Brigham and Women's Hospital
Founding Member, Mass General Brigham

IBS for the Internist:
the old (and neglected) and the new

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CONTINUING MEDICAL EDUCATION
DEPARTMENT OF MEDICINE

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

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Medicine Residency @MGH
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- Clinical focus: IBS, constipation, fecal incontinence
- Research focus: Epidemiology of functional GI diseases, brain-gut interactions in eating disorders, pathophysiology of fecal incontinence

Disclosures

- Research support from Ardelyx and Restalsis
- Consultant for Anji, Ardelyx, Mahana, Gelesis, GI Supply, Restalsis, and Sanofi
- Grant funding from NIH NIDDK

Objectives

- Understand the biopsychosocial model of IBS and how it can help your patients
  - Typical IBS workup
  - Psychological overlap and neuromodulators
  - Explaining the disease to patients
- Discuss new insights/approaches in IBS with particular focus on what patients ask/care about
  - Dietary changes
  - Probiotics
  - Fecal Microbiota Transplant

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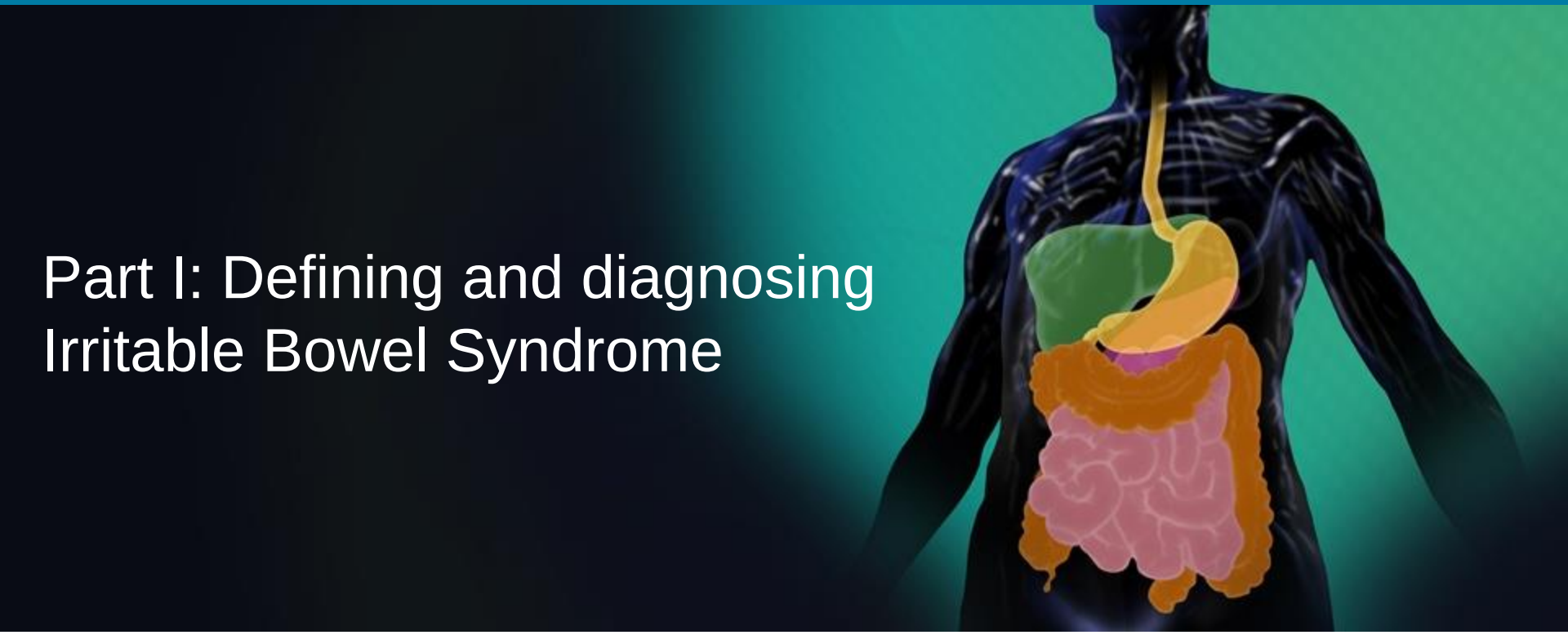

Part I: Defining and diagnosing Irritable Bowel Syndrome

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IBS: You can run from it, but you can't hide

US Prevalence: 5.3% (was much higher in previous definitions)

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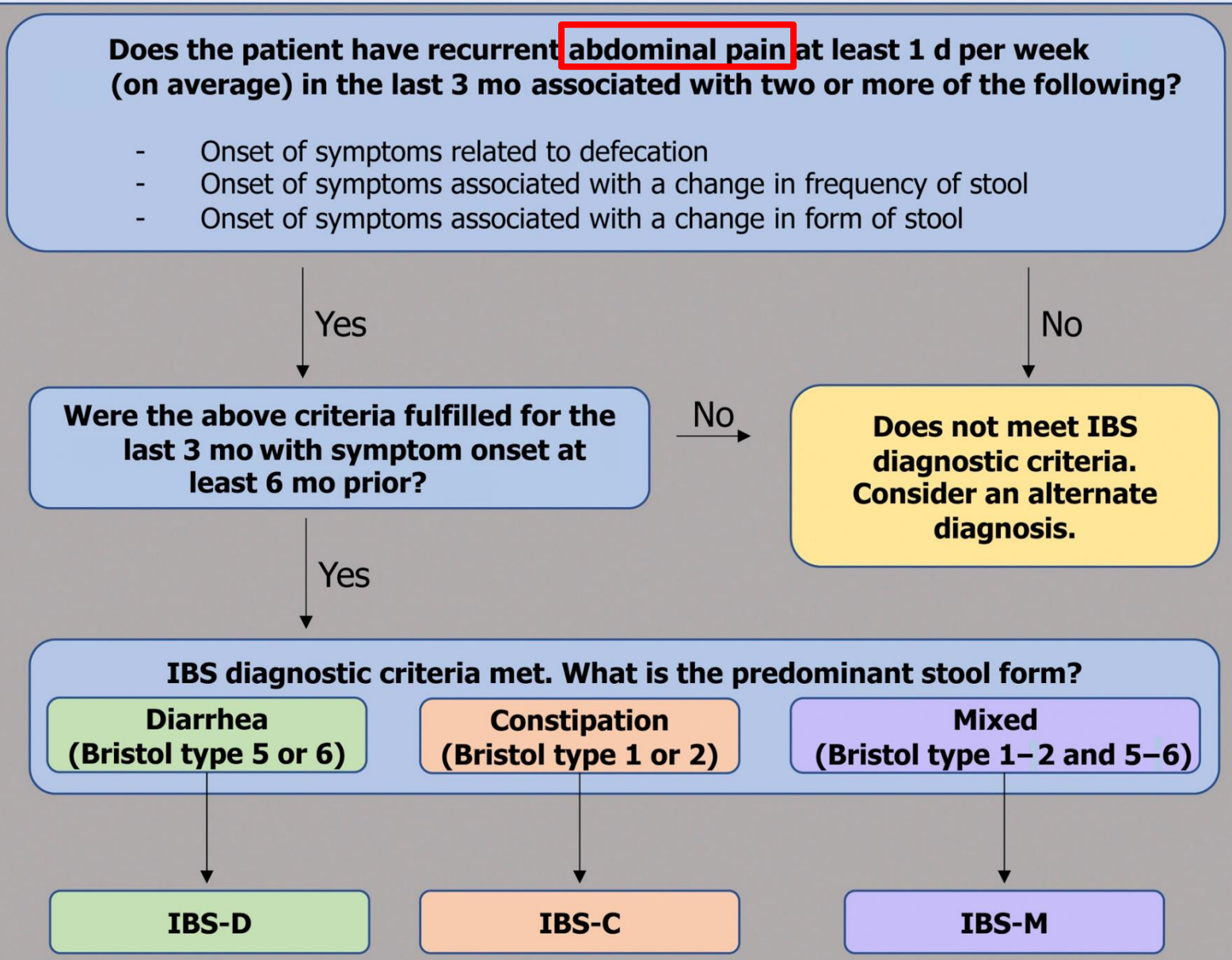
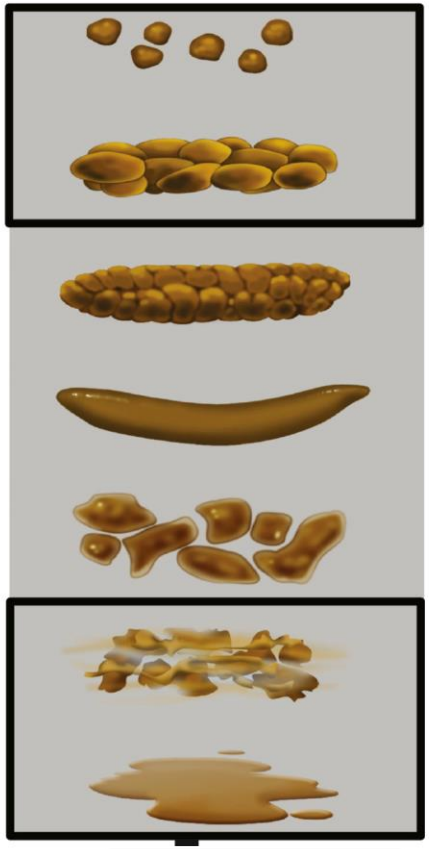
Sperber AD, Bangdiwala SI et al. *Gastroenterology.* 2021 Jan;160(1):99-114.e3.

Irritable Bowel Syndrome: Rome IV Criteria



Harer KN and Eswaran SL. *Gastroenterol Clin North Am*. 2021 Mar;50(1):183-199.

