Innovative surgical procedures in the modern era of diabetes treatment: friend or foe?

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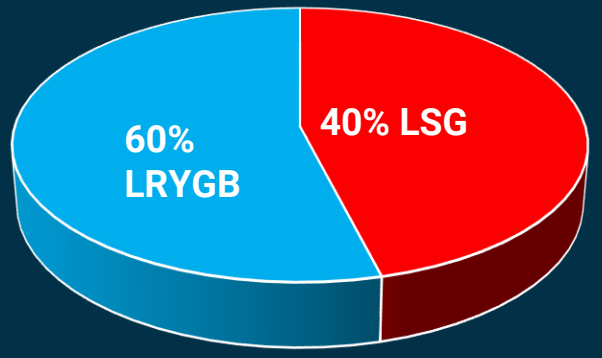
Disclosures

- Lecture fees: Novo Nordisk
- Employment: University of Turku, Turku University Hospital, private practice Terveystalo
- PI: SLEEVEPASS, APPAC
- IFSO-EC President elect
- Editor-in-Chief, Scandinavian Journal of Surgery
- Editor, BJS
- Editorial Board Member JAMA Surgery and Surgery
- Data safety monitoring committee: BEST trial, MAGNET-study
- Research grants:
  - Europen Research Council
  - Academy of Finland
  - Sigrid Jusélius Foundation
  - Mary and Georg C. Ehrnrooth foundation
  - Government research grant foundation (EVO)

Primary procedures



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erc European Research Council

SUOMEN AKATEMIA

SIGRID JUSELIUS STIFTELSE

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New era of diabetes treatment and OMMs > MBS science requirement
EBM: level of evidence in innovative surgical procedures
Case SADI-S
Randomized clinical trials
Long-term follow-up
MBS science in the new era
Innovative surgical procedures: what needs to be done?

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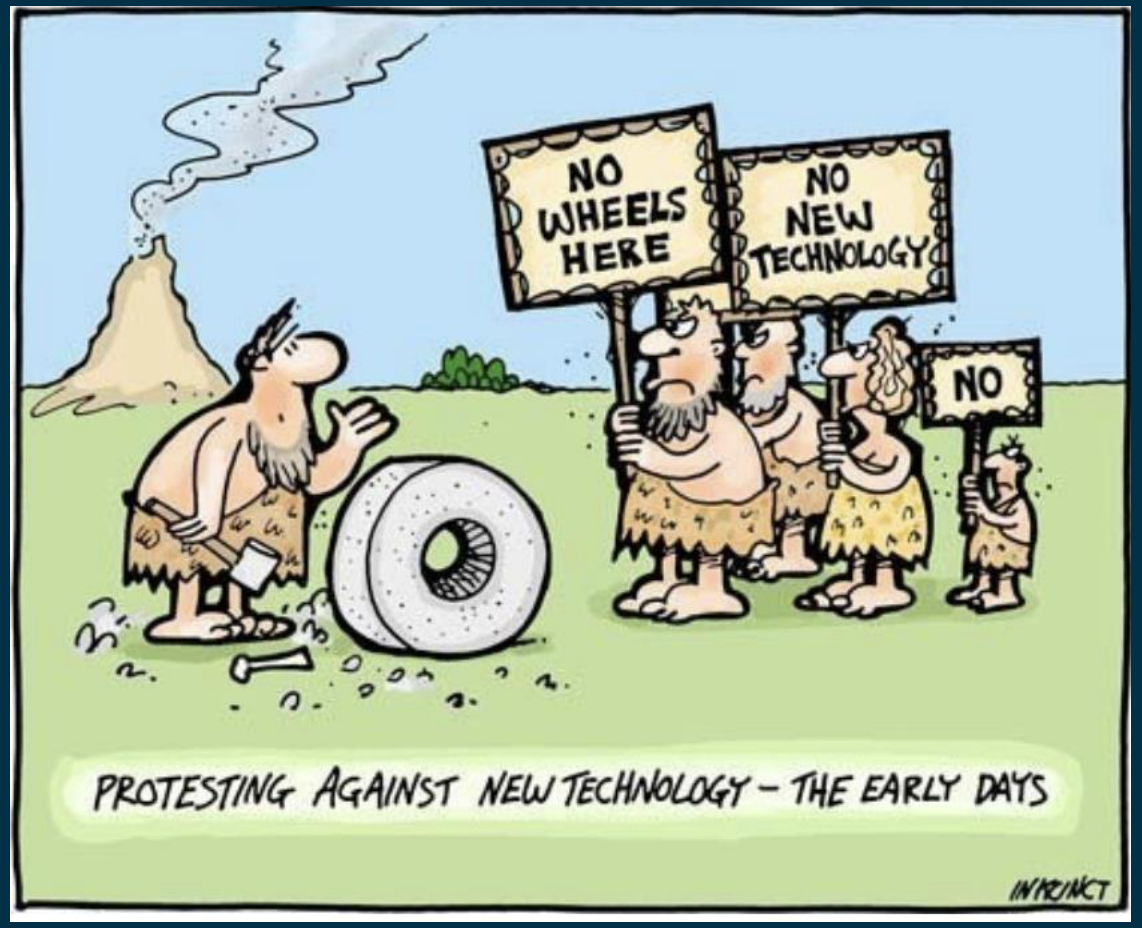
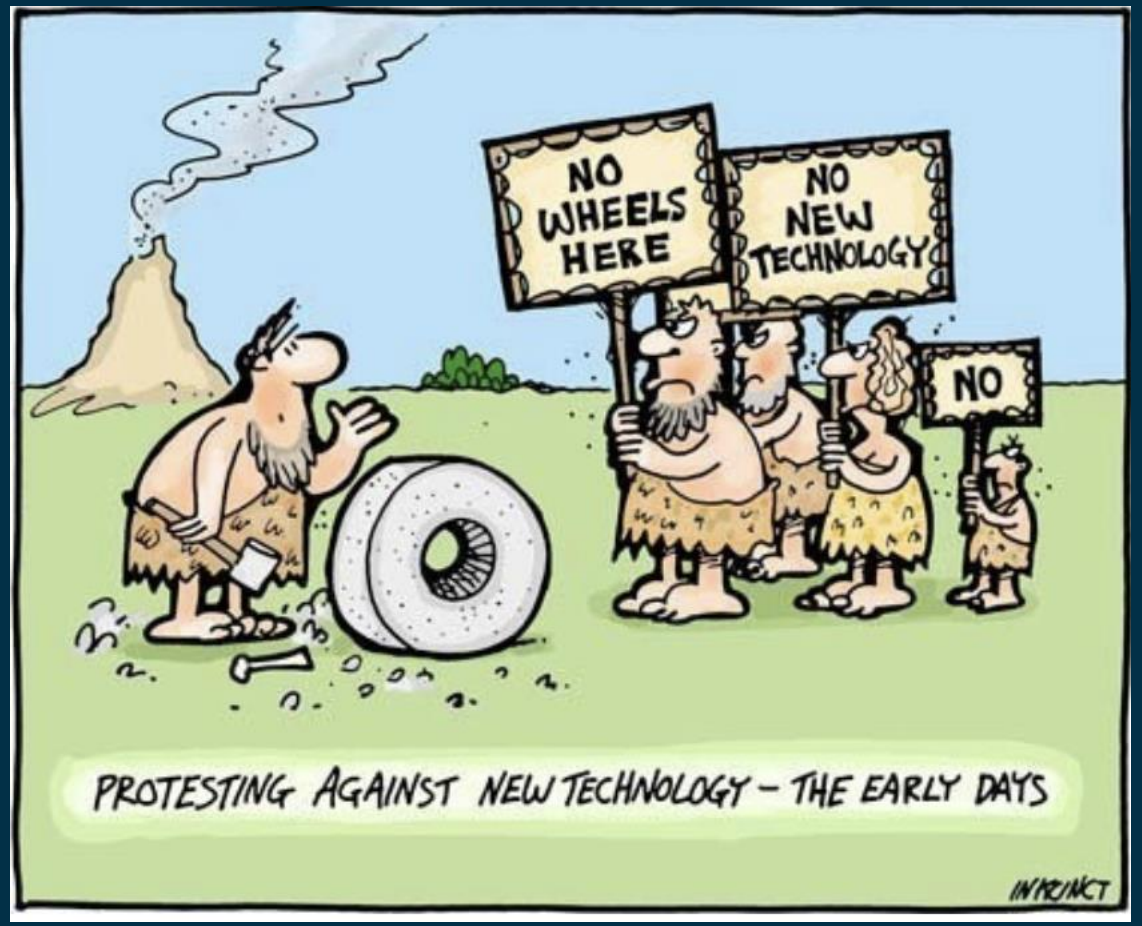
Clarunis
University Digestive Health Care Center
St. Clara Hospital and University Hospital Basel Switzerland


