoing endoscopic gastric remodeling	Prophylactic antibiotics	No prophylactic antibiotics	• Rate of gastric ulcer • Rate of bleeding SAE
10	Adults with obesity undergoing endoscopic gastric remodeling	PPIs	No PPIs	• Rate of postprocedure infection
11	Adults with obesity	Aspiration therapy + lifestyle modification	Lifestyle modification	• %TWL • SAE rate
12	Adults with obesity	Transpyloric shuttle + lifestyle modification	Lifestyle modification	• %TWL • SAE rate
13	Adults with obesity	Duodenal–jejunal bypass liner + lifestyle modification	Lifestyle modification	• HbA1c reduction • %TWL • SAE rate
14	Adults with obesity	Duodenal mucosal resurfacing + lifestyle modification	Lifestyle modification	• HbA1c reduction • SAE rate

%TWL, Percentage of total weight loss; *SAE*, serious adverse event; *PPI*, proton pump inhibitor; *PONV*, postoperative nausea and vomiting; *ED*, emergency department.

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SUPPLEMENTARY TABLE 2. Charactesristics of the included studies with patients who were overweight

Study	Country	Study design	No. of sites (no. of subjects for the entire study)	BMI indication (kg/m^2) (no. of subjects in this BMI subgroup)	Follow-up (mo)	Age (y)	Female sex (%)	BMI (kg/m^2)
Intragastric balloon								
Fittipaldi-Fernandez 2020[55]	Brazil	Observational	5 (5444)	27.0-29.9 (371)	6	38 ± 38*	75*	36.94 ± 5.67*
Moore 2018[56]	USA	Observational	108 (1343)	25.0-29.9 (124)	5-6	45.7 ± 10.8*	79*	35.4 ± 5.4*
Endoscopic gastric remodeling								
Barrichello 2019[57]	USA Brazil	Observational	7 (193)	25.0-29.9 (12)	12	42.3 ± 9.6*	100	29.7 ± .0
Duodenal–jejunal bypass liner								
Laubner 2018[58]	Germany	Observational	14 (235)	≥27 with T2DM	12†	52 ± 10	62	43.1 ± 6.9
Betzel 2017[59]	Netherlands	Observational	1 (185)	28.0-45.0 with T2DM	12	52 ± 8	49	35.1 ± 4.3
Cohen 2013[60]	Sweden	Observational	1 (16)	<36 with T2DM	12†	50 ± 7	35	30.0 ± 3.6

BMI, Body mass index; *T2DM*, type 2 diabetes mellitus.
For randomized controlled trials, only the data from the interventional arm were extracted to combine with those of the observational studies.
*Studies included patients in different overweight and obesity classes. Demographics reflected those of the entire cohort.
†Included for a pooled serious adverse event rate only.

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SUPPLEMENTARY TABLE 3. Characteristics of the included studies with patients with classes I and II obesity