Stool form as a surrogate for colonic transit time



Type 1	Separate hard lumps, like nuts (hard to pass)
Type 2	Sausage-shaped but lumpy
Type 3	Like a sausage but with cracks on the surface
Type 4	Like a sausage or snake, smooth and soft
Type 5	Soft blobs with clear-cut edges
Type 6	Fluffy pieces with ragged edges, a mushy stool
Type 7	Watery, no solid pieces, entirely liquid

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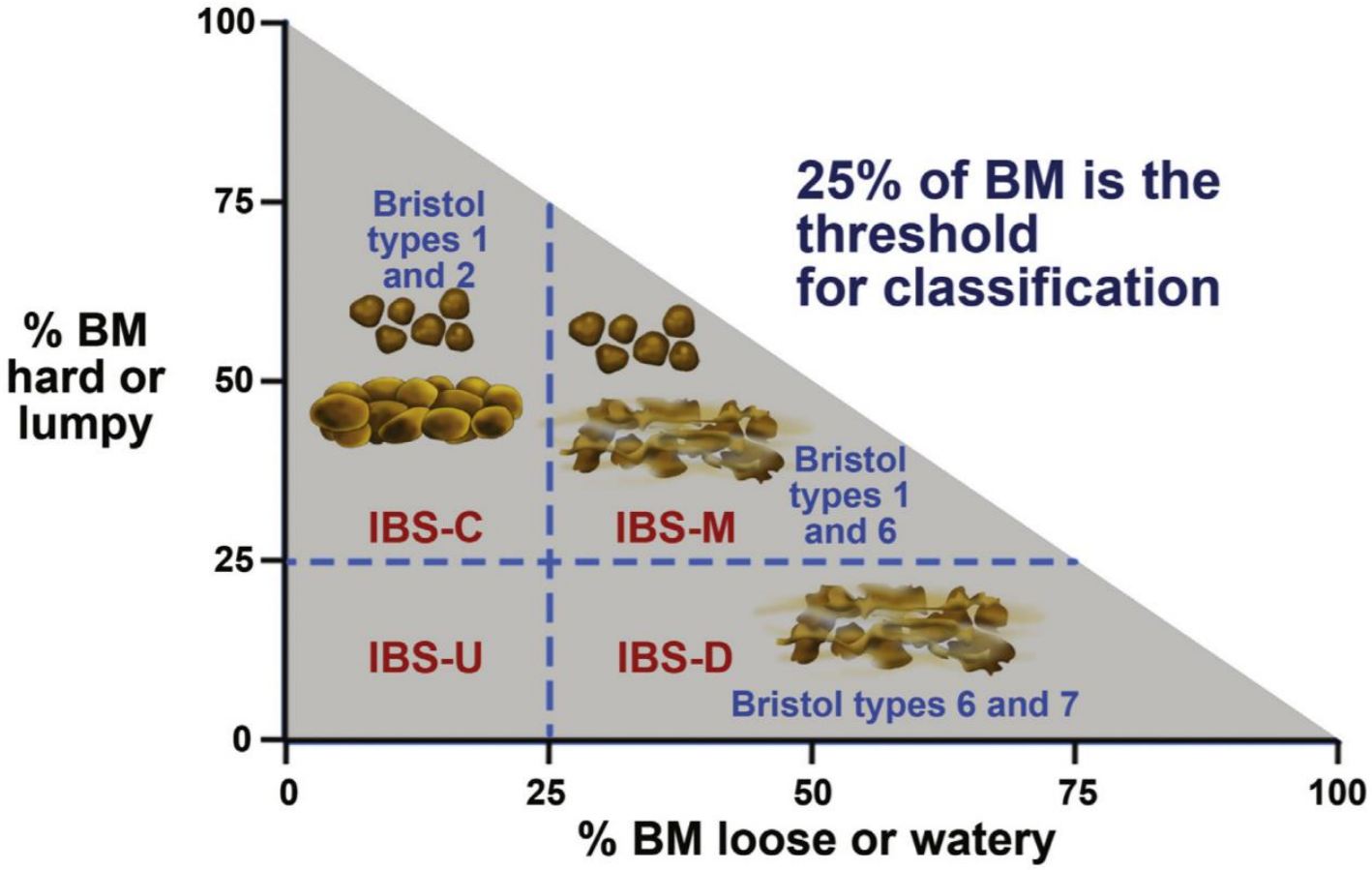
Drossman D, Hasler WL. *Gastroenterology.* 2016; 150:1393-1407.

Stool form defines IBS subtype



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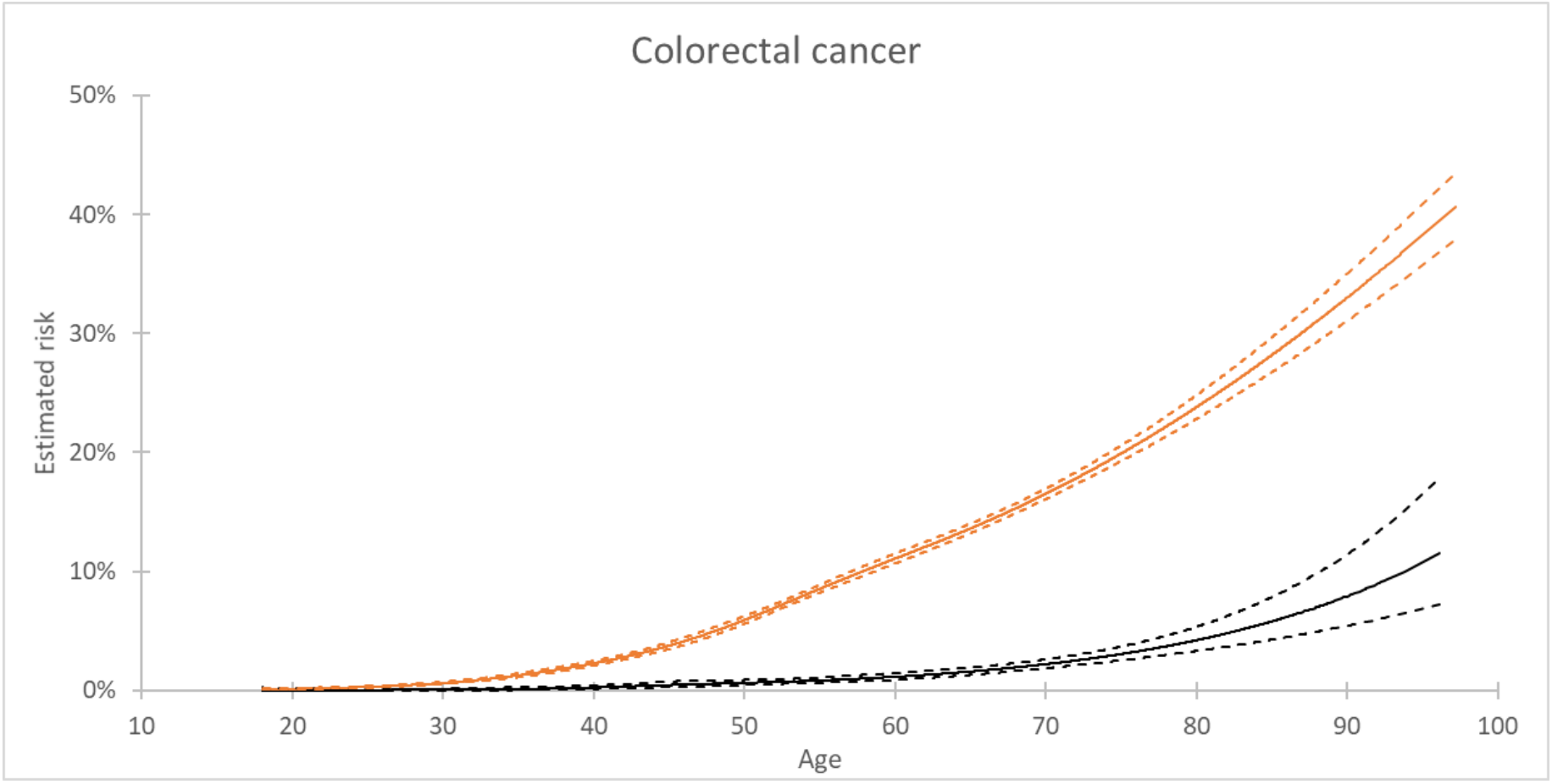
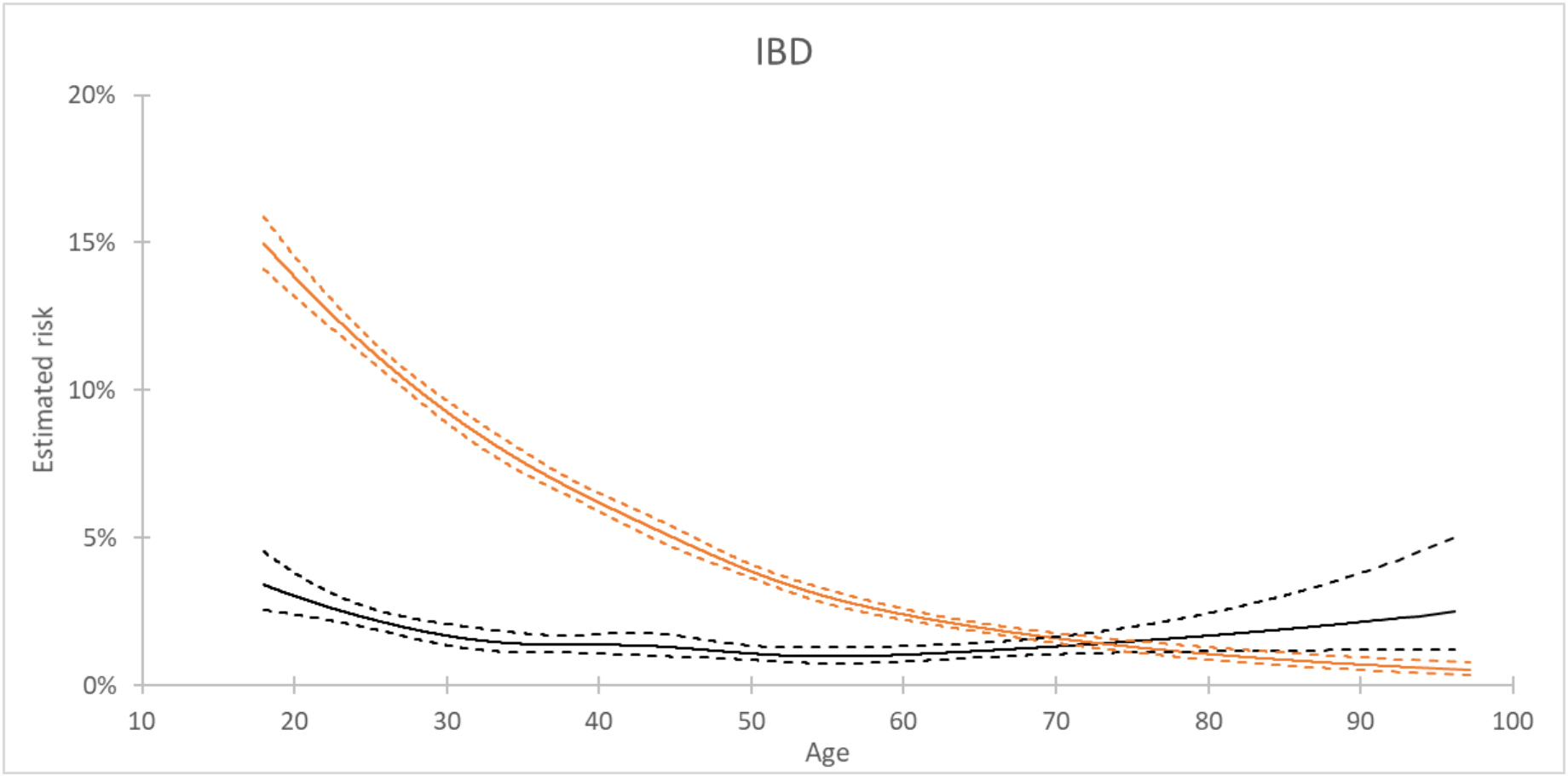
Drossman D, Hasler WL. *Gastroenterology.* 2016; 150:1393-1407.

