The Scientific Evidence Supporting the New Guidelines

Prof Maurizio De Luca, Head Department of Durgery, Rovigo, Trecenta and Adria Hospitals, Italy



IFSO-ASMBS Guidelines on Indication for MBS

The Scientific Evidence Supporting the New Guidelines

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President Elect Italian Society of Bariatric Surgery and Metabolic Disorders (SICOB)
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 Committee Italian Society of Obesity (SIO)
Scientific Committee The Upper Gastrointestinal Surgeons (TUGS)



I have no potential conflict of interest to report





Obesity Surgery, 1, 257-265

National Institutes of Health Consensus Development Conference Draft Statement on

Gastrointestinal Surgery for Severe Obesity 25–27 March 1991

- BMI> 40 kg / m²
- BMI> 35 kg / m^2 in the presence of specific comorbidities:
 - Hypertension
 - Ischemic heart disease
 - Type 2 diabetes
 - Obstructive sleep apnea syndrome
 - Obesity syndrome / hypoventilation (Picwick syndrome)
 - Non-alcoholic fatty liver disease and steatohepatitis
 - Dyslipidemia
 - Gastro-oesophageal reflux disease
 - Asthma
 - Venous stasis
 - Severe urinary incontinence
 - Disabling arthropathy
 - Severely reduced quality of life
- Between 18 and 60 years of age
- Proven failure of nutritional and behavioral therapy and longstanding obesity (> 5 years)
- Patients must be motivated and able to provide a valid consent, are willing to undergo periodic inspections and follow an established dietary regime
- Absence of major contraindications (very high operative risk, limited life expectancy due to illness, severe cirrhosis, alcohol abuse / drugs etc.).





Obesity Surgery. 1, 257-265

National Institutes of Health Consensus Development Conference

Gastrointestinal Surgery for Severe Obesity 25-27 March 1991

I) 1991 NIH Consensus described:

Dominant procedures VBG and RYGB mainly open

II) Currently:

- SG and RYGB mainly laparoscopically and robotically
- VBG is of historical interest and no longer performed
- Other procedures performed include AGB Ψ , standard BPD Ψ , BPD-DS Ψ , OAGB \uparrow , SADI-S \uparrow

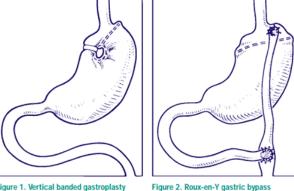


Figure 1. Vertical banded gastroplasty



2022: in light of significant advances in the understanding of the disease of obesity and in MBS, the **leadership of the ASMBS and IFSO** have convened to produce this joint statement.

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



ORIGINAL CONTRIBUTIONS



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

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

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





SURGERY FOR OBESITY AND RELATED DISEASES

Surgery for Obesity and Related Diseases 18 (2022) 1345-1356

Original article

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

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MBS is recommended for individuals with BMI >35 kg/m², regardless of presence, absence, or severity of comorbidities.

MBS is recommended in patients with T2D and BMI >30 kg/m²

MBS should be considered in individuals with BMI of 30–34.9 kg/m² who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods





Clinical obesity in the Asian population is recognized in individuals with BMI >25 kg/m²

Children and adolescents with BMI >120% of the 95th percentile and a major co-morbidity, or a BMI >140% of the 95th percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center

There is **no** evidence to support an **age limit** on patients seeking MBS, but careful selection that includes assessment of **frailty** is recommended





Studies failed to demonstrate a significant difference in perioperative complications, length of obesity surgery stay, 30-day mortality, or long-term outcomes after MBS when individuals with BMI >60 kg/m² were compared with those with BMI <60 kg/m²

Furthermore, studies have shown that MBS can be performed safely in patients with BMI >70 kg/m²





There are reports to suggest that MBS may be effective as a **bridge to total joint arthroplasty** in individuals with class II/III obesity when performed >2 years prior to joint surgery

In patients with severe obesity and an **abdominal wall hernia** requiring elective repair, MBS should be considered first to induce significant weight loss

MBS is associated with an 88% risk reduction of progression of MAFDL to cirrhosis

Patients with endstage organ disease can achieve meaningful weight loss and **improve their eligibility to** receive an organ transplant





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

1 Scope & Purpose
3
2 Stakeholder Involvement
3 Rigour of Development
4 Clarity & Presentation
5 Applicability
3
6 Editorial Independence
2