WELCOME TO THE ERA
OF GLP1-RA'S!
ce Welcome &
Ceremony.
Next Gene
Metabo
rated Fu
Speakers:
Lee Kaplan
IFSO
MELBOURNE 2024

Innovation is important…




NO WHEELS HERE
NO NEW TECHNOLOGY
NO
PROTESTING AGAINST NEW TECHNOLOGY – THE EARLY DAYS


DATA > OPINION
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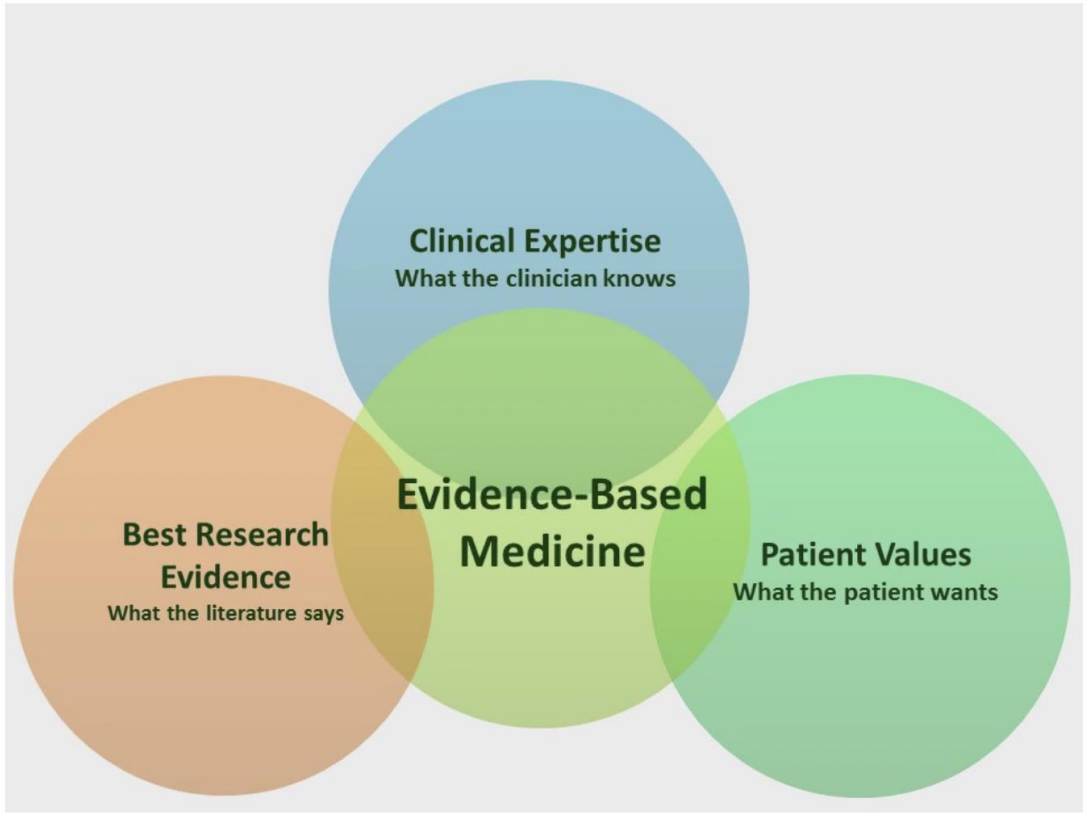
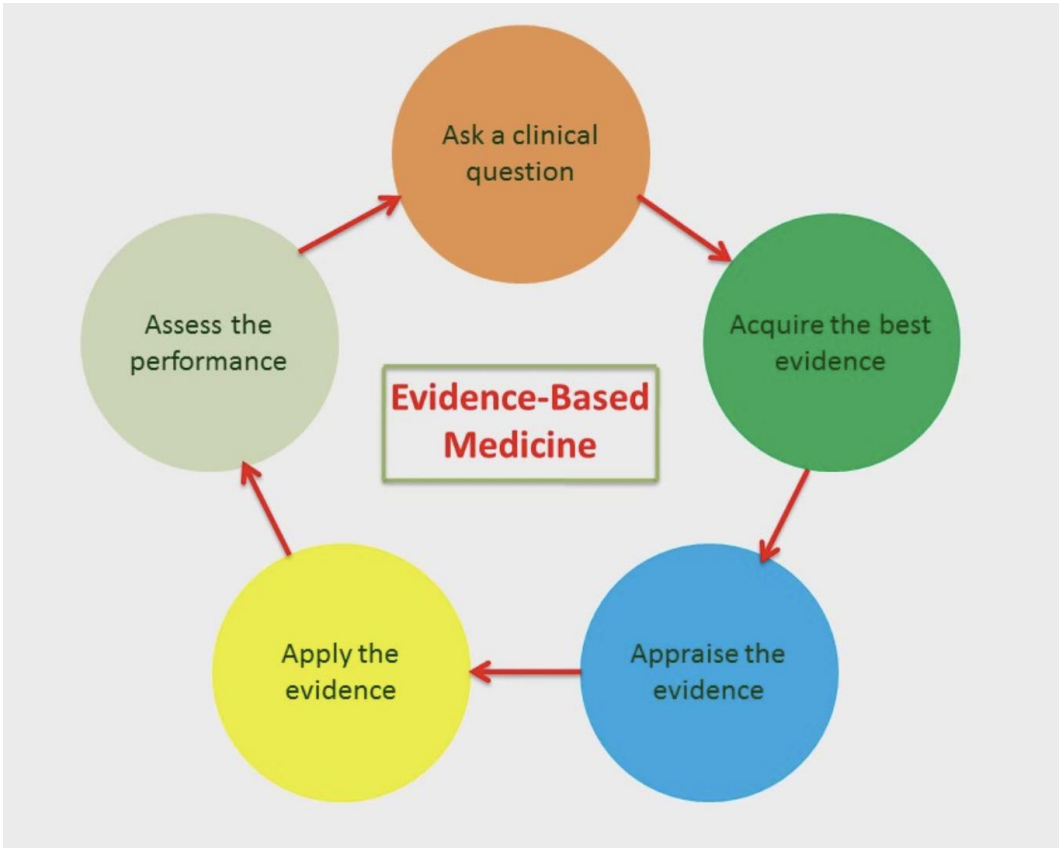
Evidence based medicine – EBM Surgery





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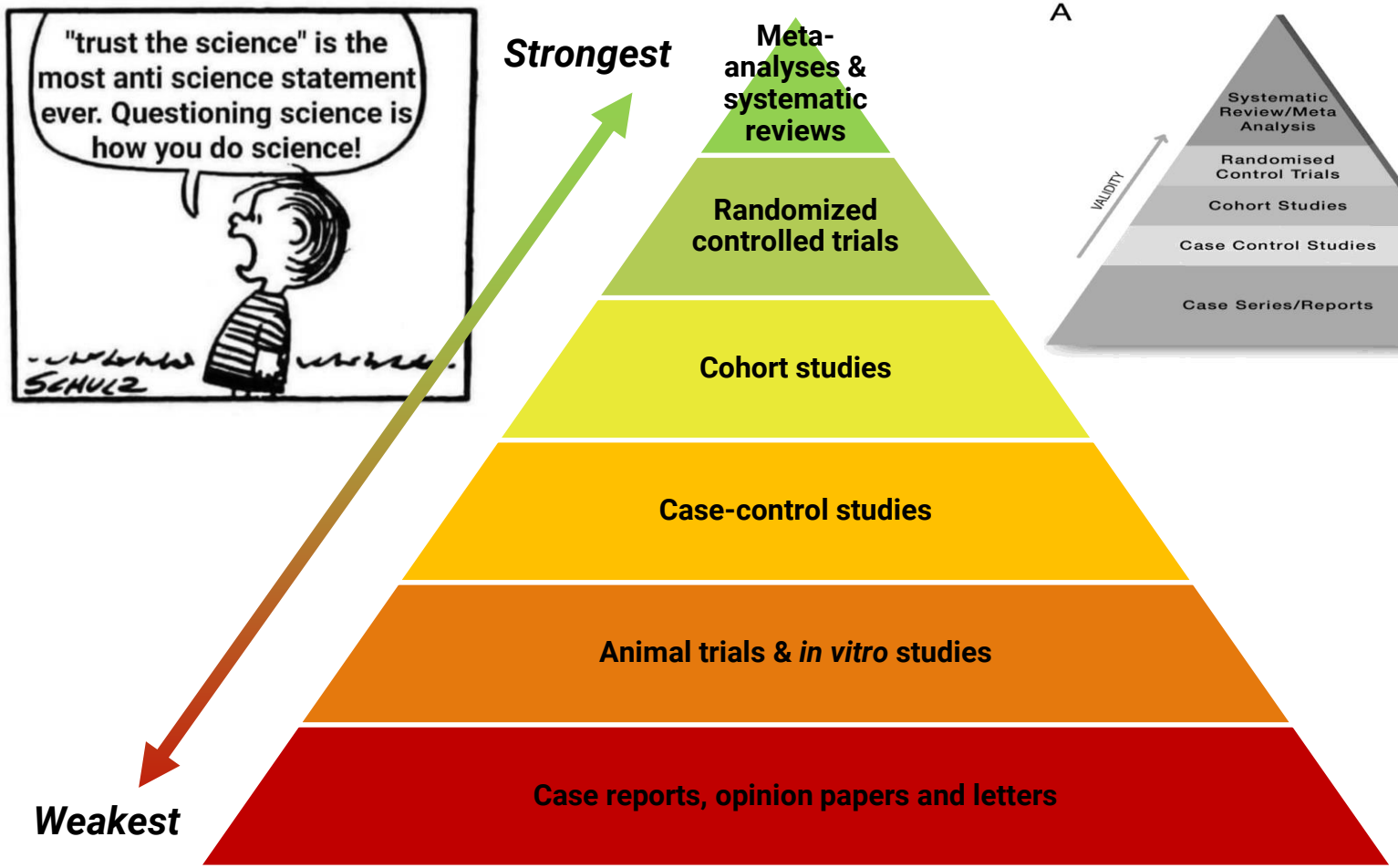
Hierarchy of scientific evidence