Why colonoscopy is *not* recommended in IBS without alarm symptoms



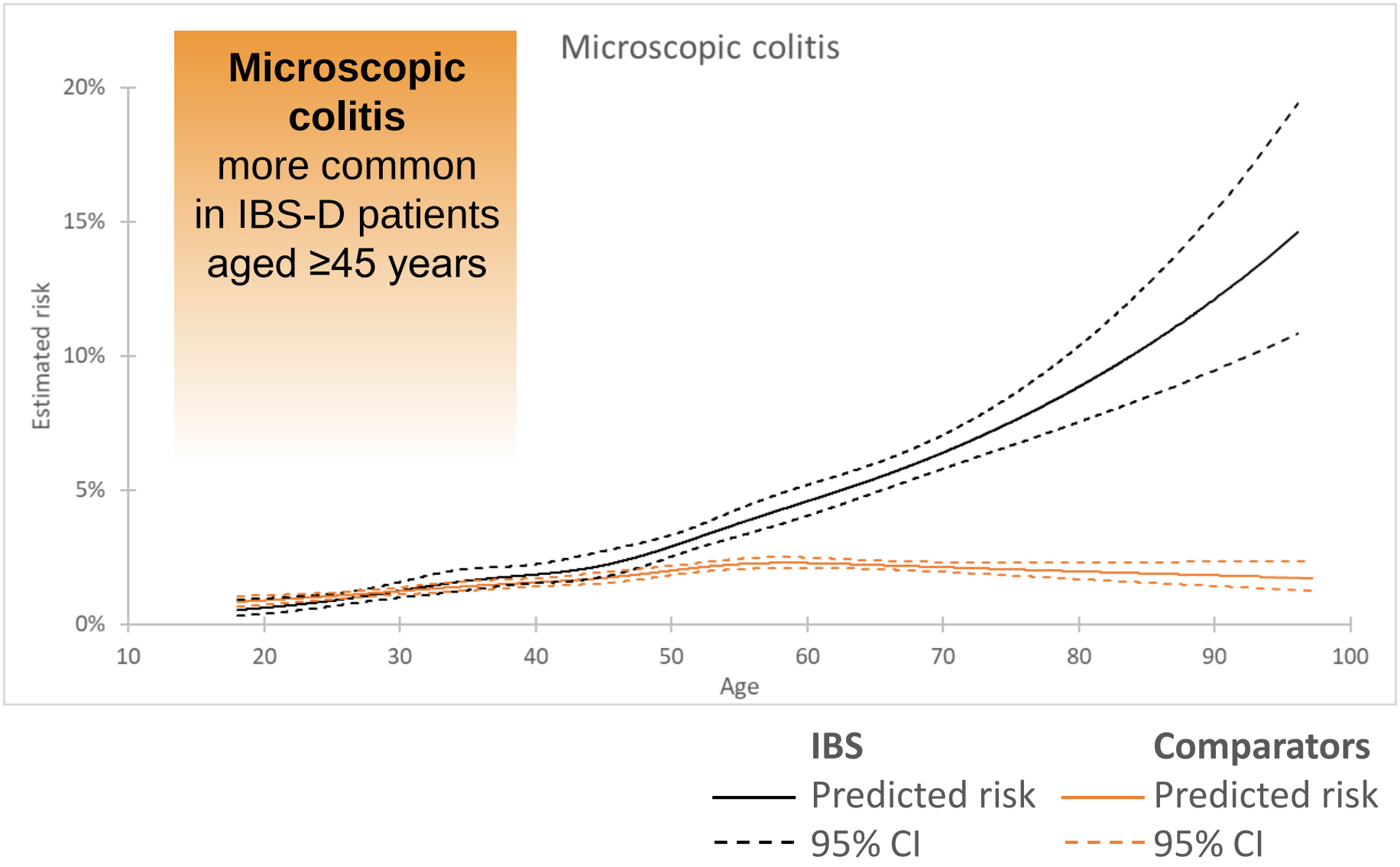
K Staller, O Olén, *et al. Eur J Intern Med*. 2021 Dec;94:85-92.

Why colonoscopy is *not* recommended in IBS without alarm symptoms



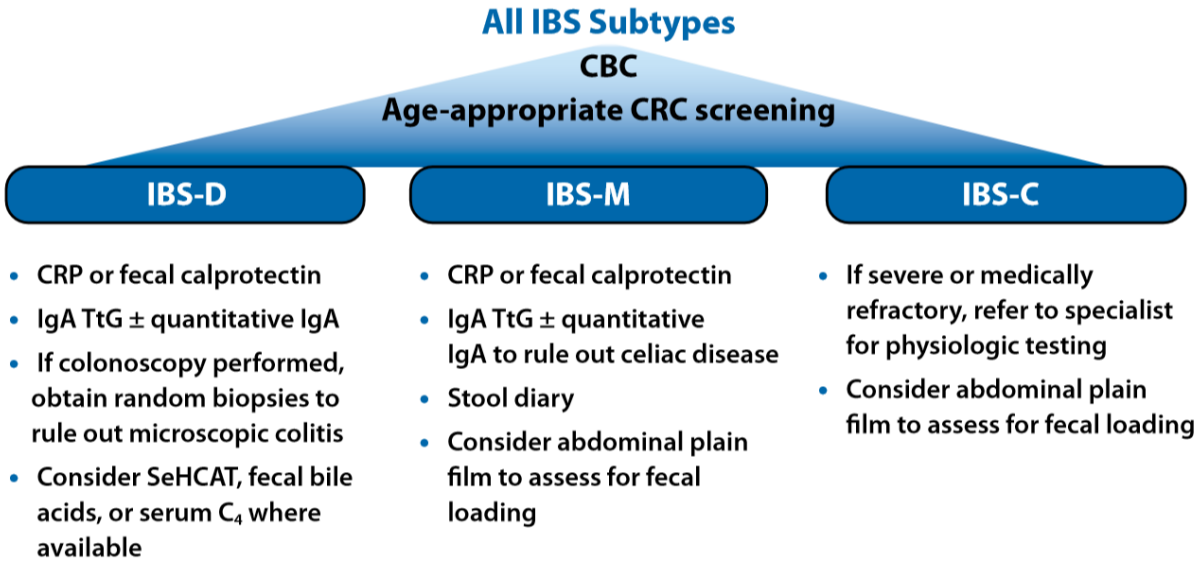
K Staller, O Olén, *et al. Eur J Intern Med*. 2021 Dec;94:85-92.

Why colonoscopy is *not* recommended in IBS without alarm symptoms…but wait



K Staller, O Olén, *et al. Eur J Intern Med*. 2021 Dec;94:85-92.

Diagnostic testing for patients with suspected IBS and no concerning* features



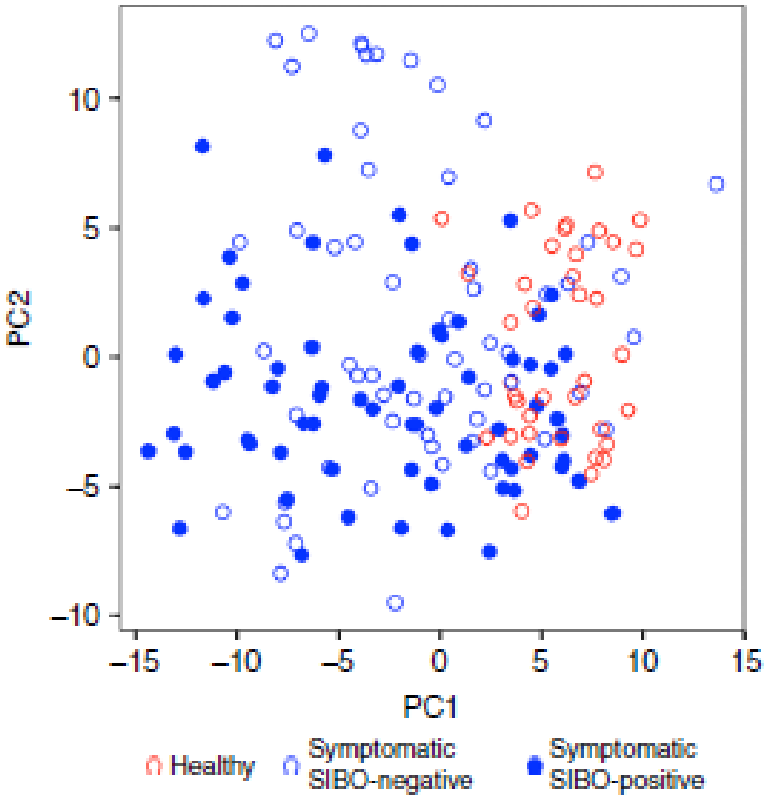
***Alarm features**

- Age ≥50 years old
- Blood in stools
- Nocturnal symptoms
- Unintentional weight loss
- Change in symptoms
- Recent antibiotic use
- Family history of organic GI disease

Modified from: Schoenfeld, PS. *Gastroenterol Hepatol (N Y)*. 2016 Aug;12(8 Suppl 3):1-11.

CBC, complete blood count; CRC, colorectal screening; CRP, C-reactive protein SeHCAT, selenium homocholic acid taurine; TTG, tissue transglutaminase.

Things you might miss? Small intestinal bacterial overgrowth (SIBO)?



- Study of 127 patients w/ GI symptoms undergoing duodenal aspirate:
  - Small bowel flora *is* altered in symptomatic pts, but has no correlation to SIBO
  - No differences in small bowel microbiome among healthy subjects w/ and without SIBO

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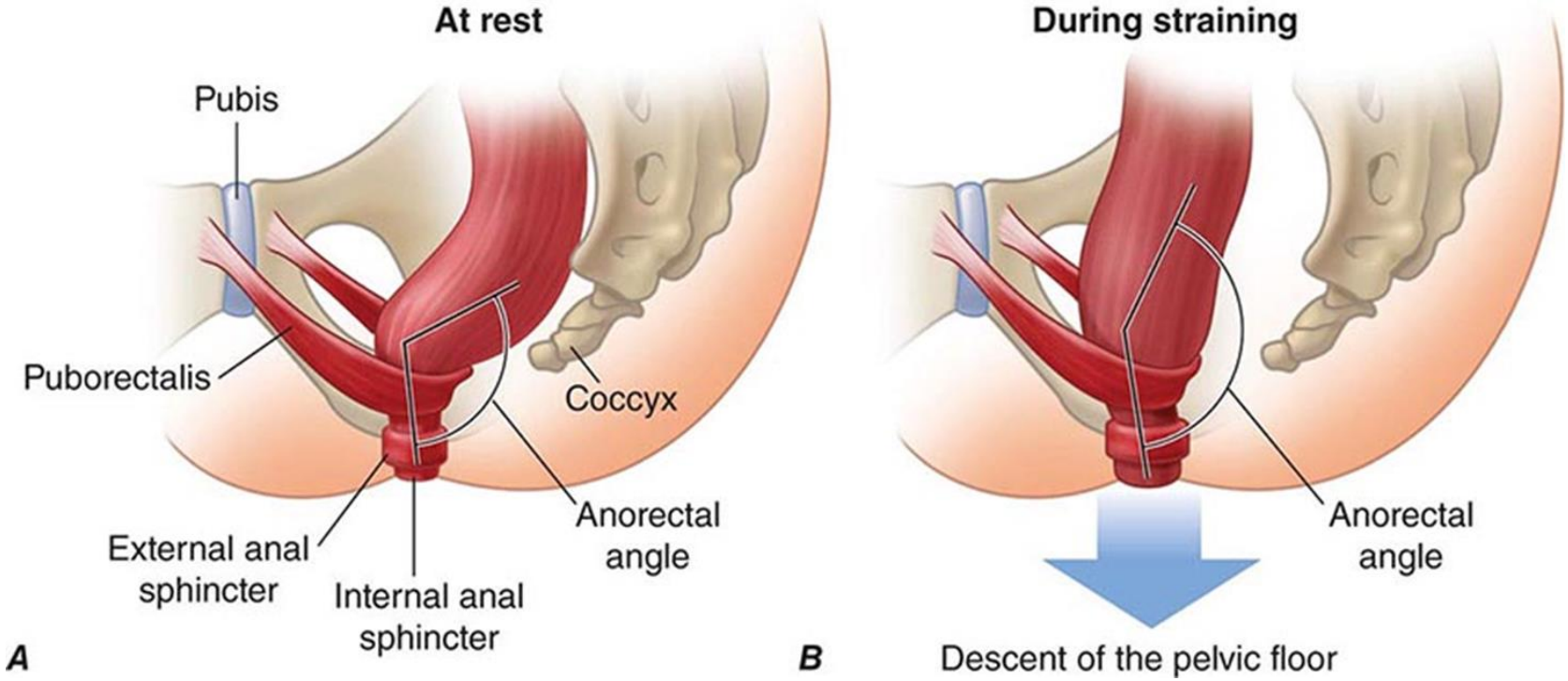
Saffouri GB, Shields-Cutler RR, et al. *Nat Commun*. 2019 May 1;10(1):2012.
Quigley EMM, Murray JA, et al. *Gastroenterology* 2020 Jul 15:S0016-5085(20)34928-3.