Clinical Practice Secondary, pre-Guidelines appraised, or filtered Meta-Analysis Systematic Review Randomized Controlled Trial Prospective, tests treatment Primary Studies Cohort Studies Prospective - exposed cohort is Observ ational observed for outcome Studies Case Control Studies Retrospective: subjects already of interest looking for risk factors Case Report or Case Series No design Narrative Reviews, Expert Opinions, Editorials

a generally accepted opinion or decision among a group of people: The general consensus in the office is that he can't do his job. Could we reach a consensus on the matter? Let's take a vote. Thesaurus: synonyms, antonyms, and over these 2023.

https://dictionary.cambridge.org > dictionary > consensus

CONSENSUS | English meaning - Cambridge Dictionary



No humans

involved

Maurizio De Luc

Animal and Laboratory Studies

The Scientific Evidence Supporting the New Guidelines

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



Obesity Surgery https://doi.org/10.1007/s11695-024-07370-7 2024



ORIGINAL CONTRIBUTIONS



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

Maurizio De Luca¹ · Scott Shikora² · Dan Eisenberg³ · Luigi Angrisani⁴ · Chetan Parmar⁵ · Aayed Alqahtani⁶ · Ali Aminian⁷ · Edo Aarts⁸ · Wendy Brown⁹ · Ricardo V. Cohen¹⁰ · Nicola Di Lorenzo¹¹ · Silvia L. Faria¹² · Kasey P. S. Goodpaster¹³ · Ashraf Haddad¹⁴ · Miguel Herrera¹⁵ · Raul Rosenthal¹⁶ · Jacques Himpens¹⁷ · Angelo lossa¹⁸ · Mohammad Kermansaravi¹⁹ · Lilian Kow²⁰ · Marina Kurian²¹ · Sonja Chiappetta²² · Teresa LaMasters²³ · Kamal Mahawar²⁴ · Giovanni Merola²⁵ · Abdelrahman Nimeri² · Mary O'Kane²⁶ · Pavlos Papasavas²⁷ · Giacomo Piatto²⁸ · Jaime Ponce²⁹ · Gerhard Prager³⁰ · Janey S. A. Pratt³ · Ann M. Rogers³¹ · Paulina Salminen³² · Kimberley E. Steele³³ · Michel Suter³⁴ · Salvatore Tolone³⁵ · Antonio Vitiello³⁶ · Marco Zappa³⁷ · Shanu N. Kothari³⁸

Received: 14 May 2024 / Accepted: 21 May 2024 © The Author(s), under exclusive licence to Springer Science+Business Media, LLC, part of Springer Nature 2024





Methods

- In order to *methodologically support* the previously published ASMBS/IFSO 2022 guidelines, **2 international teams of researchers** were created.
- > One team of seven researcher (MDL, GM, AI, GP, ST, SC, AV) performed systematic reviews for different items, according to the PRISMAS
- > 13 PRISMAs were carried out (for 13 items) with 12 different systematic reviews
 - PRISMA on item 2 (BMI 35-40 kg/m2 without obesity-associated medical problems) produced no studies
 - Systematic review on **item 6** (MBS prior to joint arthroplasty) produced controversial results



TWO INDEPENDENT RESEARCHERS FOR EVERY ITEM ANALYZED EACH ARTICLE

IN CASE OF DISAGREEMENT A THIRD RESEARCHER (MDL) WAS CONSULTED



- ➤ The second team (MDL, MK, ST) was tasked to resolve any issues that were not answered by the PRISMA (item 2) and systematic review (item 6).
- Delphi survey was constructed and consisted of two consecutive rounds.
- ➤ 49 recognized MBS experts from 18 different countries participated in this Delphi survey