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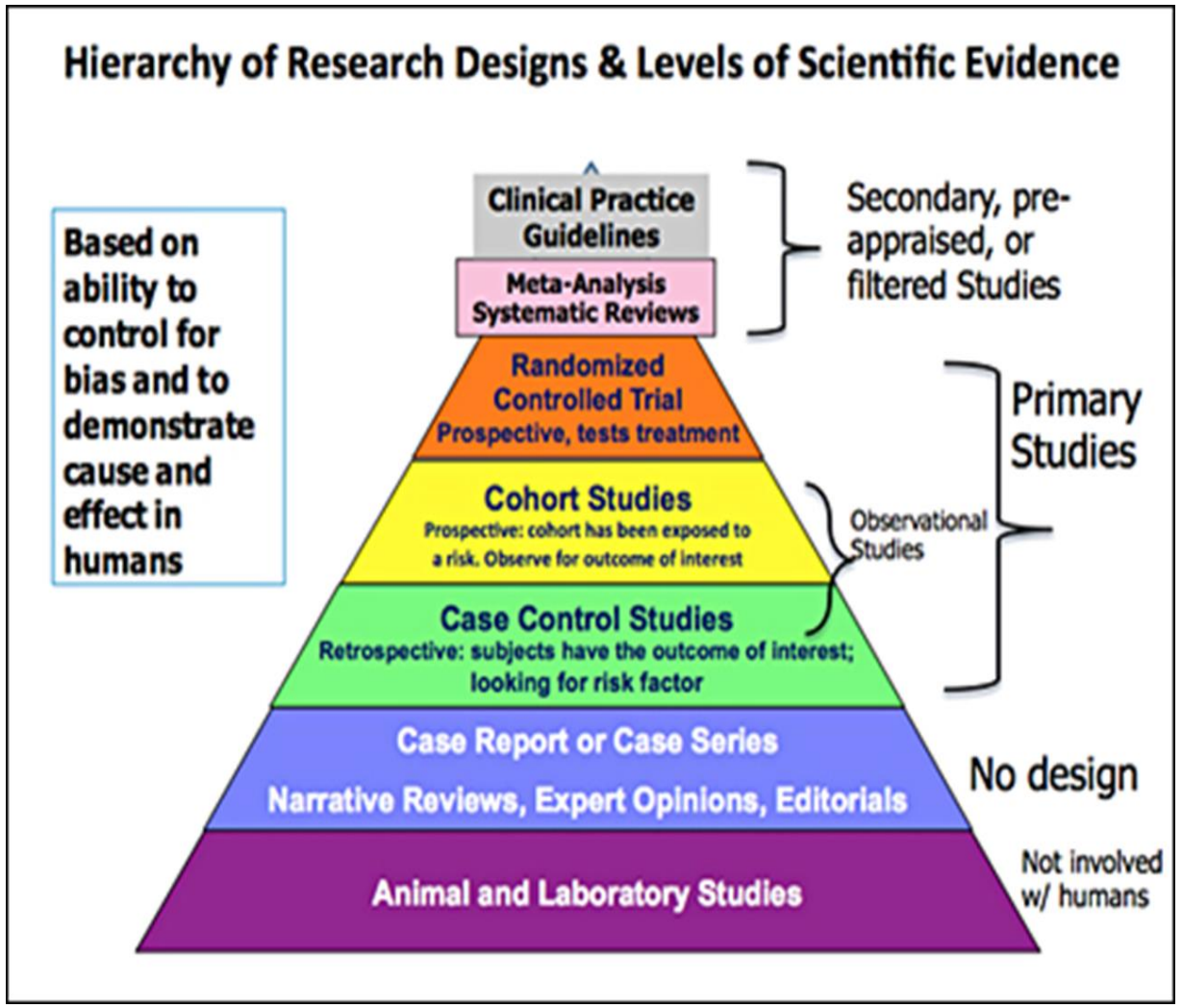
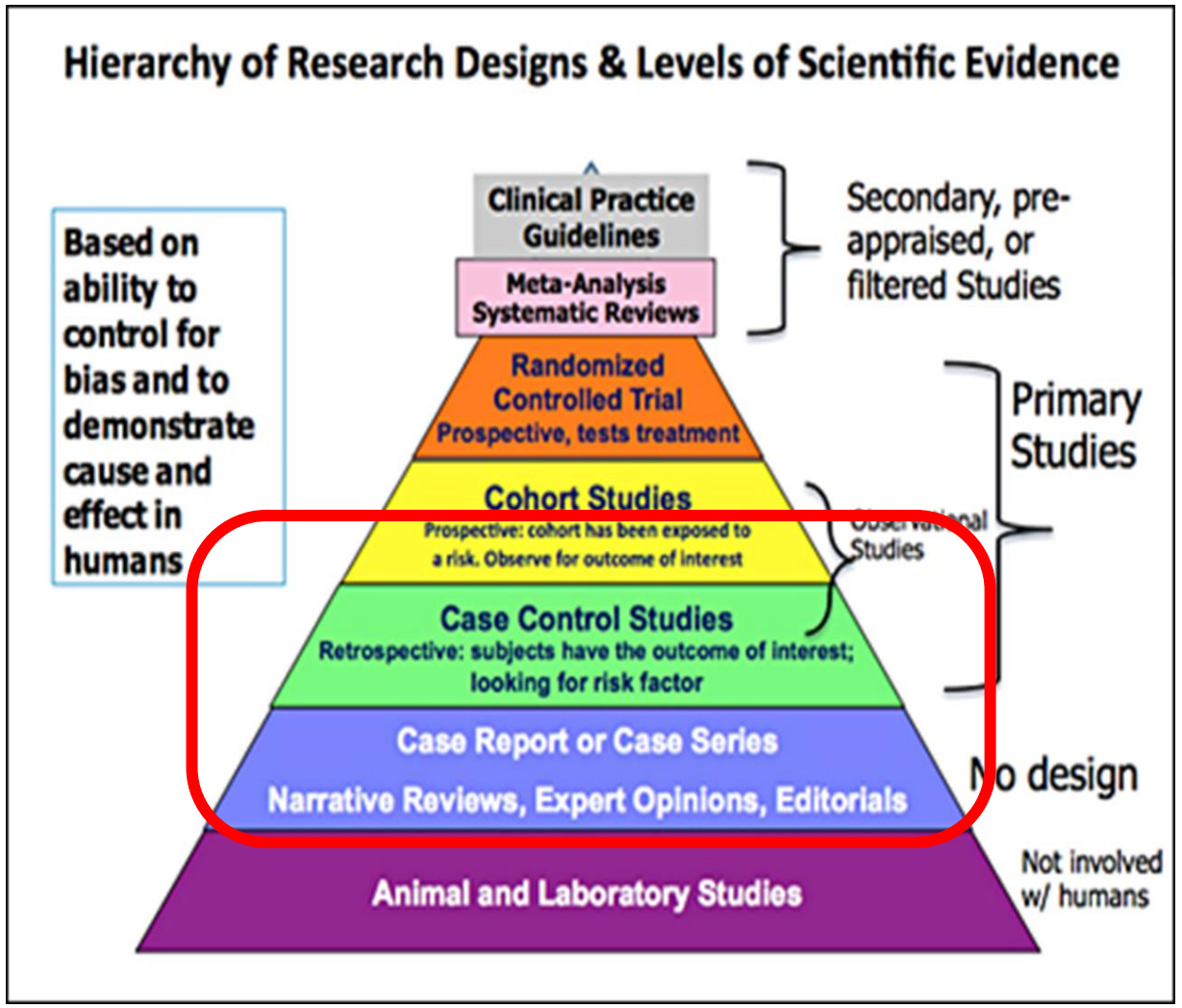
EBM: Levels of evidence