Things you might miss in IBS-C: pelvic floor dysfunction/rectal evacuation disorders

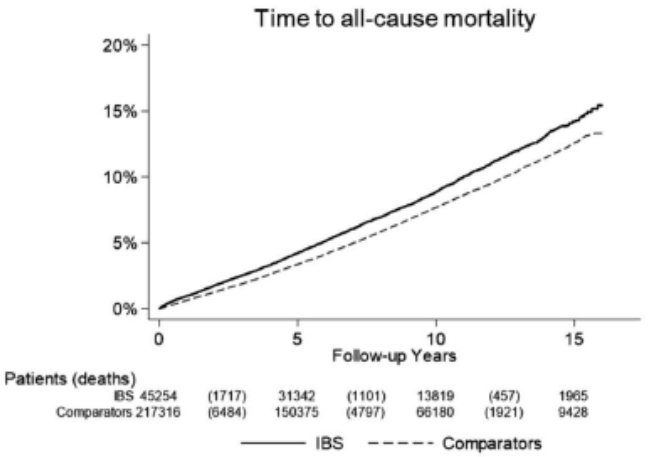


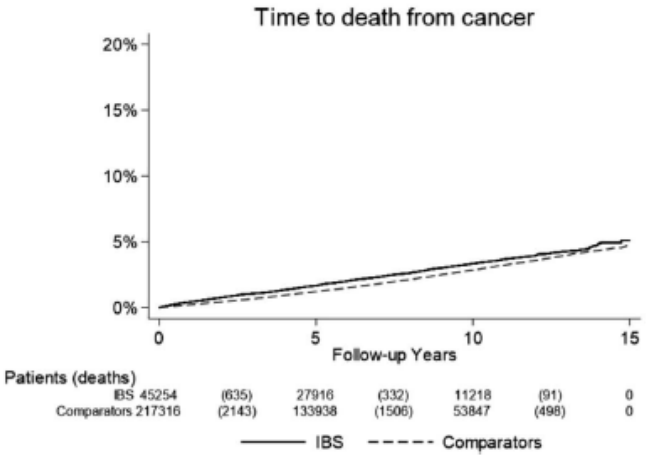
- Rectal evacuation disorders diagnosed in up 25% of constipated patients at the tertiary level
- History of anorectal symptoms not reliable either way

Image: Lembo A, Camilleri M. *New England Journal of Medicine* 2003; 349(14): 1360-1368.

No, IBS will not kill you

- Mortality concern is a major driver of care seeking in patients with IBS
- In this nationwide cohort of >45,000 individuals: <u>no association between IBS and mortality</u>
- No increased risk of mortality from cancer either
- Clinicians should spend more time on patient education and effective treatment approaches





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K Staller, O Olén, *et al. Am J Gastroenterol.* 2020 May;115(5):746-755.

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Part II: Dietary treatments for irritable bowel syndrome

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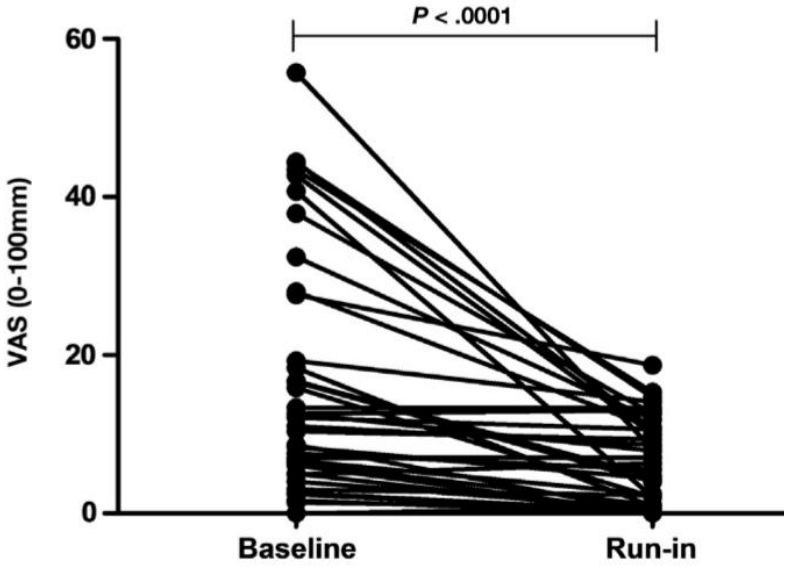
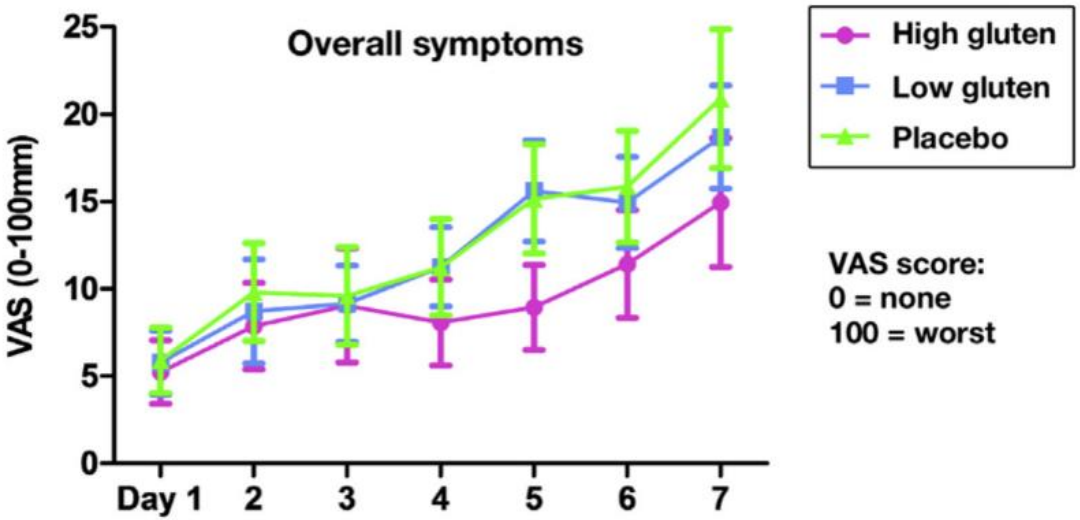
Patient demand for dietary advice in IBS outstrips the supply of available evidence for providers

- More than 70% of IBS patients believe that food plays a role in their symptoms
- Self-reported food intolerance in IBS is associated with more severe symptom severity
- Like it or not, your patients will look to you for dietary guidance
- Evolution of concept of non-celiac gluten (wheat) sensitivity

“Which diet to choose? Gluten-free or low-FODMAP?”



Low FODMAP run-in



Blinded re-introduction of high FODMAP foods

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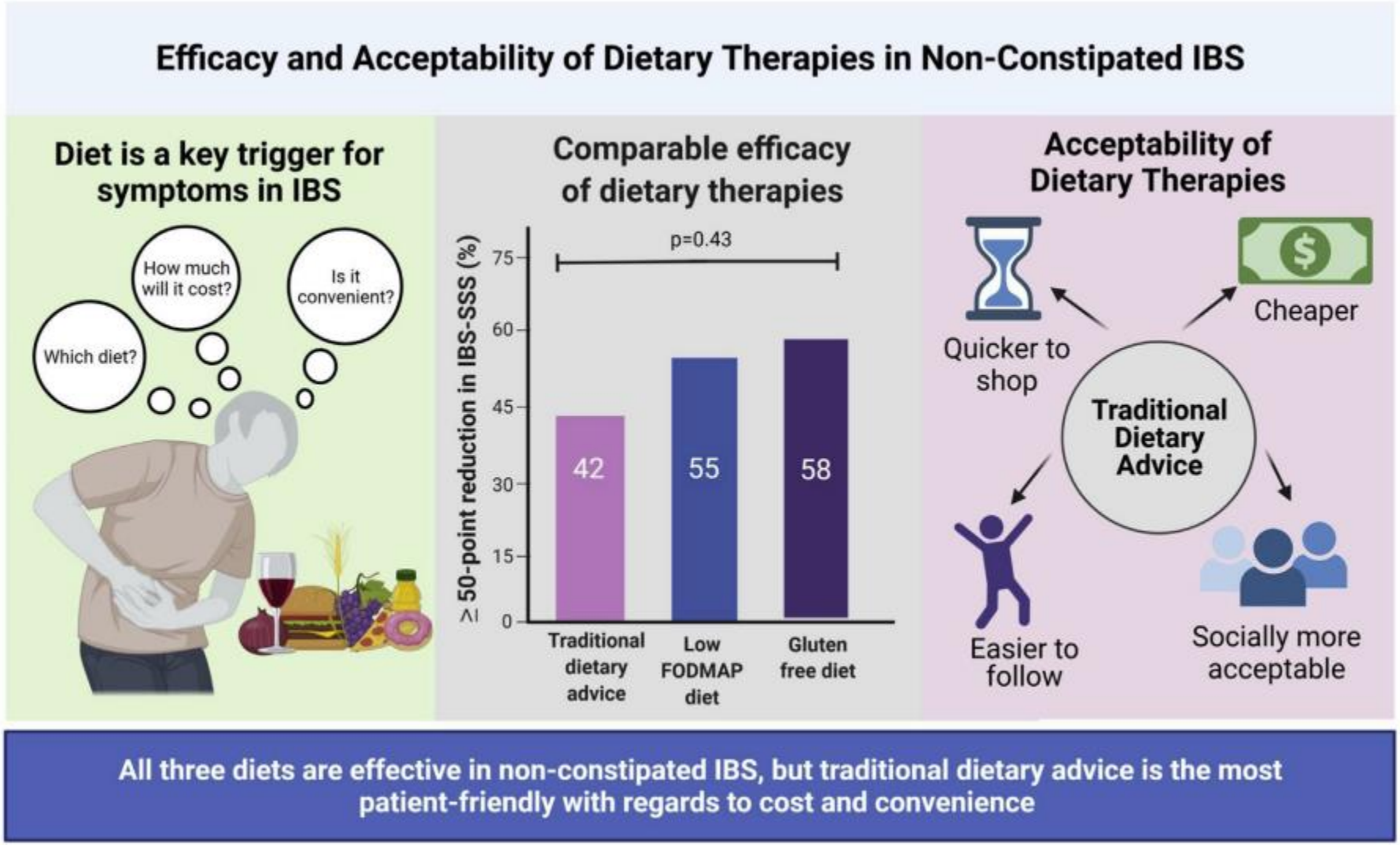
Biesiekierski JR, Peters SL, *et al*. *Gastroenterology*. 2013;145:320-328.