First Name	Last Name	Country
Edo	Agarts,	Netherland
Ahmad	Aly	Australia
Ali	Aminian	USA
Luigi	Angrisani	Italy
Ahmad Abdallah	Bashir	Jordan
Estuardo	Behrens	Guatemala
Helmuth Thorlakur	Billy	USA
Sonja	Chiappetta	Italy
Jean-Marc	Chevallier	France
Ricardo Vitor	Cohen	Brazil
Maurizio	De Luca	Italy
Pierre Y	Garneau	Canada
Khaled Aly	Gawdat	Egypt
Ashraf	Haddad	Jordan
Jacques M	Himpens	Belgium
Farah Anwari	Husain	USA
Angelo	Iossa	Italy
Mohammad	Kermansarayi	Iran
Shanu Nikhil	Kothari	USA
Lilian	Kow.	Australia
Marina	Kurian	USA
Teresa LeAnn	LaMasters	USA
Silvia	Leite Faria	Brazil
Ken Wing King	Loi	Australia
Kamal K	Mahawar	UK
Corrigan Lee	McBride	USA
Giovanni	Merola	Italy
Monali.	Misra	USA
Abdelrahman Ali	Nimeri	USA
Joe	Northup	USA
Mary	O'Kane	UK
Paylos	Papasayas	USA
Richard M	Peterson	USA
Giacomo	Piatto	Italy
Luis	Poggi	Peru
Jaime	Ponce	USA
Gerhard	Prager	Austria
Janey Sue Andrews	Pratt	USA
Almino Cardoso	Ramos	Brazil
Ann M	Rogers	USA
Paulina Nathaniel James	Salminen Sann	Finland USA
John David	Scott	USA
Scott Alan	Shikora	USA
Michel	Suter	Switzerland
Salvatore	Tolone	Italy
Antonio	Vitiello	Italy
Cunchuan	Wang	China





Delphi survey

- 9 statements regarding 2 items were analysed:
 - BMI 35-40 kg/m2 without obesity-associated medical problems and (item 2)
 - MBS prior to joint arthroplasty (item 6)
- Consensus was reached when the agreement/disagreement rate was equal to or greater than 70%.
- ➤ An online platform (Survey Monkey) was used.
- 7 statements reached consensus in the first round and 2 statements reached consensus in the second round of voting





GRADE OF RECOMMENDATION	LEVEL OF EVIDENCE	TYPE OF STUDY
A	1 a	Systematic review of [homogeneous] randomized controlled trials
A	1 b	Individual randomized controlled trials [with narrow confidence intervals]
В	2 a	Systematic review of [homogeneous] cohort studies of "exposed" and "unexposed" subjects
В	2b	Individual cohort study / low-quality randomized control studies
В	3 a	Systematic review of [homogeneous] case-control studies
В	3b	Individual case-control studies
С	4	Case series, low-quality cohort or case-control studies
D	5	Expert opinions based on non-systematic reviews of results or mechanistic studies

Evidence-Based Medicine, Stony Brook University Libraries, 14 March 2023



Recommendations

- > 13 recommendations were expressed from the panel
- ➤ 12 different systematic reviews from the 13 PRISMA were carried out.
 - PRISMA on item 2 (BMI 35-40 kg/m2 without obesity-associated medical problems) produced no studies.
 - Systematic review on item 6 (MBS prior to joint arthroplasty) produced controversial results

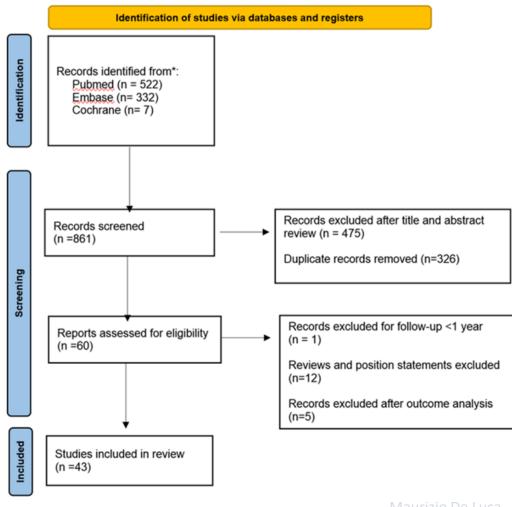
Criteria	PRISMA and DELPHI	Level of Evidence	Grade of Recommendation
MBS for BMI 30 - 34.9 kg/m ²	PRISMA	2a	В
MBS for BMI 35-40 kg/m ² without obesity-associated comorbidities	PRISMA Insufficient data	5	D
BMI thresholds in the Asian	DELPHI PRISMA	2a	В
population	1 111311111	Zu	J
MBS in the Ider population	PRISMA	2a	В
MBS for the pediatric and adolescents	PRISMA	1b	А
MBS prior to joint Arthroplasty	PRISMA Conflicting data DELPHI	2b	В
MBS and abdominal wall hernia repair	PRISMA	2b	В
MBS prior to organ transplantation	PRISMA	2b	В
MBS for BMI ≥ 60 kg/m ²	PRISMA	2a	В
MBS in patients with liver cirrhosis	PRISMA	2b	В
MBS in patients with heart failure	PRISMA	2b	В
Multidisciplinary care	PRISMA	2c	В
Revisional surgery	PRISMA	2b	В



➤ 43 articles were included in the present review, 29 (69%) were conducted on non-Asian patients and 13 (31%) on Asian patients.