Study	Country	Study design	No. of sites (no. of subjects)	BMI indication (kg/m^2)	Intervention or device	Comparator	Age (y)	Female sex (%)	BMI (kg/m^2)
Intragastric balloon									
Konopko-Zubrzycka 2009[61]	Poland	RCT	1 (36) I:21, C:15		Orbera + Low intensity LM	Low intensity LM	I: 41 ± 12 C: 43 ± 9	I: 48 C: 60	I: 47.3 ± 5.7 C: 47.1 ± 6.9
Abu Dayyeh 2021[39]	USA	RCT	7 (288) I: 187, C: 101	30.0-39.9	Spatz + Moderate-intensity LM	Moderate-intensity LM	I: 44 ± 9 C: 44 ± 9	I: 87 C: 89	I: 35.8 ± 2.6 C: 35.8 ± 2.7
Sullivan 2018[44]	USA	RCT	15 (387) I: 198, C: 189	30.0-39.9	Obalon + moderate-intensity LM	Sham + moderate intensity LM	I: 43 ± 10 C: 43 ± 9	I: 86 C: 90	I: 35.2 ± 2.7 C: 35.5 ± 2.7
Courcoulas 2017[40]	USA	RCT	15 (255) I: 125, C: 130	30.0-39.9	Orbera + moderate-intensity LM	Moderate-intensity LM	I: 39 ± 9 C: 41 ± 10	I: 90 C: 90	35 for total population
Ponce 2015[43]	USA	RCT	15 (326) I: 187, C: 139	30.0-39.9	ReShape + moderate-intensity LM	Sham + moderate-intensity LM	I: 44 ± 10 C: 44 ± 10	I: 95 C: 95	I: 35.3 ± 2.8 C: 35.4 ± 2.6
Ponce 2013[42]	USA	RCT	3 (30) I: 21, C: 9	30.0-39.9	ReShape + moderate-intensity LM	Moderate-intensity LM	I: 39 ± 9 C: 45 ± 7	I: 81 C: 100	I: 34.7 ± 2.6 C: 35.6 ± 2.0
Fuller 2013[41]	Australia	RCT	1 (66) I: 31, C: 35	30.0-39.9	Orbera + moderate-intensity LM	Moderate-intensity LM	I: 43 ± 9 C: 48 ± 7	I: 68 C: 66	I: 36.0 ± 2.7 C: 36.7 ± 2.9
Endoscopic gastric remodeling									
Abu Dayyeh 2022[45]	USA	RCT	9 (209) I: 85, C: 124	30.0-39.9	Overstitch + moderate-intensity LM	Moderate-intensity LM	I: 47 ± 9 C: 46 ± 10	I: 88 C: 84	I: 35.5 ± 2.6 C: 35.7 ± 2.6
Huberty 2021[62,*]	Belgium Italy	RCT	2 (71) I: 49, C: 22	30.0-39.9	Endomina + Low-intensity LM	Low-intensity LM	I: 38 ± 10 C: 45 ± 12	I: 94 C: 91	I: 34.8 ± 2.7 C: 34.2 ± 2.5
Miller 2017[46]	Europe	RCT	3 (44) I: 34, C: 10	30.0-39.9	Incisionless Operating Platform + moderate-intensity LM	Moderate-intensity LM	I: 38 ± 10 C: 39 ± 13	I: 74 C: 90	I: 36.2 ± 3.3 C: 37.2 ± 3.7
Sullivan 2017[47]	USA	RCT	11 (332) I: 221, C: 111	30.0-39.9	Incisionless Operating Platform + Low-intensity LM	Sham + Low-intensity LM	I: 44 ± 9 C: 45 ± 9	I: 88 C: 91	I: 36.0 ± 2.4 C: 36.2 ± 2.2
Aspiration therapy									
Thompson 2017[52]	USA	RCT	10 (171) I: 111, C: 60	35.0-55.0	Aspiration therapy + moderate-intensity LM	Moderate-intensity LM	I: 42 ± 10 C: 47 ± 12	I: 87 C: 88	I: 42.0 ± 5.1 C: 40.9 ± 3.9
Sullivan 2013[48]	USA	RCT	1 (18) I: 11, C: 7	35.0-50.0	Aspiration therapy + moderate-intensity LM	Moderate-intensity LM	I: 38 ± 2 C: 45 ± 3	I: 100 C: 75	I: 42.0 ± 1.4 C: 39.3 ± 1.1
Transpyloric shuttle									
Rothstein 2022[49]	USA	RCT	9 (270) I: 181, C: 89	30.0-39.9	Transpyloric shuttle + moderate-intensity LM	Sham + moderate-intensity LM	I: 43 ± 9 C: 44 ± 9	I: 93 C: 93	I: 36.8 ± 2.2 C: 36.1 ± 2.4
Duodenal–jejunal bypass liner									
Thompson 2022[50]	USA	RCT	25 (320) I: 213, C: 107	30.0-55.0	DJBL + moderate-intensity LM	Sham + moderate-intensity LM	I: 53 ± 8 C: 52 ± 8	I: 60 C: 65	I: 38.4 ± 5.7 C: 38.3 ± 5.3
Ruban 2022[51]	UK	RCT	2 (170) I: 85, C: 85	30.0-50.0	DJBL + moderate-intensity LM	Moderate-intensity LM	I: 52 ± 8 C: 52 ± 9	I: 46 C: 46	I: 36.8 ± 5.0 C: 35.8 ± 4.2
Koehestanie 2014[63,*]	Netherlands	RCT	3 (77) I: 38, C: 39	30.0-50.0	DJBL + moderate-intensity LM	Moderate-intensity LM	I: 50 [42-58] C: 49 [44-55]	I: 38 C: 36	I: 34.6 [32.4-38.1] C: 36.8 [32.6-42.0]
Duodenal mucosal resurfacing									
Mingrone 2021[64]	Europe Brazil	RCT	11 (108) I: 56, C: 52	24.0-40.0	Duodenal mucosal resurfacing + moderate-intensity LM	Sham + moderate-intensity LM	I: 58 ± 14 C: 56 ± 14	I: 30 C: 31	I: 31.5 ± 4.7 C: 30.7 ± 5.7