Maybe any diet will do?



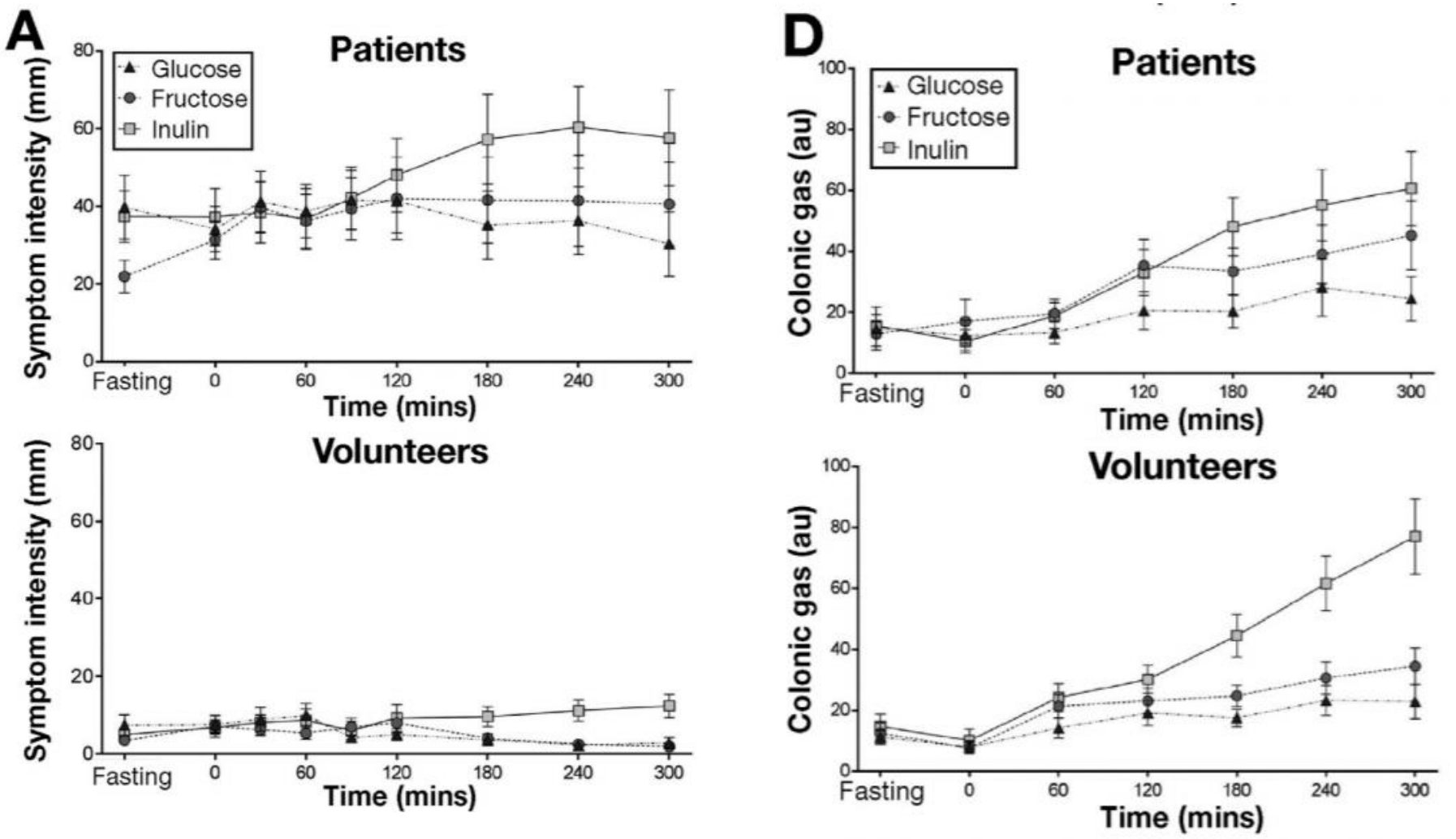
Rej A, Sanders DS *et al*. *Clin Gastroenterol Hepatol*. 2022 Dec;20(12):2876-2887.e15..

Caveats of dietary interventions in IBS

- Risk of bias in many dietary trials
- Effect of reintroduction/maintenance phase less certain
- Need a qualified dietician
  - No data on efficacy of printed handouts
  - Monash University app
- Caution in patients w/ disordered eating
  - Can reinforce harmful cognitions/ behaviors
  - Look out for “orthorexia nervosa”
    - Obsessive focus on food choice
    - Food for health>pleasure

Gastroenterol Hepatol (N Y). 2017 Jan;13(1):36-45.

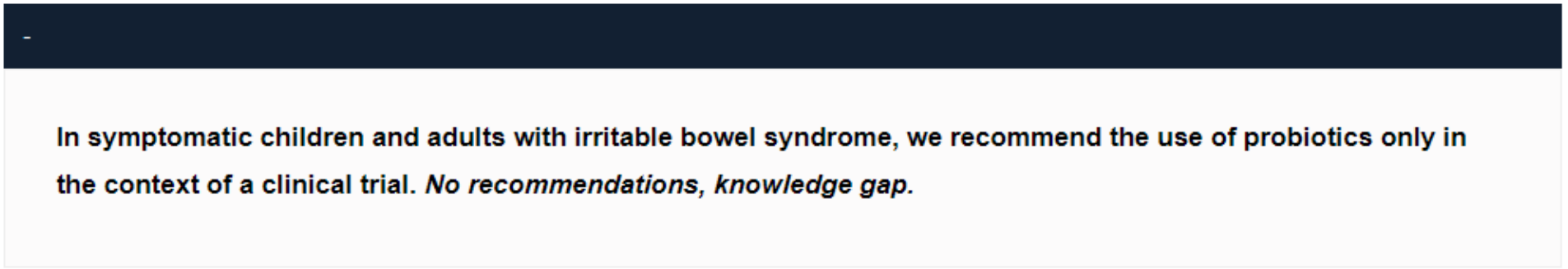
Response to FODMAPs, a matter of nerves?



Major G, Pritchard S, et al. *Gastroenterology.* 2017 Jan;152(1):124-133.e2.

Questions about probiotics are a reality of taking care of patients with IBS

- Probiotics likely provide some benefit to patients with IBS
- On the whole, products containing



In symptomatic children and adults with irritable bowel syndrome, we recommend the use of probiotics only in the context of a clinical trial. ***No recommendations, knowledge gap.***

- Any advice to patients limited by poor quality of existing data

Quigley, EM. *J Clin Gastroenterol*. 2015 Nov-Dec;49 Suppl 1:S60-4.

Su GL, Ko CW, *et al. Gastroenterology.* 2020 Aug;159(2):697-705.

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Fecal microbiota transplant for IBS

- FMT trials for IBS have been mixed
- Recent long-term trial results:
  - Patients with IBS receiving FMT continued to have fewer abdominal symptoms and fatigue and a better QOL than before procedure
  - 3 years after FMT: the response rate was 64.9% in 30g group, 71.8% in 60g group, vs. 27% in the placebo group

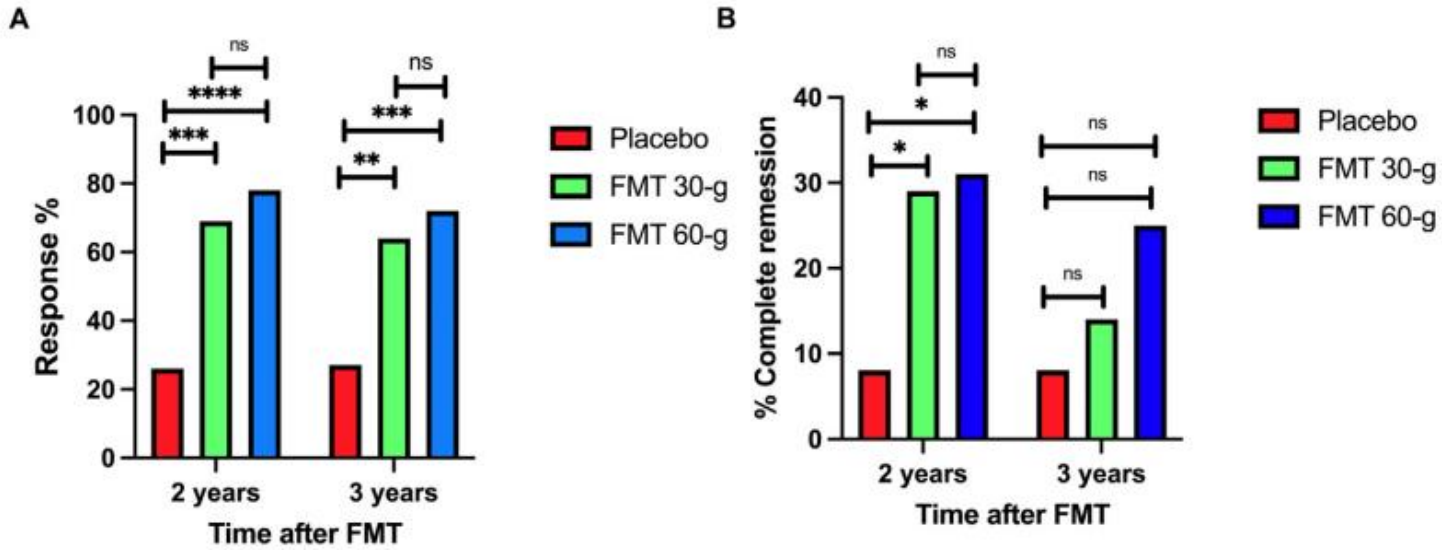

Figure 2. Response rates (*A*) and complete remission rates (*B*) in the placebo, 30-g, and 60-g groups at 2 and 3 years after FMT. ns, not significant; **P* < .05; ***P* < .01; ****P* < .001; *****P* < .0001.

El-Salhy, M, Winkel R, et al. Gastroenterology. 2022 Oct;163(4):982-994.e14.