- LEVEL I
  - Gold standard
  - RCTs
- LEVEL II
  - Controlled trials without randomization.
  - Cohort or case-control analytic studies.
  - Multiple time series studies
- LEVEL III
  - Expert opinion and experience
  - Small sample sizes
  - No control group
  - Large margin for error
- LEVEL IV
  - Personal experience
  - Lacks any statistical validity

EBM: Levels of evidence: new innovative MBS procedures



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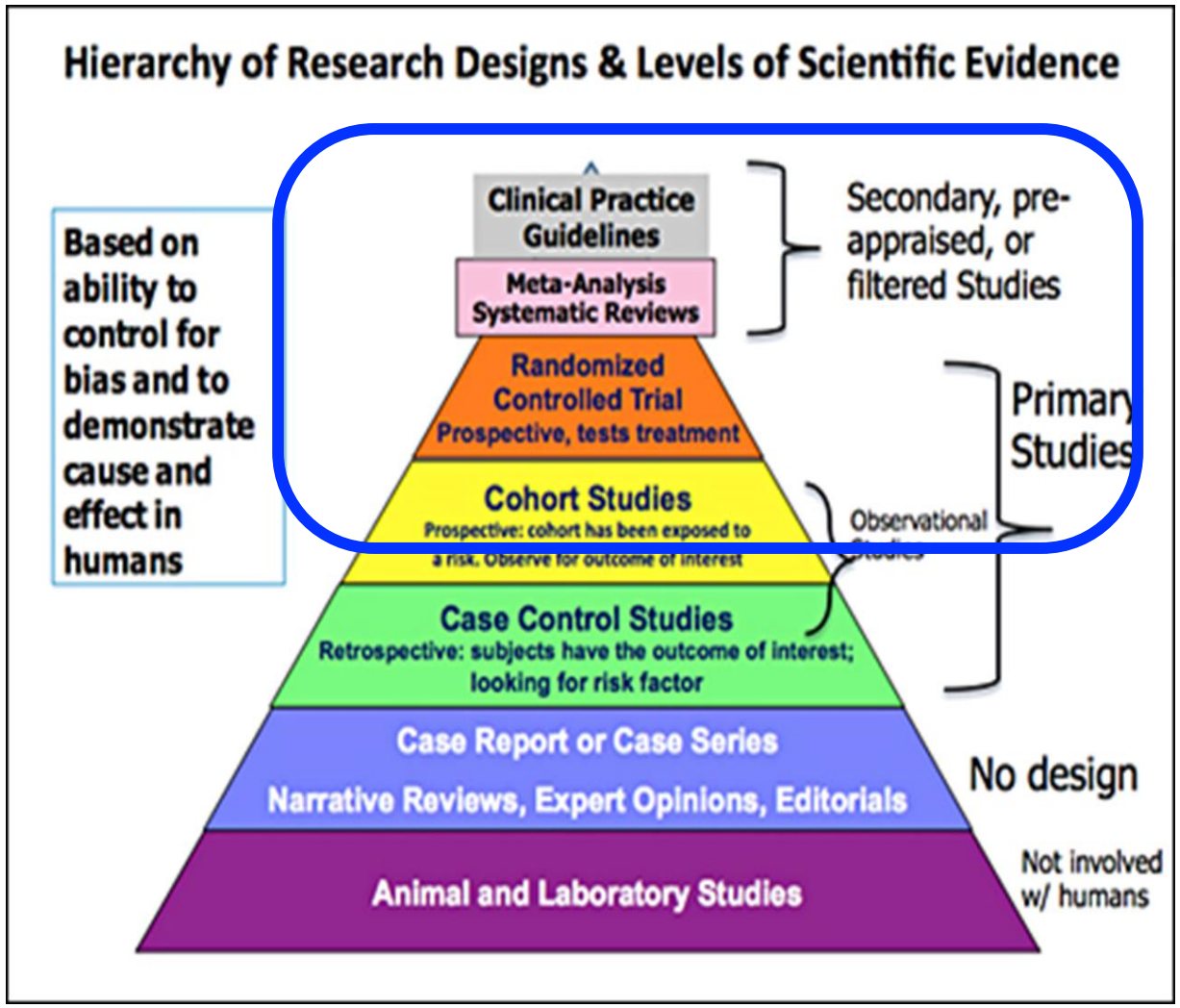
EBM: New era of GLP1-RAs
Outcomes and safety profile
MBS with long-term follow-up LRYGB +, LSG +-?



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Obesity Surgery (2021) 31:3–25
https://doi.org/10.1007/s11695-020-05134-7

SADI-S

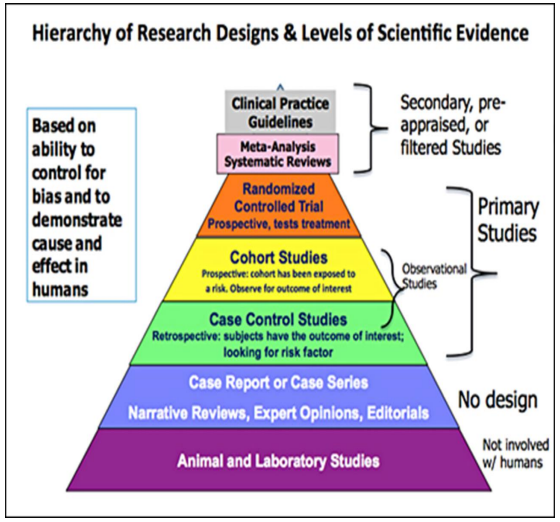
ORIGINAL CONTRIBUTIONS

Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement—Update 2020

Wendy A. Brown[1] · Guillermo Ponce de Leon Ballesteros[1] · Geraldine Ooi[1] · Kelvin Higa[1] · Jacques Himpens[1] · Antonio Torres[1] · Scott Shikora[1] · Lilian Kow[1] · Miguel F. Herrera[1] · on behalf of the IFSO appointed task force reviewing the literature on SADI-S/OADS

- Previous IFSO position statement in 2018
- 2018-2020: +25 case series and 3 case reports
- A total of 42 case series and 8 case reports
- Risk of bias: Newcastle-Ottawa scale (low, moderate or high)

- All case reports excluded (high risk of bias)
- 1 study with low risk of bias
- 41 studies with moderate risk of bias



Quick Pubmed Search: all similar articles with IFSO 2020 position statement - 141 papers

A flow-chart how to choose study type:

Is it possible to randomize?

Do Randomized Controlled Study!