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SUPPLEMENTARY TABLE 4. Characteristics of the included studies with patients with class III obesity

Study	Country	Study design	No. of sites (no. of subjects for the entire study)	BMI indication (kg/m²) (no. of subjects in this BMI subgroup)	Follow-up (mo)	Age (y)	Female sex (%)	BMI (kg/m²)
Intragastric balloon								
Fittipaldi-Fernandez 2020[55]	Brazil	Observational	5 (5444)	≥40 (1264)	6	38 ± 38*	75*	36.94 ± 5.67*
Moore 2018[56]	USA	Observational	108 (1343)	>40 (192)	5-6	45.7 ± 10.8*	79*	35.4 ± 5.4*
Khan 2013[65]	UK	Observational	1 (40)	>60 (40)	6	45 ± 1.4	74	69.1 ± 1.0
Zerrweck 2012[66]	France	Observational	1 (23)	>60 (23)	6	44 ± 10.8	65	65 ± 3.8
Konopko-Zubrzycka 2009[61]	Poland	Observational	1 (21)	≥40 (21)	6	41 ± 11.9	48	47.3 ± 5.7
Gottig 2009[67]	Germany	Observational	1 (109)	>50 (109)	6	39.1 ± 8.4	41	68.8 ± 8.9
Mohamed 2008[69]	UK	Observational	1 (50)	≥40 (50)	6	41.4 ± 7.9	70	52.8 ± 8.2
Spyropoulos 2007[68]	Greece	Observational	1 (26)	≥50 (26)	6	40.8 ± 8.1	12	65.3 ± 9.8
Frutos 2007[70]	Spain	Observational	1 (31)	>40 (31)	6	40.08 ± 11.1	68	55.2 ± 6.9
Alfalah 2006[71]	France	Observational	1 (10)	≥50 (10)	6	33 ± 11	100	64.4 ± 7
Busetto 2005[72]	Italy	Observational	1 (17)	>40 (17)	6	26-62	0	55.8 ± 9.9
Busetto 2004[73]	Italy	Observational	1 (43)	>50 (43)	6	43.3 ± 10.5	40	58.4 ± 6.6
Endoscopic gastric remodeling								
Lopez-Nava 2019[110]	Spain	Observational	1 (435)	≥40 (161)	12	45 ± 11	61	44.5 ± 3.8
Barrichello 2019[57]	USA Brazil	Observational	7 (193)	≥40 (16)	12	42.3 ± 9.6*	44	42.2 ± .1
*Aspiration therapy**								
Nystrom 2018[75]	Sweden	Observational	5 (201)	35-70 (201)	12	46 ± 11	75	43.6 ± 7.4
Thompson 2017[52] (interventional arm only)	USA	RCT†	10 (111)	35-55 (111)	12	42 ± 10	87	42.0 ± 5.1
Sullivan 2013[48] (interventional arm only)	USA	RCT†	1 (10)	40-50 or 35.0-39.9 with comorbidities (10)	12	39 ± 2	100	42.0 ± 1.4
*Duodenal–jejunal bypass liner**								
Thompson 2022[50] (interventional arm only)	USA	RCT†	25 (212)	30-55 with T2DM	12	53 ± 8	60	38.4 ± 5.7
Ruban 2022[51] (interventional arm only)	UK	RCT†	2 (85)	30-50 with T2DM	12	52 ± 8	46	36.8 ± 5.0
Obermayer 2021[76]	Austria	Observational	1 (10)	30.0-49.9 with T2DM	9‡	48 ± 9	60	43.3 ± 5.0
Roehlen 2020[77]	Germany	Observational	1 (71)	≥30 with T2DM	9-12‡	47 (range, 21-66)	70	45.2 ± 8.0
Deutsch 2018[78]	Israel	Observational	1 (39)	≥30 with T2DM	9-12‡	58 ± 8	42	37.3 ± 4.9
Laubner 2018[58]	Germany	Observational	14 (235)	≥27 with T2DM	12	52 ± 10	62	43.1 ± 6.9
Patel 2018[79]	UK	Observational	3 (31)	30-50 with T2DM	12	50 ± 8	51	40.0 ± 5.8
Quezada 2018[80]	Chile	Observational	1 (17)	40-60 or ≥35 with a comorbidity + T2DM	12	35 ± 10*	69*	42.2 ± 5.0*
Betzel 2017[59]	Netherlands	Observational	1 (165)	28-45 with T2DM	12	52 ± 8	44	35.1 ± 4.2
Gollisch 2017[81]	Germany	Observational	1 (20)	≥35 with T2DM	12	53 [47-61]	70	41 [38-46]
Stratmann 2016[82]	Germany	Observational	1 (16)	≥ 35 with T2DM	12	50 ± 8	19	48.8 ± 8.5
Koehestanie 2014[63] (interventional arm only)	Netherlands	RCT†	1 (34)	30-50 with T2DM	6‡	50 [42-58]	38	34.6 [32.4–38.1]
De Moura 2012[83]	Brazil	Observational	1 (22)	40-60 with T2DM	12	46 ± 11	86	44.8 ± 7.4
Rodriguez 2009[84] (interventional arm only)	Chile	RCT	1 (12)	30-50 with T2DM	12	45 ± 7	67	38.9 ± 5.9