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Part III: Thinking about pharmacologic treatments for IBS

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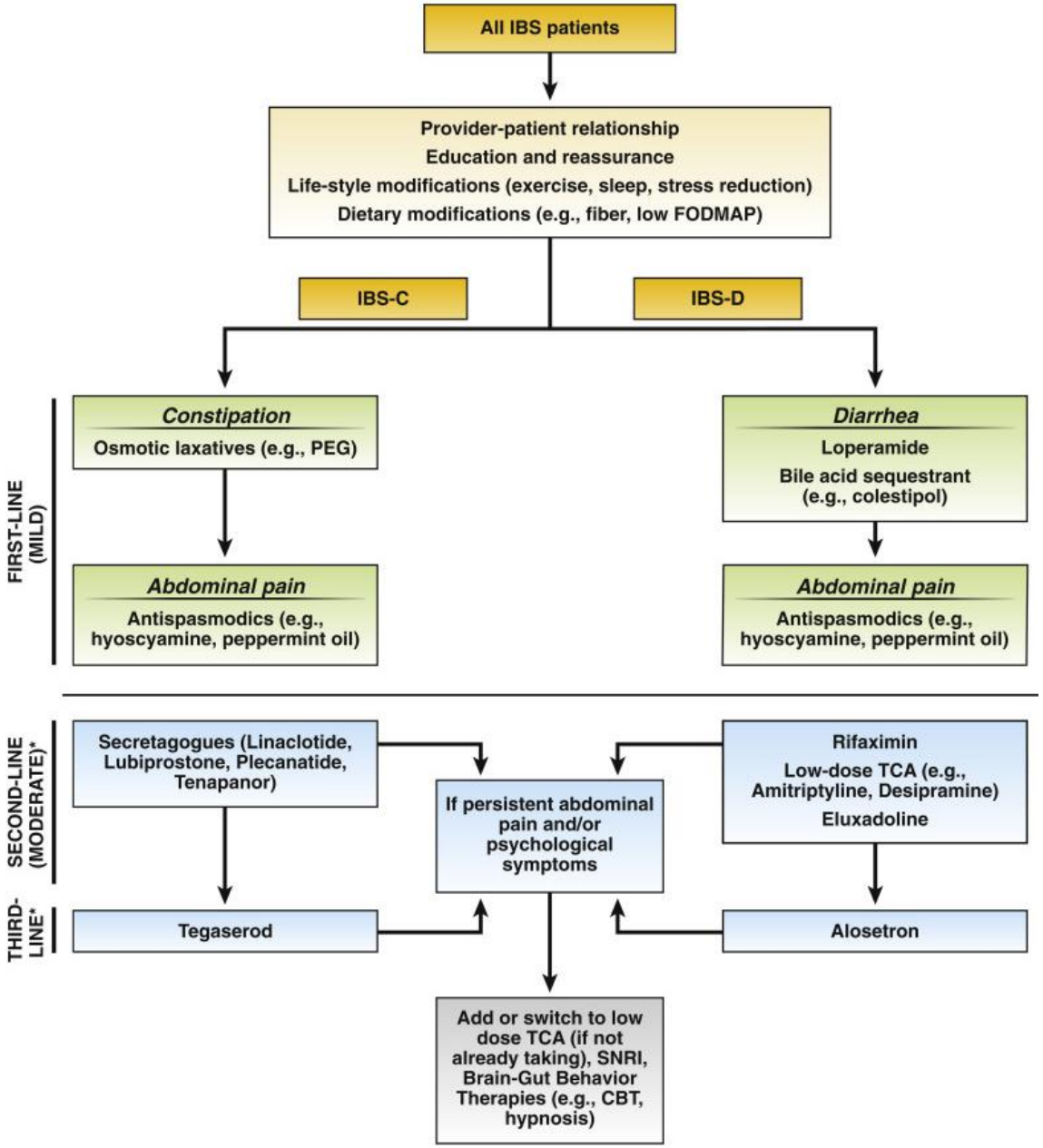
Latest guidelines for the treatment of IBS

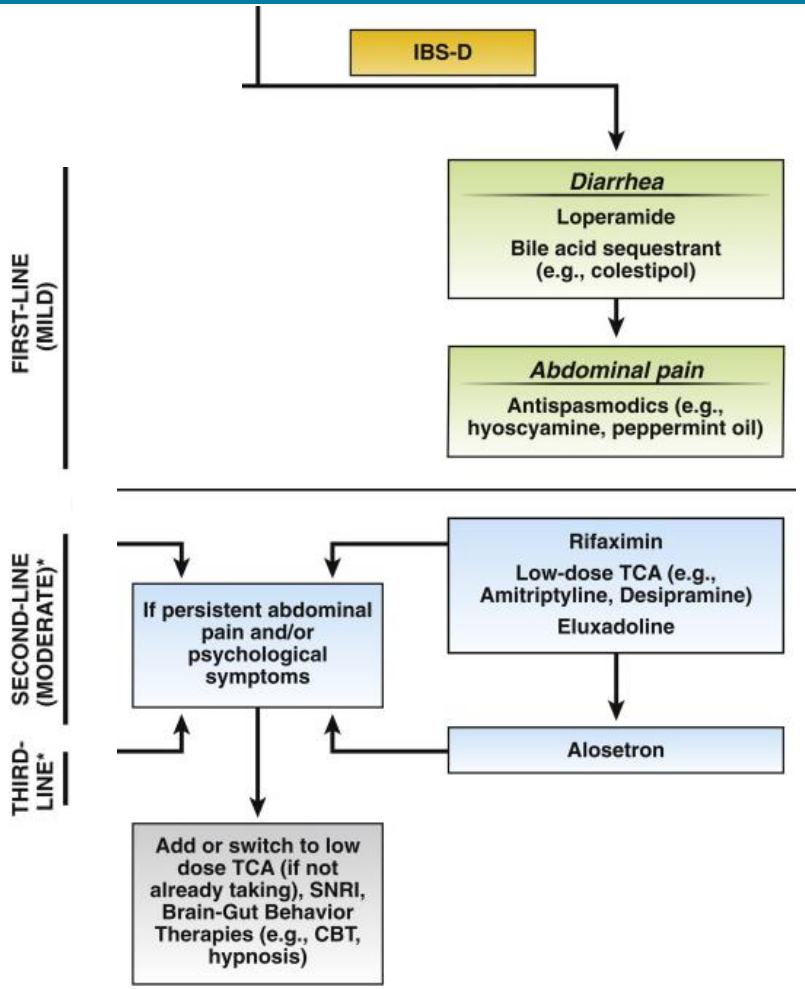
https://gastro.org/clinical-guidance/pharmacological-management-of-irritable-bowel-syndrome-with-diarrhea-ibs-d/



*Selection of the medication should be based on the clinical features and needs of the patient.

TCA, tricyclic antidepressant; SNRI, serotonin-norepinephrine reuptake inhibitor; PEG, polyethylene glycol; CBT, cognitive behavioral therapy

IBS-D treatment



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https://gastro.org/clinical-guidance/pharmacological-management-of-irritable-bowel-syndrome-with-diarrhea-ibs-d/

AGA treatment guidelines (IBS-D)

1. In patients with IBS-D, AGA suggests using eluxadoline. Implementation remark: Eluxadoline is contraindicated in patients without a gallbladder or those who drink more than 3 alcoholic beverages per day.

2a. In patients with IBS-D, AGA suggests using rifaximin.

2b. In patients with IBS-D with initial response to rifaximin who develop recurrent symptoms, AGA suggests retreatment with rifaximin.

3. In patients with IBS-D, AGA suggests using alosetron.

4. In patients with IBS-D, AGA suggests using loperamide.

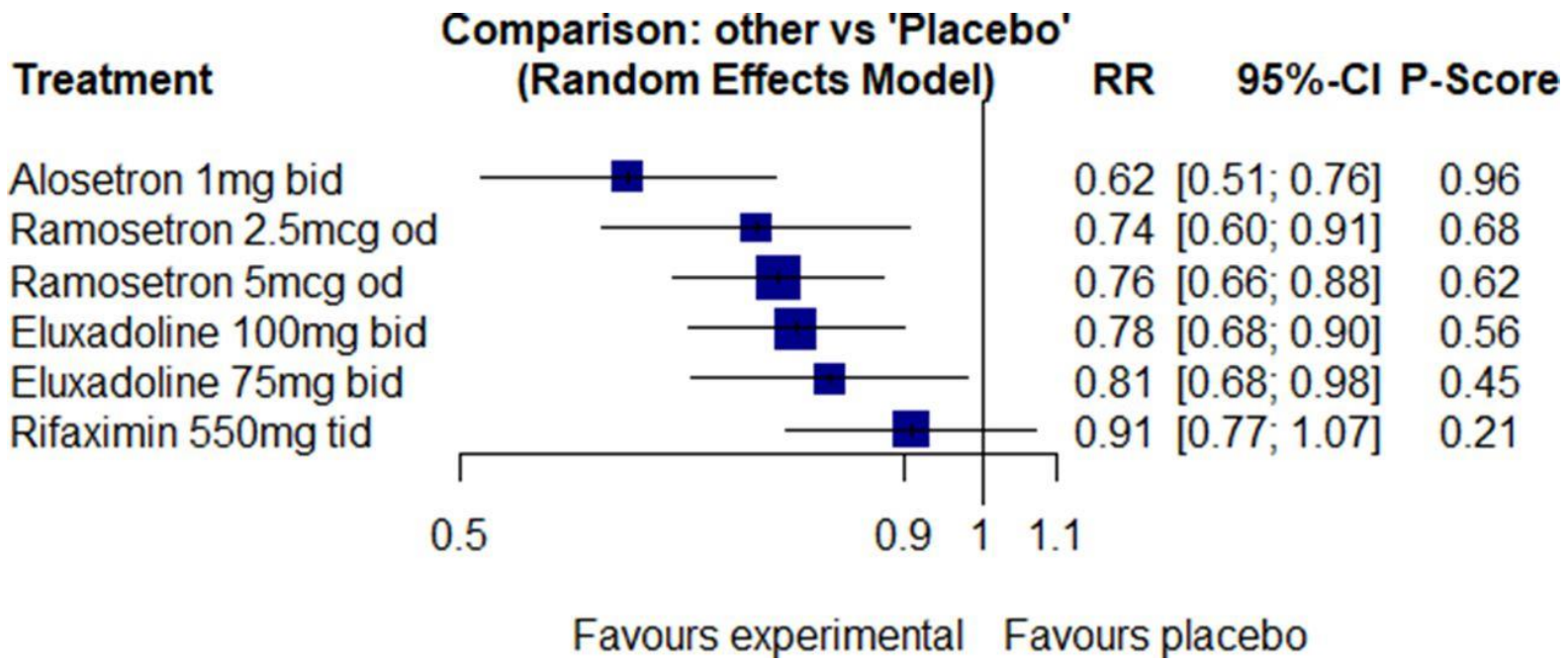
5. In patients with IBS, AGA suggests using tricyclic antidepressants (TCAs).

6. In patients with IBS, AGA suggests against using selective serotonin reuptake inhibitors (SSRIs).

7. In patients with IBS, AGA suggests using antispasmodics.

Lembo A, Sultan S, *et al*. *Gastroenterology*. 2022 Jul;163(1):137-151.