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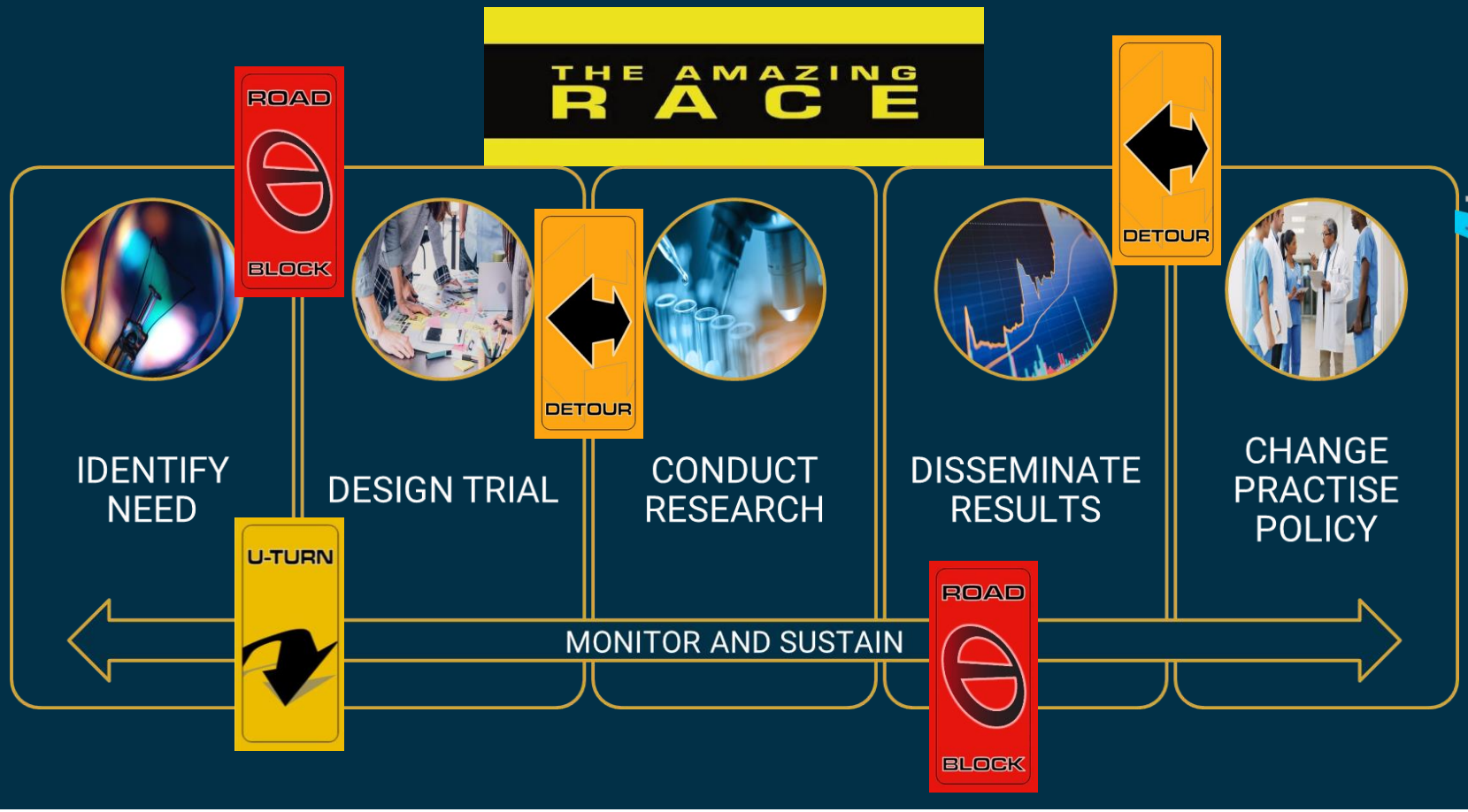
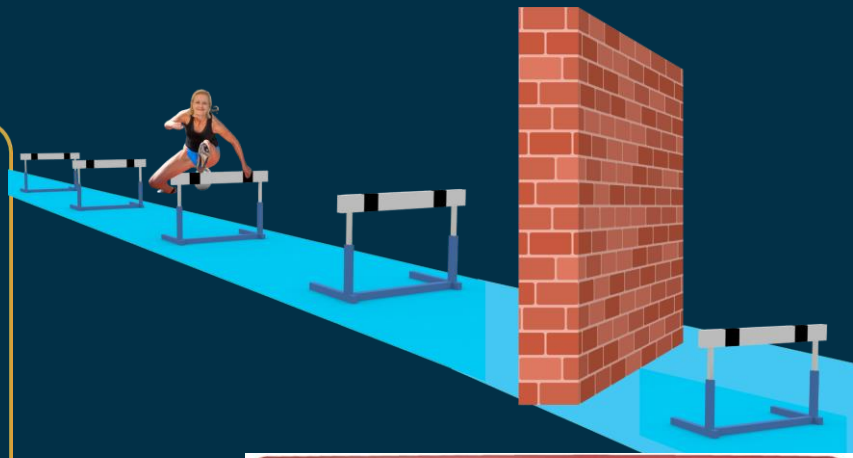
Conducting a randomized clinical trial is challenging: Overarching model on improving research relevance and change practice*

*adopted from ANZMUSC

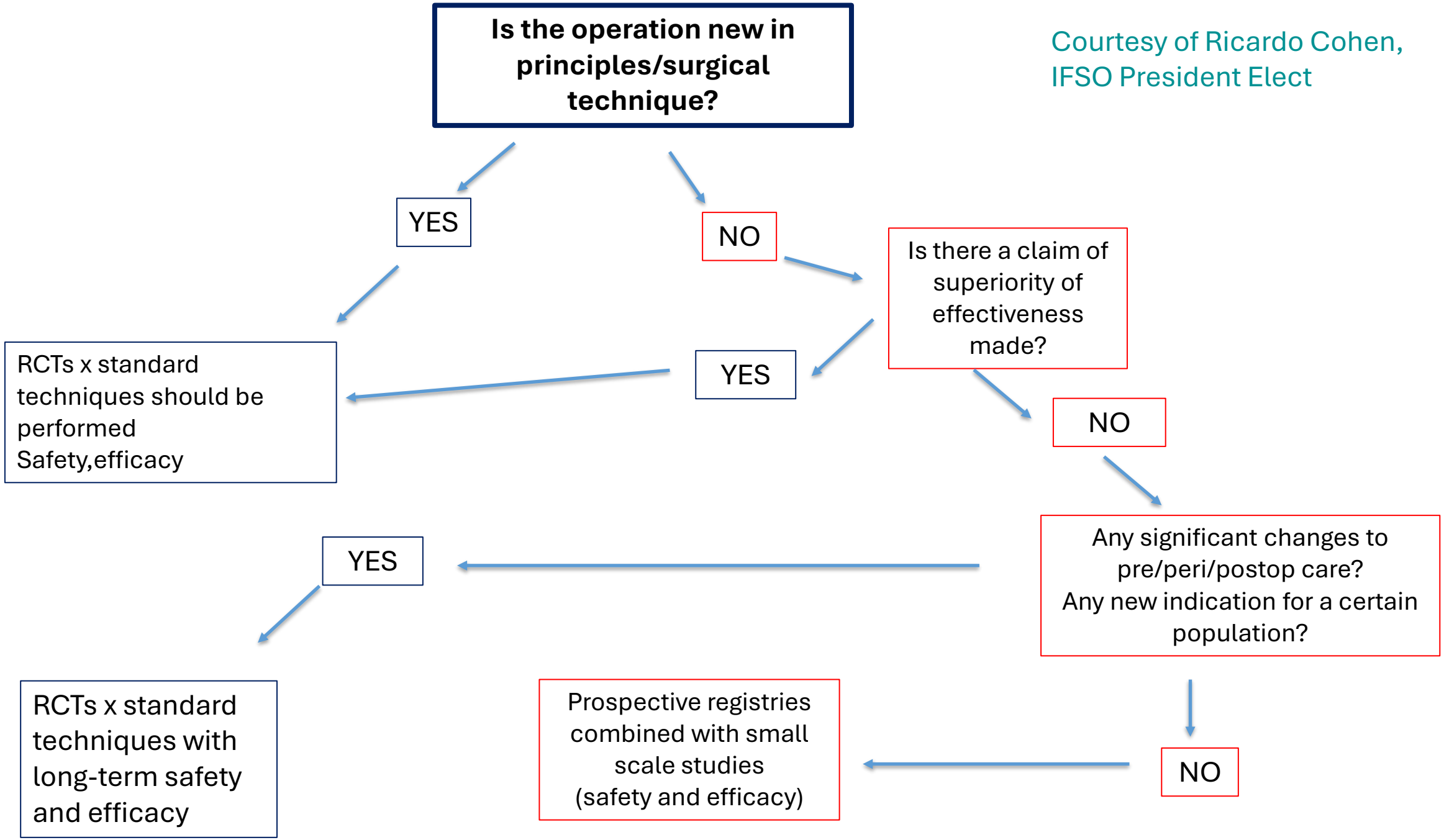
Conducting a randomized clinical trial is challenging





When are Randomized Trials Unnecessary in MBS ?

Courtesy of Ricardo Cohen, IFSO President Elect



Courtesy of Ricardo Cohen, IFSO President Elect

Adapted from Ideal D framework, BJS, 2016

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BJS, 2023, **110**, 1300–1308
https://doi.org/10.1093/bjs/znad160
Advance Access Publication Date: 28 June 2023
Systematic Review

Two decades of surgical randomized controlled trials: worldwide trends in volume and methodological quality

Aagje J. M. Pronk[1,2], Anne Roelofs[1,2], David R. Flum[3], H. Jaap Bonjer[2,4], Mohammed Abu Hilal[5], Marcel G. W. Dijkgraaf[6,7], Marc G. Besselink[1,2,*] and Usama Ahmed Ali[1,2]

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Abstract

Background: RCTs are essential in guiding clinical decision-making but are difficult to perform, especially in surgery. This review assessed the trend in volume and methodological quality of published surgical RCTs over two decades.

Methods: PubMed was searched systematically for surgical RCTs published in 1999, 2009, and 2019. The primary outcomes were volume of trials and RCTs with a low risk of bias. Secondary outcomes were clinical, geographical, and funding characteristics.

Results: Some 1188 surgical RCTs were identified, of which 300 were published in 1999, 450 in 2009, and 438 in 2019. The most common subspecialty in 2019 was gastrointestinal surgery (50.7 per cent). The volume of surgical RCTs increased mostly in Asia (61, 159, and 199 trials), especially in China (7, 40, and 81). In 2019, countries with the highest relative volume of published surgical RCTs were Finland and the Netherlands. Between 2009 and 2019, the proportion of RCTs with a low risk of bias increased from 14.7 to 22.1 per cent ($P = 0.004$). In 2019, the proportion of trials with a low risk of bias was highest in Europe (30.5 per cent), with the UK and the Netherlands as leaders in this respect.