Values are mean ± standard deviation or median [interquartile range].
BMI, Body mass index; *RCT*, randomized controlled trial; *T2DM*, type 2 diabetes mellitus.
*Studies included patients in different overweight and obesity classes. Demographics reflected those of the entire cohort.
†For RCTs, only the data from the interventional arm were extracted to combine with those of the observational studies.
‡Included for a pooled serious adverse event rate only.

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SUPPLEMENTARY TABLE 5. Evidence profile for supporting the use of endoscopic bariatric and metabolic therapies in different BMI categories

Outcomes	No. of subjects (studies)	Certainty of the evidence (Grading of Recommendations Assessment, Development and Evaluation)	Benefits*	Harms†
BMI 27.0-29.9 kg/m^2 with ≥1 comorbidity				
%TWL at 6-12 mo	692 (4 observational)	Very low	11.9% TWL [7.7-16.0]	—
HbA1c reduction at 12 m	436 (3 observational)	Very low	1.0% [.6-1.5]	—
SAE rate	7416 (6 observational)	Very low	—	2.7% [1.2-6]
BMI 30.0-39.9 kg/m^2				
%TWL at 6-12 mo	2886 (14 RCTs)	Moderate	Mean difference of 6.3% TWL [5.3-7.3]	—
HbA1c reduction at 12 mo	490 (2 RCTs)	Moderate	Mean difference of .7% [.4-1.1]	—
SAE rate	3599 (16 RCTs)	Low	—	14 more per 1000 [6-30]
BMI ≥40 kg/m^2				
%TWL at 6-12 mo	2776 (20 observational)	Very low	13.1% TWL [10.8-15.4]	—
HbA1c reduction at 12 mo	815 (10 observational)	Very low	1.3% [1.0-1.6]	—
SAE rate	2042 (26 observational)	Very low	—	6.9% [5.7-8.2]

BMI, Body mass index; *%TWL*, percentage of total weight loss; *SAE*, serious adverse event; *RCT*, randomized controlled trial; —, not applicable.
*Pooled mean [95% confidence interval] for observational studies and mean difference [95% confidence interval] for RCTs.
†Pooled SAE rate [95% confidence interval] for observational studies and absolute risk [95% confidence interval] for RCTs.

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2022

MDPI

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 Ragghianti [21] and Matteo Monami [21,*] on behalf of the Panel and Evidence Review Team for the Italian Guidelines on Surgical Treatment of Obesity

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

La terapia chirurgica dell'obesità e delle complicanze associate

2023

S.I.C.OB.

LINEE GUIDA

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CONSENSUS STATEMENT

2024

Check for updates

Italian guidelines for the management of adult individuals with overweight and obesity and metabolic comorbidities that are resistant to behavioral treatment

M. Chianelli · L. Busetto · R. Vettor · B. Annibale · A. Paoletta · E. Papini, et al. *[full author details at the end of the article]*

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De Luca M et al. Development of the Italian Clinical Practice Guidelines on Bariatric and Metabolic Surgery: Design and Methodological Aspects. Nutrients. 2022 Dec 30;15(1):189.
Guidelines of Italian Society of Bariatric Surgery and Metabolic Disorders (SICOB) 2023

Chianelli M et al. Italian guidelines for the management of adult individuals with overweight and obesity and metabolic comorbidities that are resistant to behavioral treatment.
J Endocrinol Invest. 2024 Jun;47(6):1361-1371.