Comparative evidence of FDA-approved IBS-D therapies…not much difference



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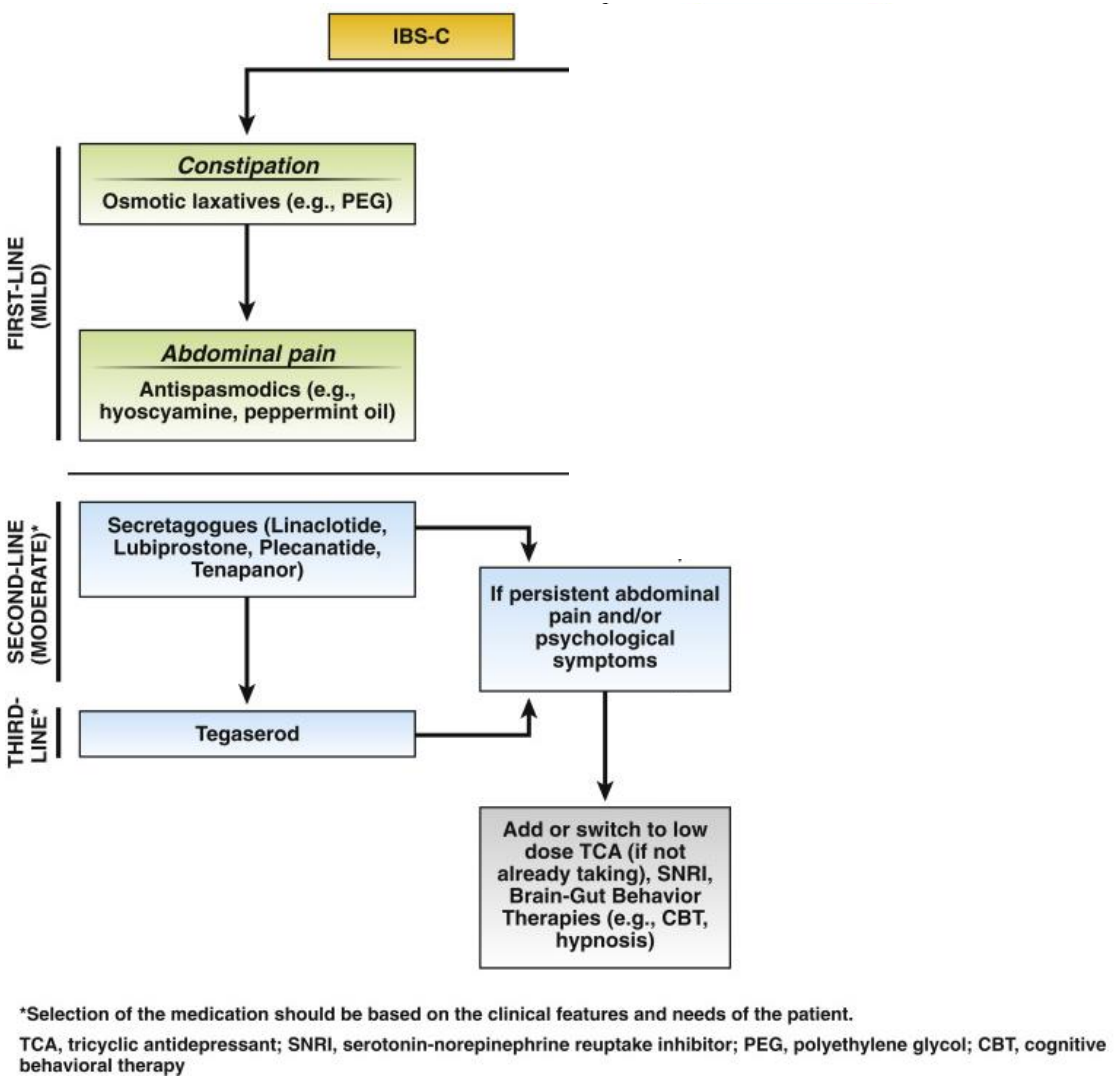
Black CJ, Burr NE, et al. *Gut*. 2020 Jan;69(1):74-82.

IBS-C treatment



*Selection of the medication should be based on the clinical features and needs of the patient.

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https://gastro.org/clinical-guidance/pharmacological-management-of-irritable-bowel-syndrome-with-diarrhea-ibs-d/

AGA treatment guidelines (IBS-C)

1. In patients with IBS-C, AGA suggests using tenapanor.

2. In patients with IBS-C, AGA suggests using plecanatide.

3. In patients with IBS-C, AGA recommends using linaclotide.

4. In patients with IBS-C, AGA suggests using tegaserod. Implementation remark: Tegaserod was reapproved for women under the age of 65 years without a history of cardiovascular ischemic events (such as myocardial infarction, stroke, TIA, or angina).

5. In patients with IBS-C, AGA suggests using lubiprostone.

6. In patients with IBS-C, AGA suggests using polyethylene glycol (PEG) laxatives.

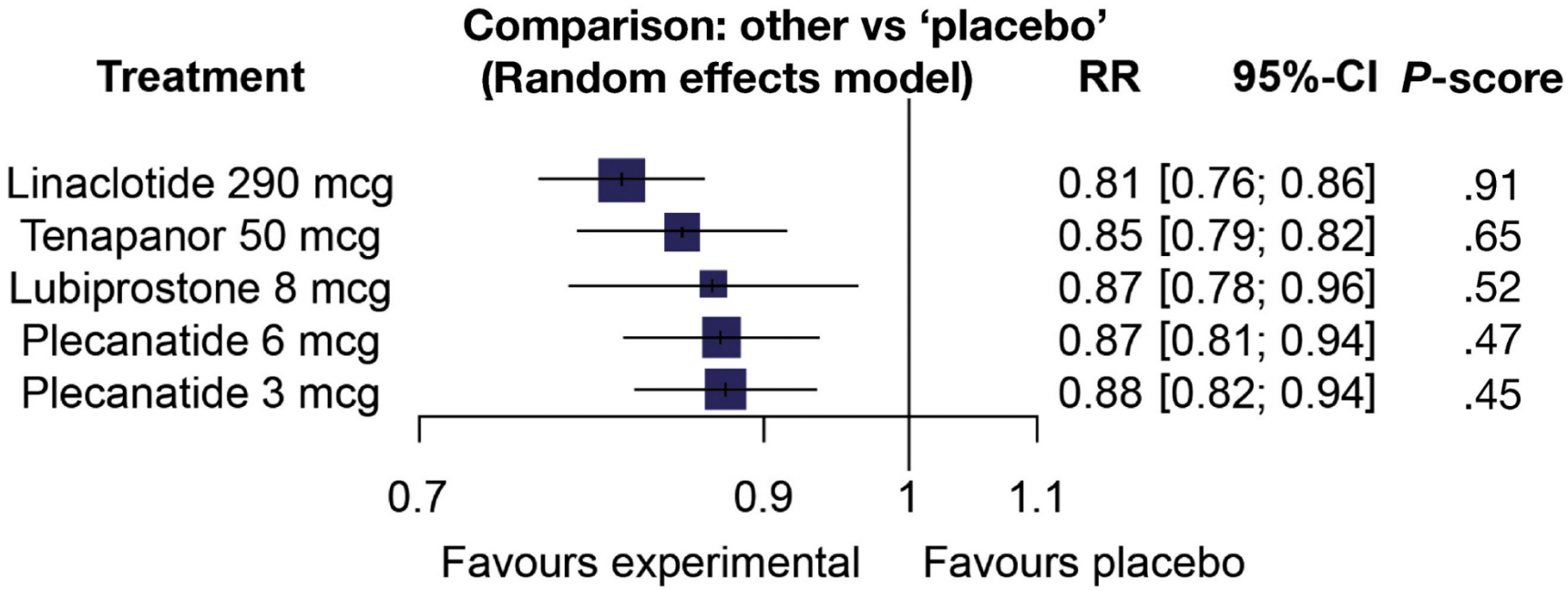
7. In patients with IBS, AGA suggests using tricyclic antidepressant (TCAs).

8. In patients with IBS, AGA suggests against using selective serotonin reuptake inhibitors (SSRIs).

9. In patients with IBS, AGA suggests using antispasmodics.

Chang L, Sultan S, *et al*. *Gastroenterology*. 2022 Jul;163(1):137-151.

Comparative evidence of FDA-approved IBS-C therapies…not much difference



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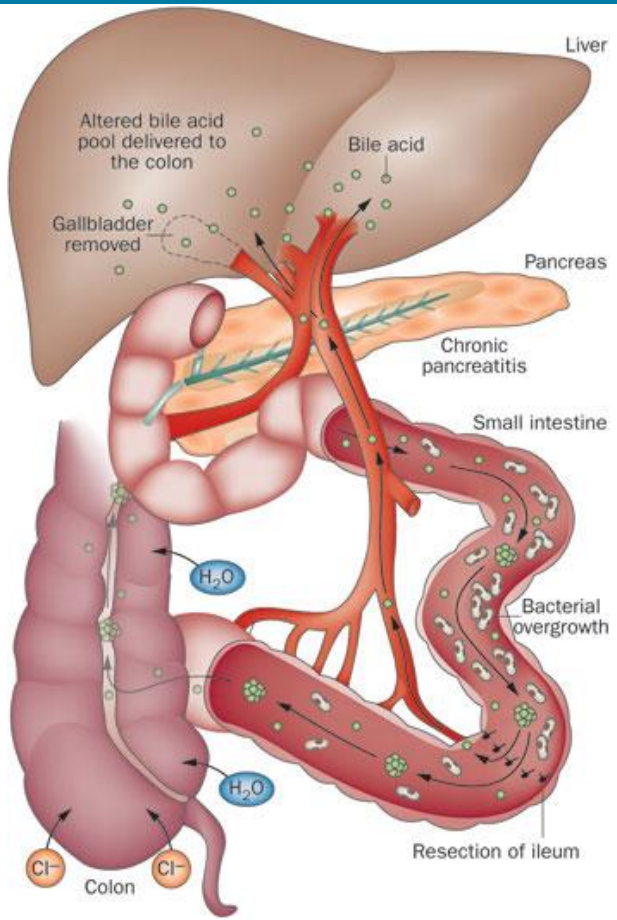
Black CJ, Burr NE, et al. *Gastroenterology*. 2018 Dec;155(6):1753-1763.

Consider bile acid diarrhea in patients with IBS-D



- Underdiagnosed in IBS-D
- Results from presence of bile acids in colonic lumen (normally completely absorbed in ileum)
- Limited testing options:
  - Best test is SeHCAT retention (limited availability in US)
  - Serum 7C4 w/ 29% sensitivity, 83% specificity compared to gold standard
  - Empiric trials of bile acid sequestrants

Vijayvargiya P, Camilleri M, *et al*. Aliment Pharmacol Ther. 2017 Sep;46(6):581-588.
Figure adapted from *Nat Rev Gastroenterol Hepatol*. 2012 Nov;9(11):661-74.

Consider bile acid diarrhea in patients with IBS-D

Cholestyramine
4 g daily initially, increased by 4 g at weekly intervals (in 1–4 divided doses) to max. 24 g daily.