➤ Operative time and length of stay (LOS) appeared comparable to available data in the literature for MBS in BMI \geq 35 kg/m².









1- MBS for BMI 30 - 34.9 kg/m2

Recommendation:

MBS is recommended for patients with T2DM and BMI of 30-34.9 kg/m2.

MBS is recommended for patients with **BMI of 30-34.9 kg/m2 and one obesity-associated medical problem.**

MBS should be considered in patients with **BMI of 30-34.9 kg/m2 who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.**

Level of Evidence 2a

Grade of recommendation B



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



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Received: 14 May 2024 / Accepted: 21 May 2024

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Thank you again to all the authors!!!

Summary of recommendations with their grade and level of evidence

Criteria	PRISMA and DELPHI	Appendix/Table	Level of Evidence	Grade of Recommendation	Recommendation	References
MBS for BMI 30 - 34.9 kg/m²	PRISMA	1	2a	В	MBS is recommended for patients BMI 30 – 34.9 kg/m ² with T2DM and/or other obesity-associated medical problems	7-35
MBS for BMI 35-40 kg/m² without obesity-associated comorbidities	PRISMA Insufficient data DELPHI	2	5	D	MBS is recommended regardless of the presence, absence, or severity of obesity-associated medical problems	-
BMI thresholds in the Asian population	PRISMA	3	2a	В	Access to MBS should not be denied solely based on the BMI	36-54
MBS in the older population	PRISMA	4	2a	В	There is no evidence to support an age limit	55-72
MBS for pediatric and adolescents	PRISMA	5	1b	А	MBS is safe in the population younger than 18 years, produces durable weight loss, and improvement obesity-associated medical problems	76-117
MBS prior to joint Arthroplasty	PRISMA Conflicting data DELPHI	6	2b	В	MBS can be considered a bridge to joint arthroplasty in patients with BMI \geq 30 kg/m ²	120-141
MBS and abdominal wall hernia repair	PRISMA	7	2b	В	In patients with severe obesity and an abdominal wall hernia, MBS-induced weight loss is suggested before hernia repair	143-165
MBS prior to organ transplantation	PRISMA	8	2b	В	Published data supports considering patients in need of SOT first to undergo MBS to improve their eligibility for transplantation	166-189
MBS for BMI ≥ 60 kg/m ²	PRISMA	9	2a	В	MBS is safe and effective in patients BMI _≥ 60 kg/m²	192-238
MBS in patients with liver cirrhosis	PRISMA	10	2b	В	MBS is associated with a reduction of progression of MAFDL to cirrhosis	239-253
MBS in patients with heart failure	PRISMA	11	2b	В	MBS can be a useful treatment adjunct in patients with obesity and heart failure	254-271
Multidisciplinary care	PRISMA	12	2c	В	Despite the low evidence level, MDT is at present the unmodifiable core of pre and post-operative obesity management	272-284
Revisional surgery	PRISMA	13	2b	В	Revisional MBS induces satisfactory metabolic outcomes with acceptable rates of complications and mortality	285-310



SNLG – Sistema Nazionale Linee Guida

National System of Guidelines

The Law of 8 March **2017**, n.24, provides that "the health professions...comply with the Recommendations provided for by the Guidelines published and drawn up by public and private bodies and institutions as well as by scientific societies and technical-scientific associations of the health professions registered in the appropriate list".