Conclusion: The volume of published surgical RCTs worldwide remained stable in the past decade but their methodological quality improved. Considerable geographical shifts were observed, with Asia and especially China leading in terms of volume. Individual European countries are leading in their relative volume and methodological quality of surgical RCTs.

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Top 10 by relative volume of surgical RCTs per 10 million inhabitants

Rank	1999 ($n = 300$)	2009 ($n = 450$)	2019 ($n = 438$)
1	Denmark 23.9	Finland 19.0	Finland 23.5
2	Finland 17.1	Netherlands 10.8	Netherlands 15.8
3	Sweden 15.5	Ireland 10.6	Denmark 10.4
4	Netherlands 8.0	Sweden 9.9	Switzerland 9.3
5	Australia 5.8	Switzerland 9.1	Norway 9.3
6	Switzerland 5.5	Austria 7.3	Sweden 8.0
7	Italy 5.4	Greece 6.5	Estonia 7.5
8	UK 5.1	UK 6.2	Lithuania 7.2
9	Singapore 4.6	Italy 6.0	Bahrain 6.09
10	Greece 4.5	Norway 4.2	Bosnia 6.05

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Table 4 Top 10 ranking for countries in 2019 based on the proportion of trials with a low risk of bias

	Trials with low risk of bias (%)†	No. of trials	Rank on the basis of no. trials per 10^7 inhabitants	Impact factor*	Adequate generation of allocation	Adequate concealed allocation	Intention-to-treat analysis	Adequate handling of drop-outs
1 UK	57.1	15	19	3.37 (2.02–21.94)	93.3	73.3	66.7	73.3
2 Netherlands	51.9	27	2	4.28 (2.72–14.78)	85.2	88.9	66.7	77.8
3 Finland	38.5	13	1	4.50 (2.48–10.48)	61.5	92.3	53.9	76.9
4 Korea	30.0	20	44	2.11 (1.47–4.12)	85.7	60.0	43.8	80.0
5 Germany	27.3	11	27	4.84 (3.18–6.26)	63.6	54.6	72.7	81.8
6 Spain	26.7	15	15	3.15 (2.20–5.68)	86.7	73.3	46.7	73.3
7 USA	22.0	50	24	3.61 (1.98–8.76)	60.0	70.0	36.0	70.0
8 Japan	20.0	35	16	2.39 (1.88–6.08)	54.3	51.4	34.3	77.1
9 China	16.0	81	39	2.24 (1.70–3.65)	59.3	51.9	21.1	55.6
10 Italy	12.5	16	17	2.00 (0.77–5.53)	62.5	56.3	25.0	68.8

*Values are median (i.q.r.) 2019 impact factors. Only countries with at least 10 published trials were analysed. †Trial with adequate generation of allocation, adequate concealment of allocation, intention-to-treat analyses, and adequate handling of drop-outs.

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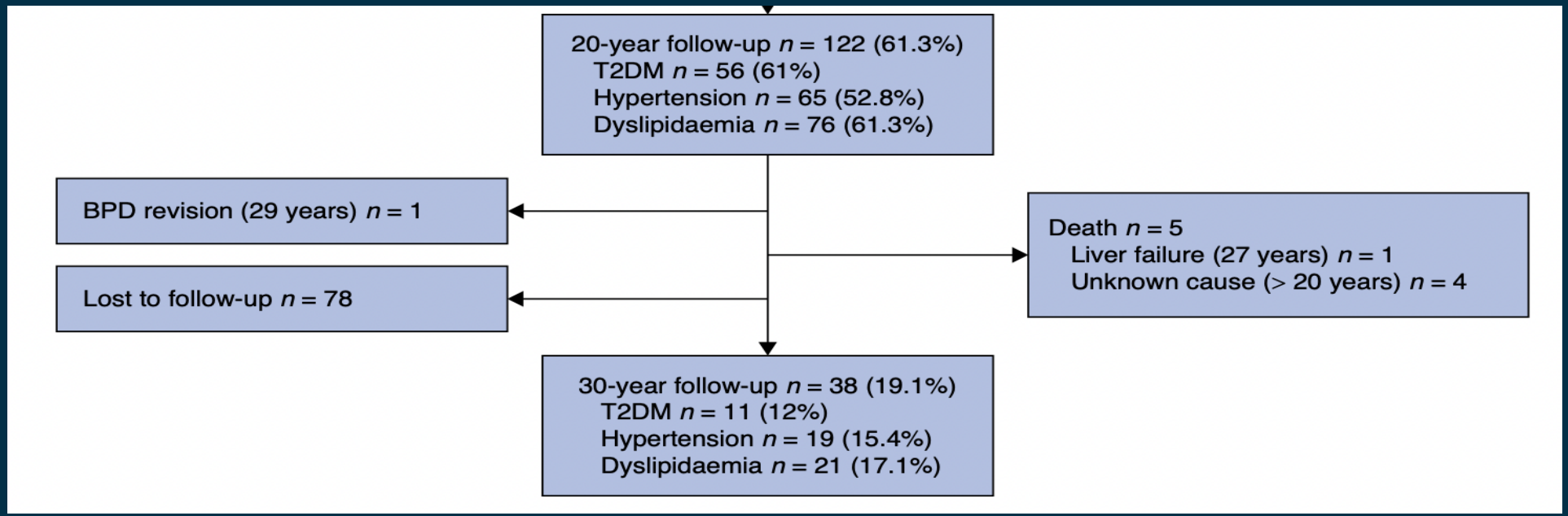
BJS, 2024, znae058
https://doi.org/10.1093/bjs/znae058
Original Article

Biliopancreatic diversion for severe obesity: long-term weight maintenance and occurrence of nutritional complications are two facets of the same coin

Francesco S. Papadia[1,2,*], Gianfranco Adami[1], Alessandra Razzetta[1], Anna Florenzano[1], Gaia Longo[2], Alice Rubartelli[2], Flavia Carlini[2], Ottavio De Cian[3] and Giovanni Camerini[1,2]



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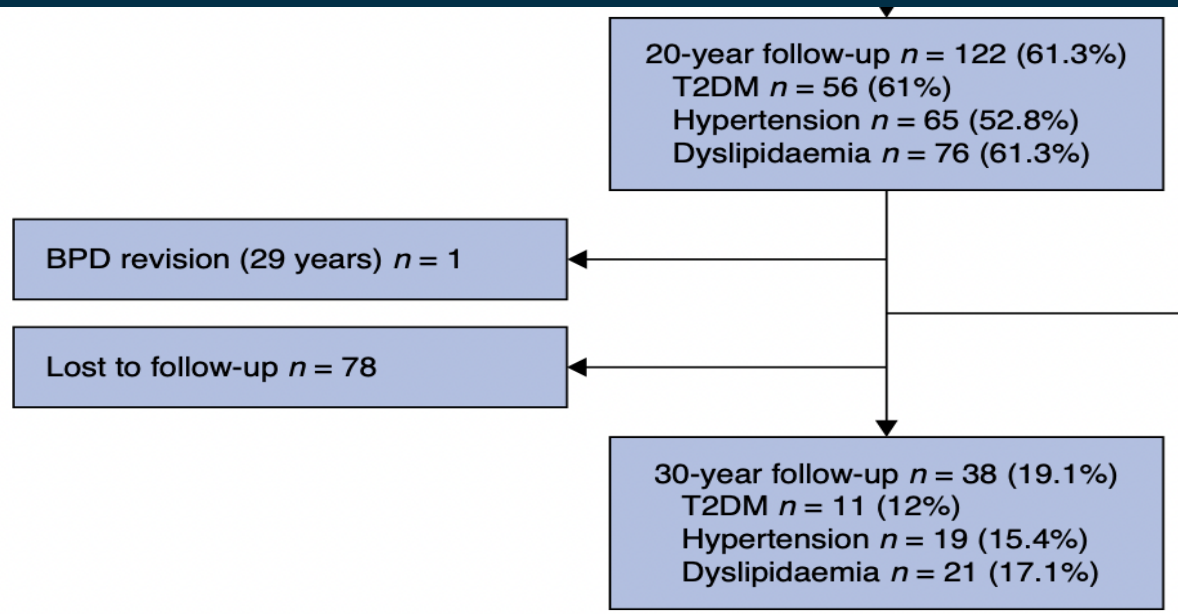

Follow-up rate at 20 years 61.3%:
60% had a nutritional complication, 4 deaths related to malnutrition (3 liver failures, one sepsis)

Follow-up rate at 30 years 19.1%:
74% had a nutritional complication, 1 more death of liver failure

6.9.2024

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BJS, 2024, znae073
https://doi.org/10.1093/bjs/znae073
Editorial