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2023

S.I.C.OB. LINEE GUIDA

- **Grading of Recommendation, Assessment, Development and Evaluation (GRADE) approach**.
- Contents of the GL were reported in accordance with the **AGREE II (Appraisal of Guidelines for REsearch and Evaluation II) checklist**.
- **Only randomized controlled trials (RCTs) included.**
- Definition of clinical questions, using the **PICOs** (**P**opulation, **I**ntervention, **C**omparison, **O**utcomes, and **S**tudy Design) conceptual framework. **32 PICOS identified.**
- The definition of questions was performed using a **two-step Delphi method.**

De Luca M et al. Development of the Italian Clinical Practice Guidelines on Bariatric and Metabolic Surgery: Design and Methodological Aspects. Nutrients. 2022 Dec 30;15(1):189.

Guidelines of Italian Society of Bariatric Surgery and Metabolic Disorders (SICOB) 2023

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ORIGINAL ARTICLE

2024

Upcoming Italian clinical practice guidelines on endoscopic bariatric treatment of overweight and obesity: design and methodological aspects

Maurizio De Luca[1] · Antonio Silverii[2] · Monica Zese[1] · Giovanni Galasso[3] · Rosario Bellini[4] · Maria Grazia Carbonelli[5] · Rita Cataldo[6] · Mariarosaria Cerbone[7] · Marco Chianelli[8] · Francesca Clemente Gregoris[9] · Rita Conigliaro[10] · Carla Micaela Cuttica[11] · Carlo de Werra[12] · Massimo Di Simone[13] · Ludovico Docimo[14] · Mario Musella[12] · Giuseppe Gagliardi[15] · Luigi Angrisani[12] · Nicola Di Lorenzo[16] · Ivo Boskoski[17] · Alfredo Genco[18] · Marco Raffaelli[17] · Andrea Anderloni[19] · Giovanni Casella[20] · Giuseppe Galloro[21] · Arianna Goracci[22] · Valentina Lorenzoni[23] · Raffaele Manta[24] · Paolo Marzullo[25] · Gerardo Medea[26] · Giuseppe Navarra[27] · Monica Ortenzi[28] · Barbara Paolini[29] · Luigi Piazza[30] · Debora Porri[31] · Farnaz Rahimi[32] · Simone Rugolotto[33] · Giulia Pontesilli[34] · Giovanni Sarnelli[35] · Luca Sessa[17] · Iris Zani[36] · Marco Antonio Zappa[37] · Giulia Bandini[38] · Benedetta Ragghianti[2] · Matteo Monami[2]

A consensus was reached for all the proposed PICOs with no need for a second round. The identified 8 clinical questions were organized into four domains:

A. Indication for endobariatric surgery (3 questions);
B. Temporary gastric procedures (2 questions);
C. Revisional surgery (1 question);
D. Endoscopic diagnosis/treatment of MBS complications (2 questions).

- Adoption of the **GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) system**
- Contents of the GL were reported in accordance with the **AGREE II (Appraisal of Guidelines for REsearch and Evaluation II) checklist**.
- Definition of clinical questions, using the **PICOs** (**P**opulation, **I**ntervention, **C**omparison, **O**utcomes, and **S**tudy Design) conceptual framework. **8 PICOS identified.**
- The definition of questions was performed using a **two-step Delphi method**
- **Systematic reviews, formal meta-analyses, and network meta-analyses performed for each PICOS** to assess and rate the available evidence about efficacy and safety of endo bariatric procedures in comparison with either no interventions, lifestyle interventions, or approved anti-obesity treatments in patients affected by overweight/obesity in **trials with a follow-up of at least 26 weeks**

De Luca M et al. Upcoming Italian Clinical Practice Guidelines on Endoscopic Bariatric Treatment of Overweight and Obesity: Design and methodological aspects.evelopment of the Italian Clinical Practice Guidelines on Bariatric and Metabolic Surgery: Design and Methodological Aspects. Updates in Surgery, 2024

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TAKE HOME MESSAGES

- Guidelines currently drive our practice
- Guidelines are recommendations from Metanalysis or Systematic Review
- **The best considered Guideline evaluation system commonly adopted is the Appraisal of Guidelines for Research and Evaluation II (AGREE II) framework.**
- **In Guideline development consider rigour of development but also applicability.**
- Provide practical tools (i.e., checklists , algorithmic pathways for perioperative care, nomograms) or advice in order to make the guidelines not only theoretically and methodologically impeccable, but also **pragmatically viable**
- For Guidelines development it is paramount to **clearly describe facilitators and barriers** to implementation allowing practitioners to anticipate and manage challenges promptly

- IN MBS there are few guidelines with an **overall assessment score ≥70% (AGRRE II) and can be considered high quality**

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IFSO European Chapter 2025

15-17 May 2025, Venice Italy

President of the Congress:
Maurizio De Luca

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Thank you for your attention!