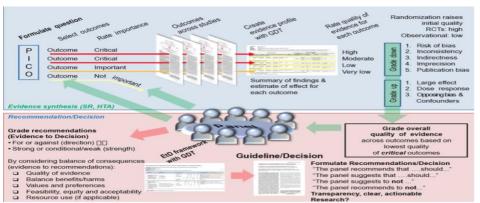
Reimbursement for Public and private hospitals depends on the acceptance of Guidelines by Minister of Health

ITALIAN MBS GUIDELINES

🔵 Ministero della Salute

Coordinator: Maurizio De Luca

- 14 scientific societies involved
- 64 authors
- 4 methodologists





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

La terapia chirurgica dell'obesità e delle complicanze associate





La seguente linea guida è stata sviluppata da SICOB in collaborazione con:

COI: Associazione Chirurghi Ospedalieri Italiani

ADI: Associazione Italiana di dietetica e nutrizione clinica

AME: Associazione Medici Endocrinologi

ANSISA: Associazione Nazionale Specialisti in Scienze dell'Alimentazione ASAND: Associazione Scientifica Alimentazione Nutrizione e Dietetica

SIC: Società Italiana di Chirurgia

SICE: Società Italiana di Chirurgia Endoscopica e nuove tecnologie

SID: Società Italliana di Diabetologia SIO: Società Italiana dell'Obesità SIEC Società Italiana Endocrinologia

SIMG Società Italiana di Medicina Generale e delle Cure Primarie

SIP: Società Italiana di Pediatria

SIUEC: Società Italiana Unitaria di Endocrinochirurgia

Published from National Health Institute on 5.9.2023

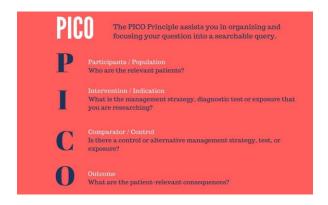


ASMBS (ASMBS)

RATING QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS

GRADE: an emerging consensus on rating quality of evidence and strength of recommendations

Guidelines are inconsistent in how they rate the quality of evidence and the strength of recommendations. This article explores the advantages of the GRADE system, which is increasingly being adopted by organisations worldwide



Box 1 | Advantages of GRADE over other systems

- Developed by a widely representative group of international guideline developers
- Clear separation between quality of evidence and strength of recommendations

Box 2 Quality of evidence and definitions

High quality— Further research is very unlikely to change our confidence in the estimate of effect

Moderate quality— Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate

Low quality— Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

Very low quality— Any estimate of effect is very uncertain

<u>Strong recommendation</u> The panel is confident that the desirable effects of adherence to the recommendation outweigh the undesirable effects.

<u>Weak recommendation</u>: The desirable effects to adherence to the recommendation probably outweigh the undesirable effects, but the panel is less confident.



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

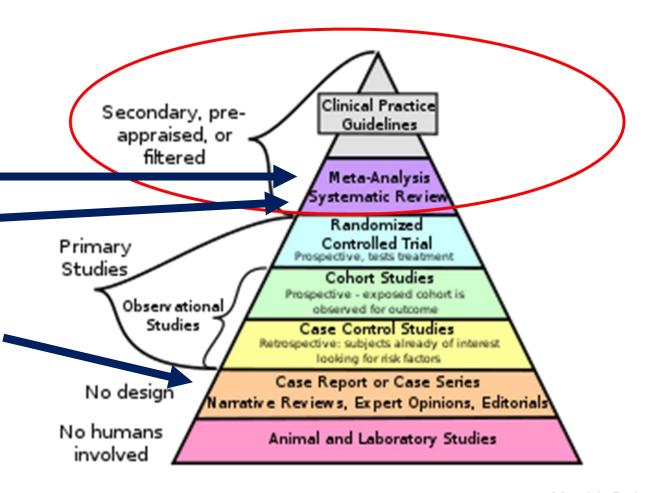
GRADE Methodology

PRISMA Systematic Review

a generally accepted opinion or decision among a group of people: The general consensus in the office is that he can't do his job. Could we reach a consensus on this his that he can't do his job. Could we reach a consensus on this his that he can't do his job. Could we reach a consensus on this his that he can't do his job. Could we reach a consensus on this his that he can't do his job. Could we reach a consensus on this his that he can't do his job. Could we reach a consensus on this his job.