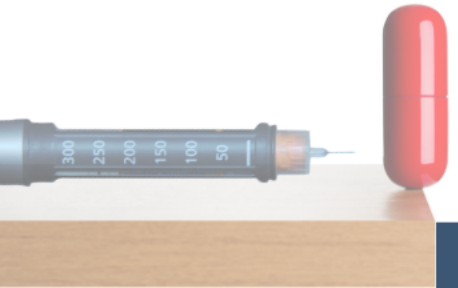
Back to the future: malabsorption is the Achilles' heel of hypoabsorptive metabolic/bariatric procedures

Ricardo V. Cohen[1,*], Paulina Salminen[2,3], Philip R. Schauer[4] and Francesco Rubino[5]

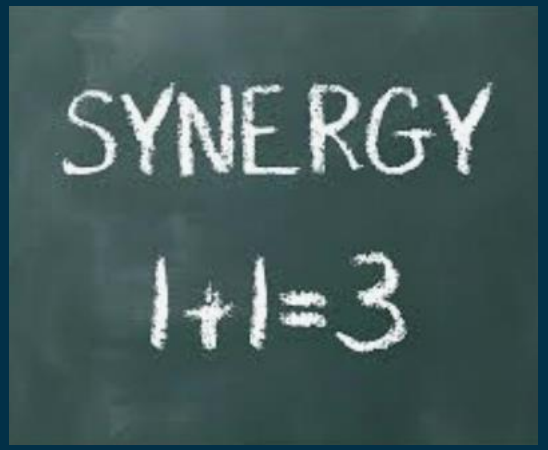
Clinical Surgical Science

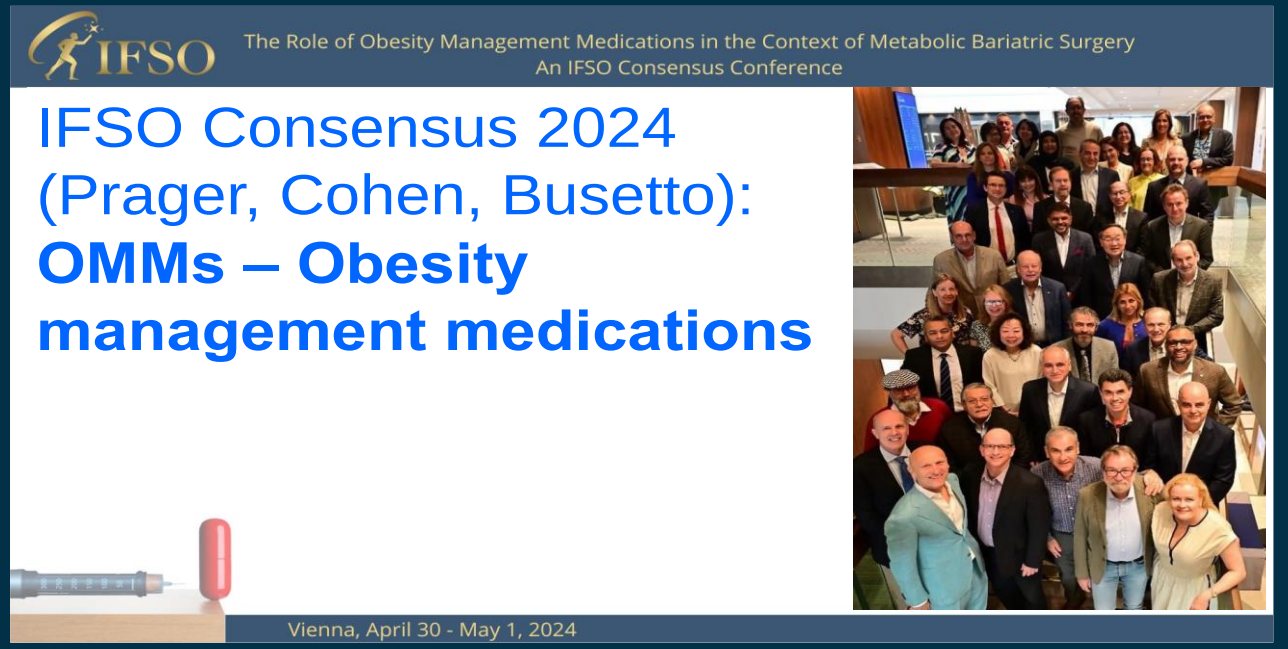
Clinical Surgical Science > MBS science in multidisciplinary collaboration

IFSO Consensus 2024 (Prager, Cohen, Busetto): **The role of obesity management medications in the context of metabolic bariatric surgery**



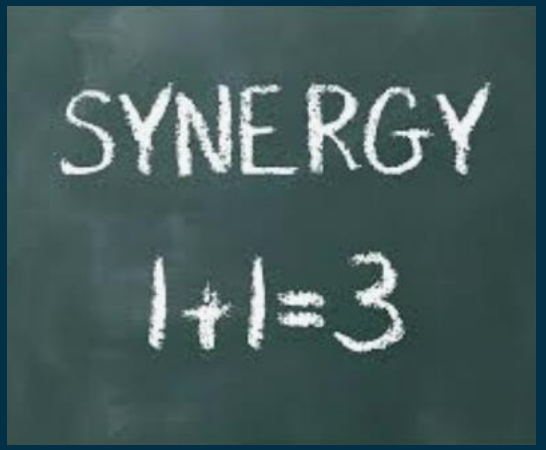
The value of national and international collaboration

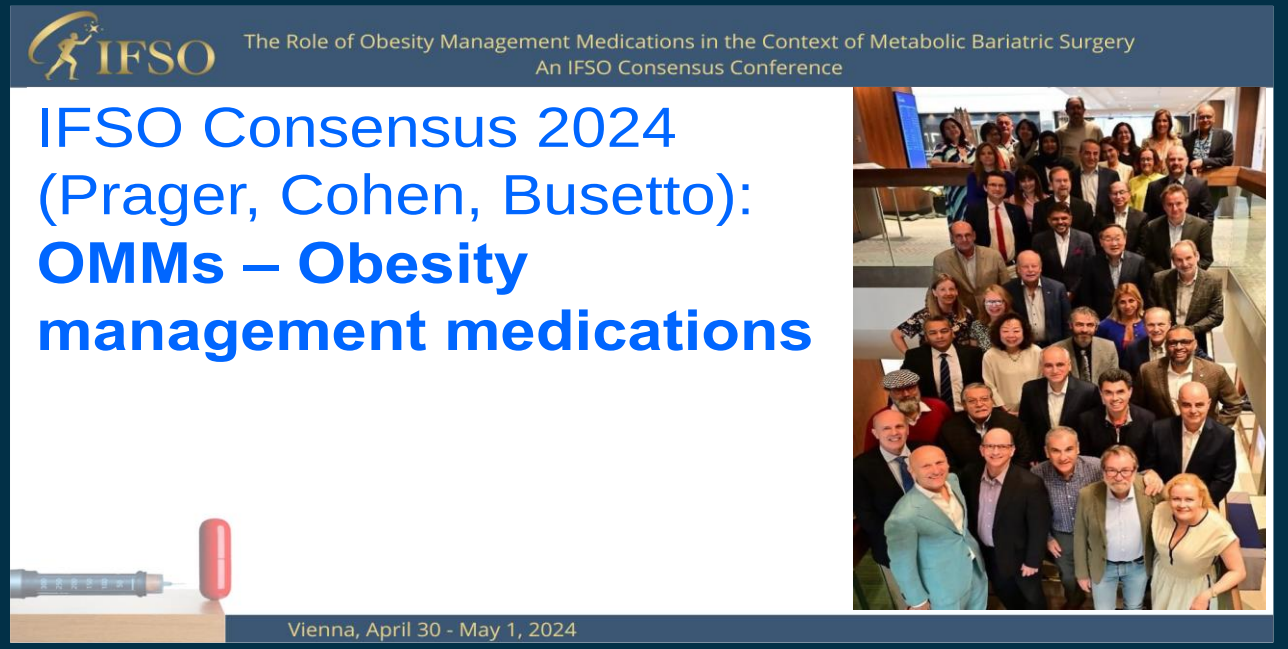




The value of national and international collaboration

- RCTs on adjuvant use of OMMs in the context of MBS are needed
- Fenotyping the patients > tailored treatment





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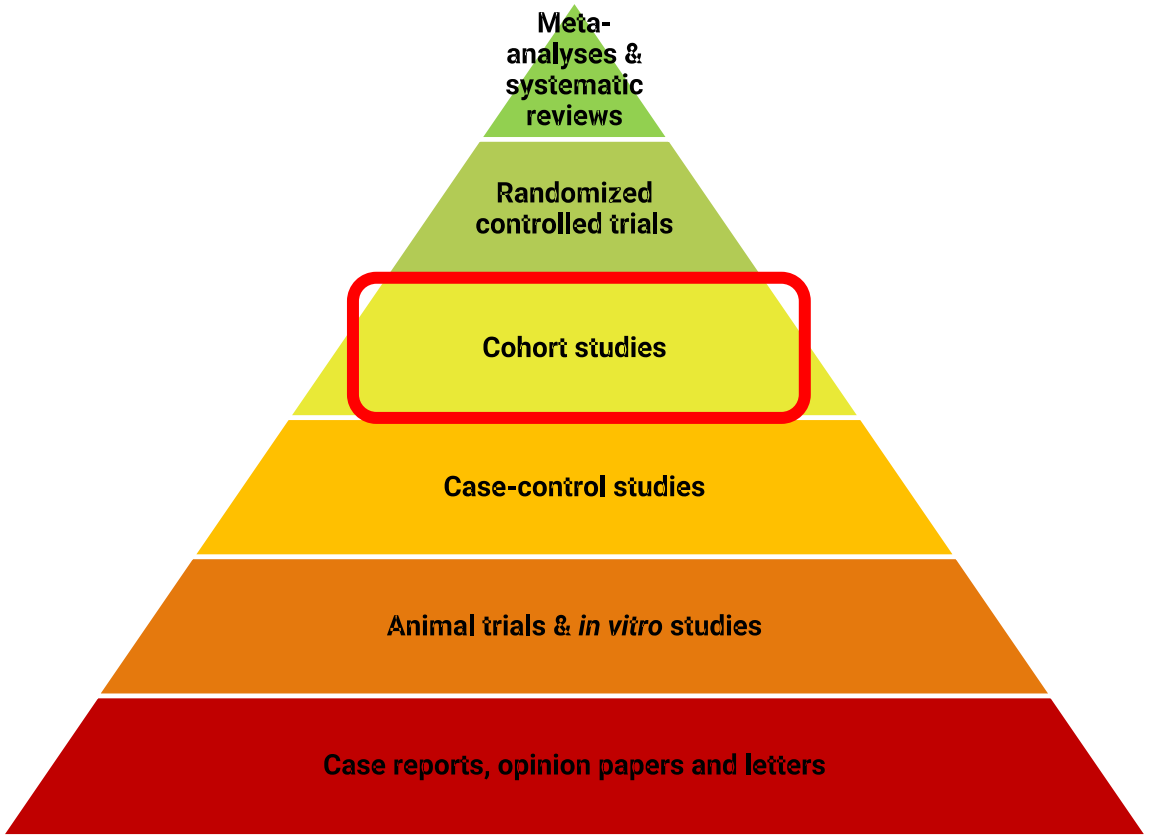
High volume centers:
Prospective observational cohort studies
High quality validated large registries:
Prospective big data



NEW INNOVATIVE SURGICAL PROCEDURES

- ✓ AT MINIMUM WITHIN A PROSPECTIVE COHORT
- ✓ LONG-TERM FOLLOW-UP

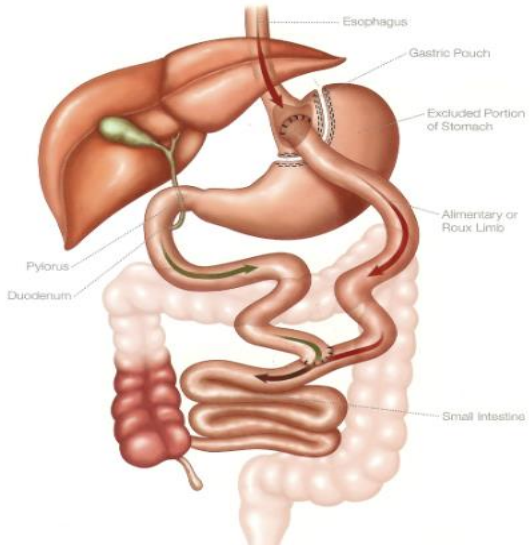
OXFORD

BJS, 2024, znae073
https://doi.org/10.1093/bjs/znae073
Editorial

Back to the future: malabsorption is the Achilles' heel of hypoabsorptive metabolic/bariatric procedures

Ricardo V. Cohen[1,*], Paulina Salminen[2,3], Philip R. Schauer[4] and Francesco Rubino[5]

Papadia *et al.* remind us that operations should be judged for their long-term effects and that novel procedures should be compared with well tested standard operations like RYGB before they are used in routine clinical practice. Secondary to this lack of robust data on longer-term efficacy and safety, the International Federation for the Surgery of Obesity and Metabolic Disorders[10] issued a position statement on innovations in metabolic and bariatric surgery, and considered that all such interventions need strict ethical supervision until long term quality data on safety are available.

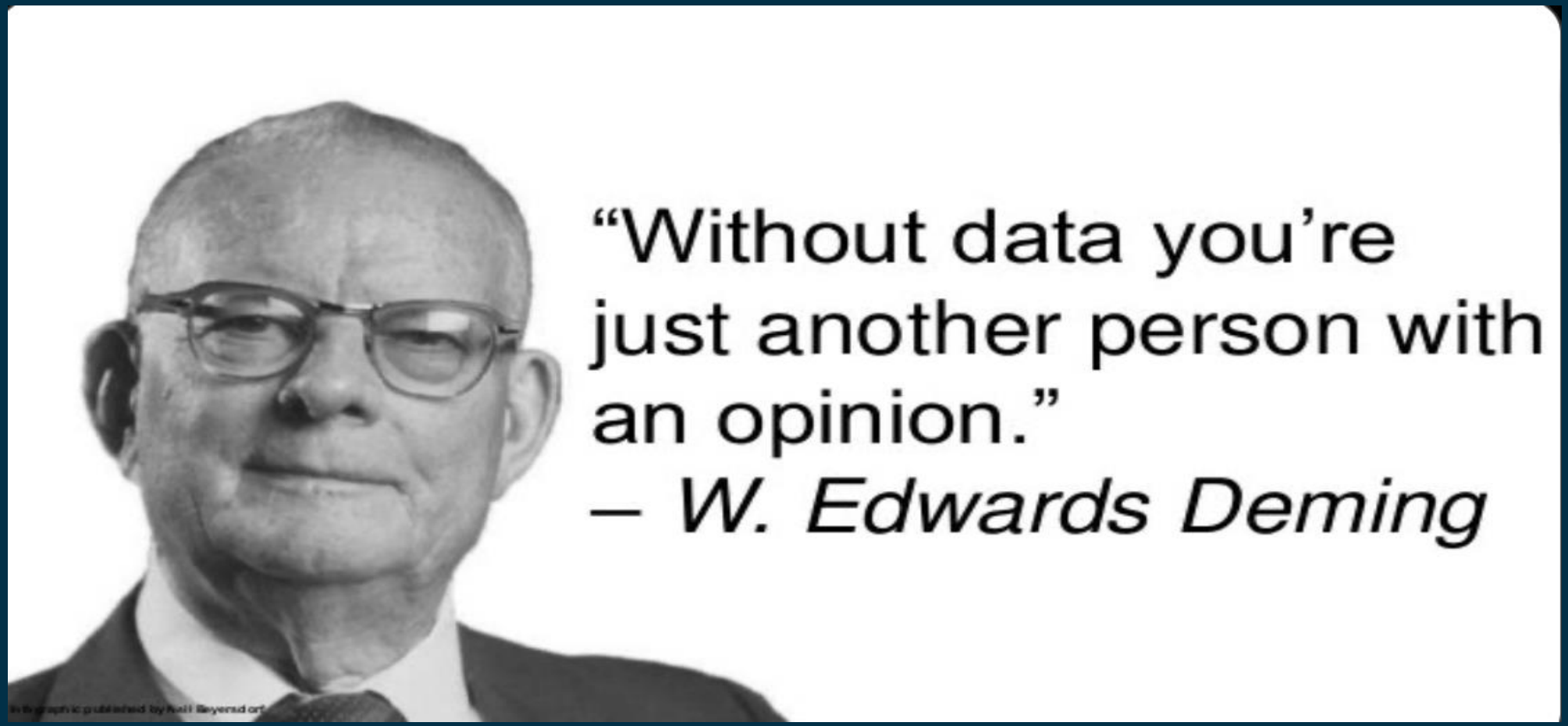


> Obes Surg. 2022 Oct;32(10):3217-3230. doi: 10.1007/s11695-022-06220-8. Epub 2022 Aug 3.

Innovative Bariatric Procedures and Ethics in Bariatric Surgery: the IFSO Position Statement

Ashraf Haddad [1], Lilian Kow [2], Miguel F Herrera [3], Ricardo V Cohen [4], Jacques Himpens [5], Jan Willem Greve [6], Scott Shikora [7]

Thank you!


“Without data you’re just another person with an opinion.”
– W. Edwards Deming