https://dictionary.cambridge.org > dictionary > consensus

CONSENSUS | English meaning - Cambridge Dictionary







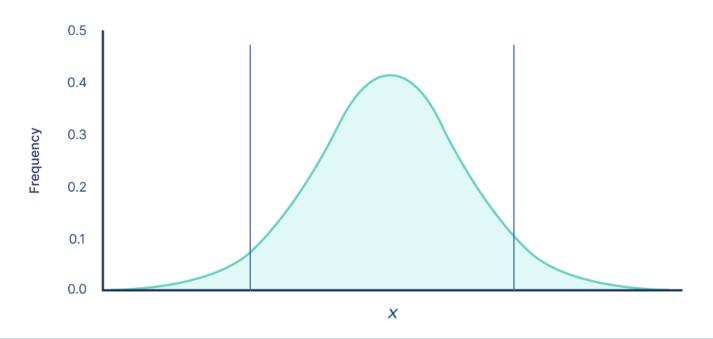
The probability of disease

W. J. Long

Proc Annu Symp Comput Appl Med Care. 1991 : 619-623

PMCID: PMC2247605

PMID: <u>1807676</u>







TRADITIONAL MEDICINE vs. PRECISION MEDICINE

Traditionally, radiation, chemotherapy, and surgery were the only means by which doctors could treat cancer. With precision medicine, doctors use a patient's genes to uncover clues for treating the disease.

RADIATION

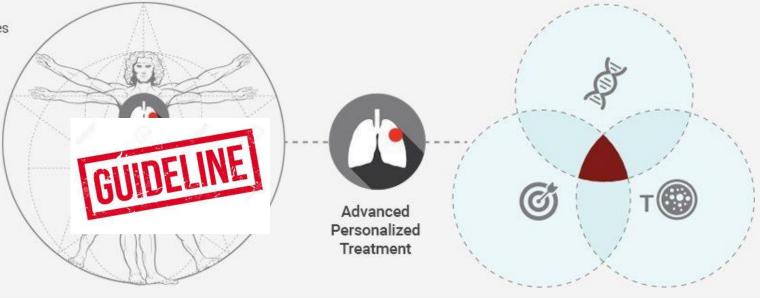
 High-energy particles damage or destroy cancer cells

CHEMOTHERAPY

· Chemicals attack cancer

SURGERY

· Operate on part of the body to diagnose or treat cancer



GENETICS

- Gene sequencing
- · Locate cancercausing genes

IMMUNOTHERAPY

- · Identify ways to customize treatment
- Find ways to turn immune system on
- Personalize treatment with immune-activating druas

TARGETED THERAPIES

- · Drugs turn specific genes on or off
- + TRADITIONAL THERAPIES









Editorial

Precision Bariatric/Metabolic Medicine and Surgery

Laurent Genser 1,2,*, Dominique Thabut 3 and Judith Aron-Wisnewsky 2,400

2023

Reviews in Endocrine and Metabolic Disorders (2023) 24:961–977 https://doi.org/10.1007/s11154-023-09801-9



Towards precision medicine in bariatric surgery prescription

Sofia S. Pereira^{1,2} • Marta Guimarães^{1,2,3} • Mariana P. Monteiro^{1,2}

Accepted: 12 March 2023 / Published online: 2 May 2023 © The Author(s) 2023





Obesity comorbidities

- · Type 2 Diabetes
- · Non-alcoholic fatty liver disease
- · Gastroesophageal reflux disease
- · Obstructive sleep apnea
- · Polycystic ovarian syndrome

Psychosocial and economic factors

- · Mental health conditions
- · executive control
- Cognitive control
- · Economic status
- Residence

Genetic background

- · Monogenic obesity
- Presence of SNPs

 (e.g., SNPs in genes

 FTO, POMC, MC4R,

 LEP, LEPR)

Eating behaviours

- Food addiction
- · Binge eating

Anthropometric factors

- Age
- Gender
- · Body mass index

Circulating biomarkers

- microRNAs
- Metabolites
- · Enteroendocrine hormones





Take Home Message

- > The new IFSO/ASMBS 2022 indication to MBS have made history
- ➤ A methodological upgrade has allowed them to be called **Guidelines**
- > GRADE method on some analyzed items does not allow us to express good level of recommendation as the literature is not robust
- There are no defined criteria for the use of a specific treatment for a patient-tailored decision in order to optimize MBS outcomes



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IFSO European Chapter 2025

15-17 May 2025, Venice Italy

President of the Congress:

Maurizio De Luca



ifso-ec2025.com



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Thank you for your attention!