Colestipol
5 g daily initially, increased in 5 g increments mothly to max. 30 g daily

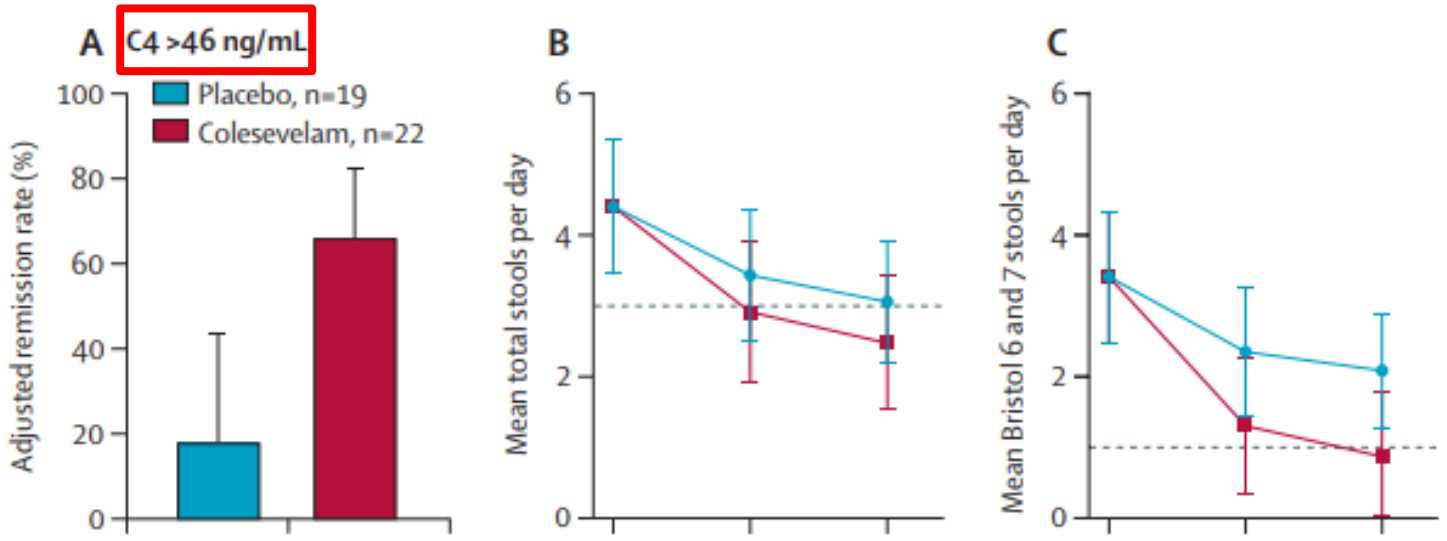
Colesevelam
3.75 g daily in 1–2 divided doses; max. 4.375 g daily

- Underdiagnosed in IBS-D
- Results from presence of bile acids in colonic lumen (normally completely absorbed in ileum)
- Limited testing options:
  - Best test is SeHCAT retention (limited availability in US)
  - Serum 7C4 w/ 29% sensitivity, 83% specificity compared to gold standard
  - Empiric trials of bile acid sequestrants

Vijayvargiya P, Camilleri M, *et al*. Aliment Pharmacol Ther. 2017 Sep;46(6):581-588.
Figure adapted from *Nat Rev Gastroenterol Hepatol*. 2012 Nov;9(11):661-74.

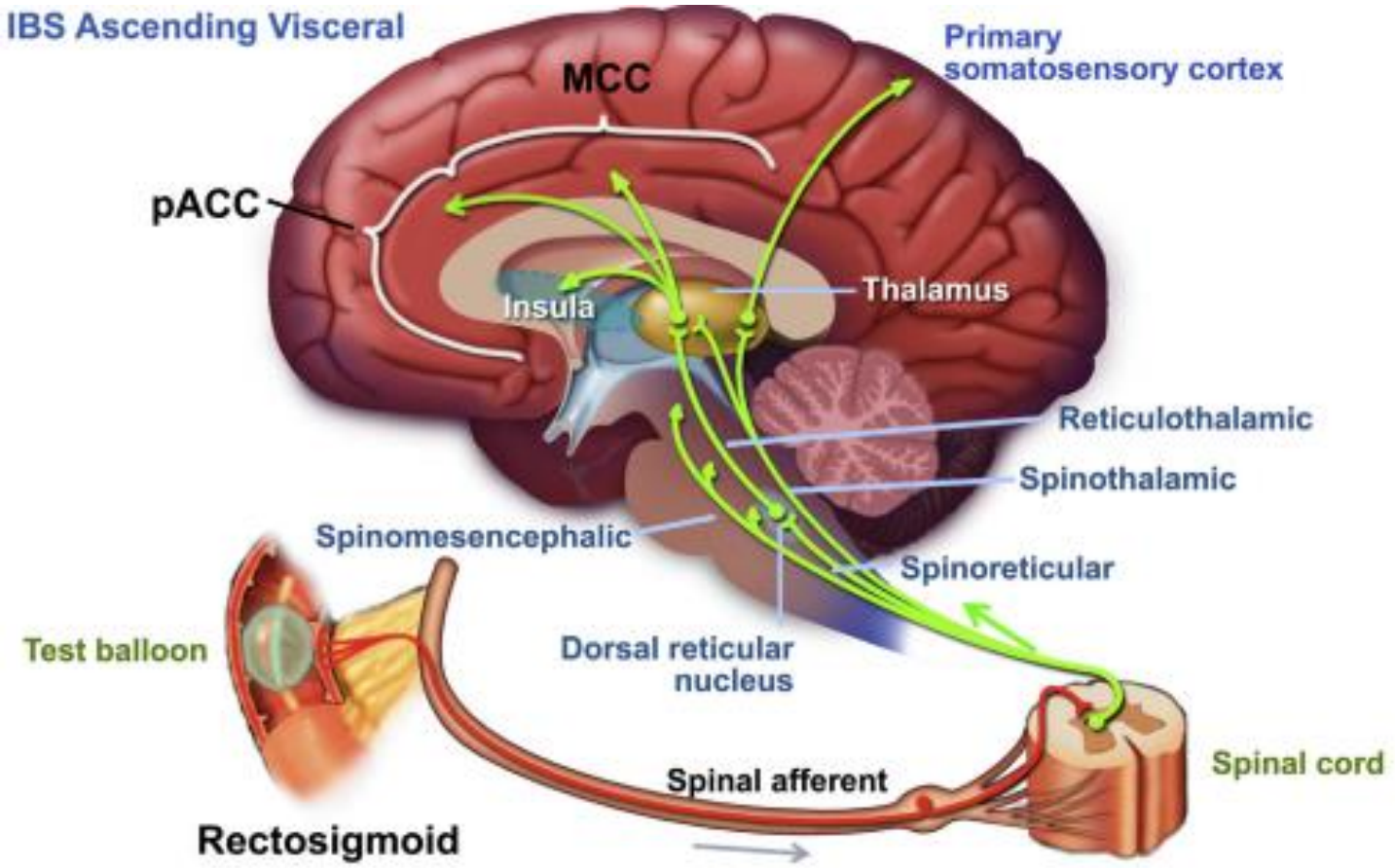
Don’t miss bile acid diarrhea in IBS-D

- New double-blind RCT from Denmark of 168 patients treated w/ colesevelam for 12 days
- Defined bile acid malabsorption as a C4 level >46 ng/mL
  - 14 (64%) of 22 participants receiving colesevelam vs. 3 (16%) of 19 participants receiving placebo achieved remission
  - Adjusted odds ratio 9.1, 95% CI 1.9–62.8; p=0.011).



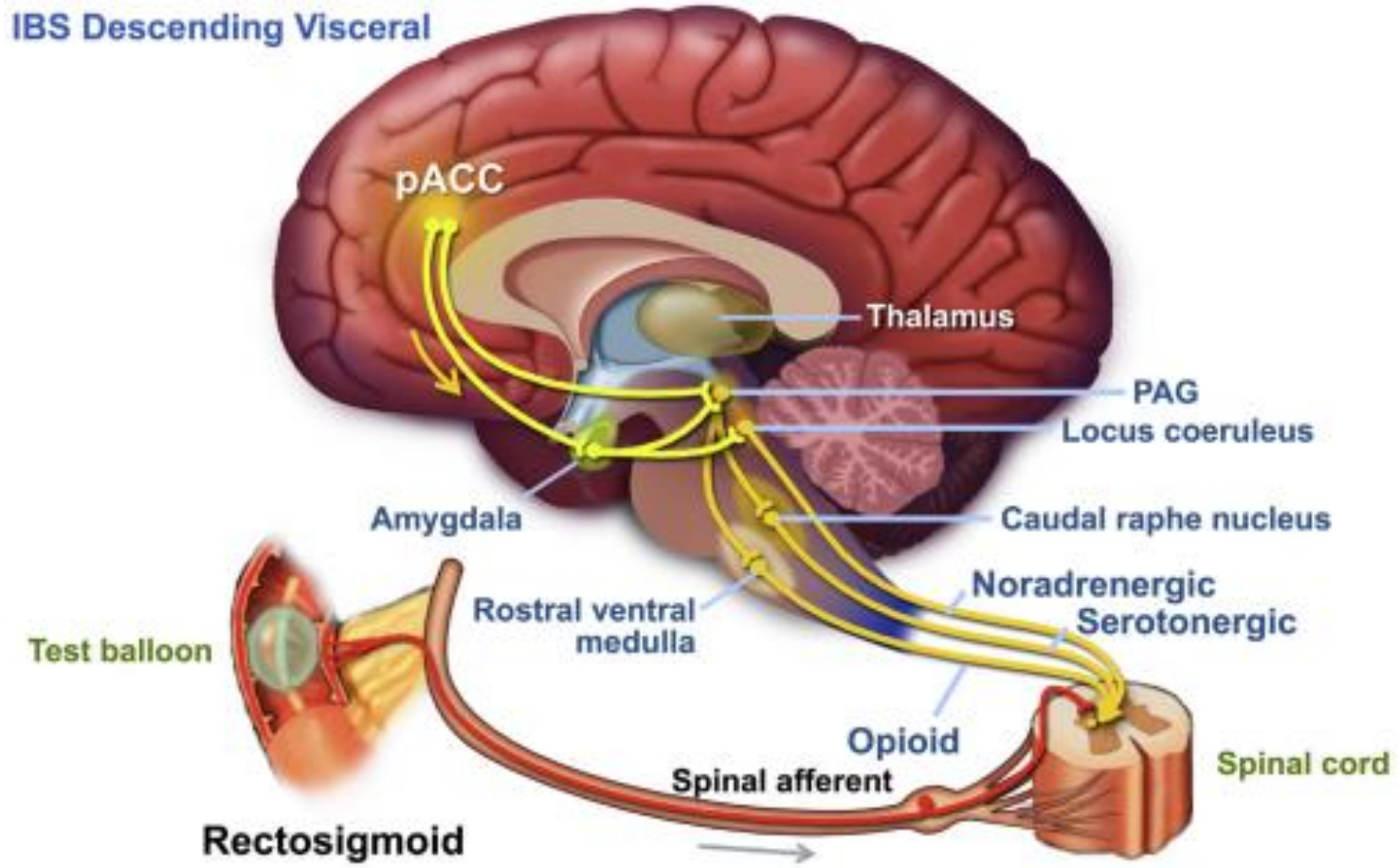
Borup C, Vinter-Jensen L, *et al*, *Lancet Gastroenterol Hepatol*. 2023 Apr;8(4):321-331.

How sensory signals from the colon reach consciousness: ascending pathways



Drossman DA, Tack J, et al. *Gastroenterology.* 2018 Mar;154(4):1140-1171.e1.

How sensory signals from the colon reach consciousness: descending pathways



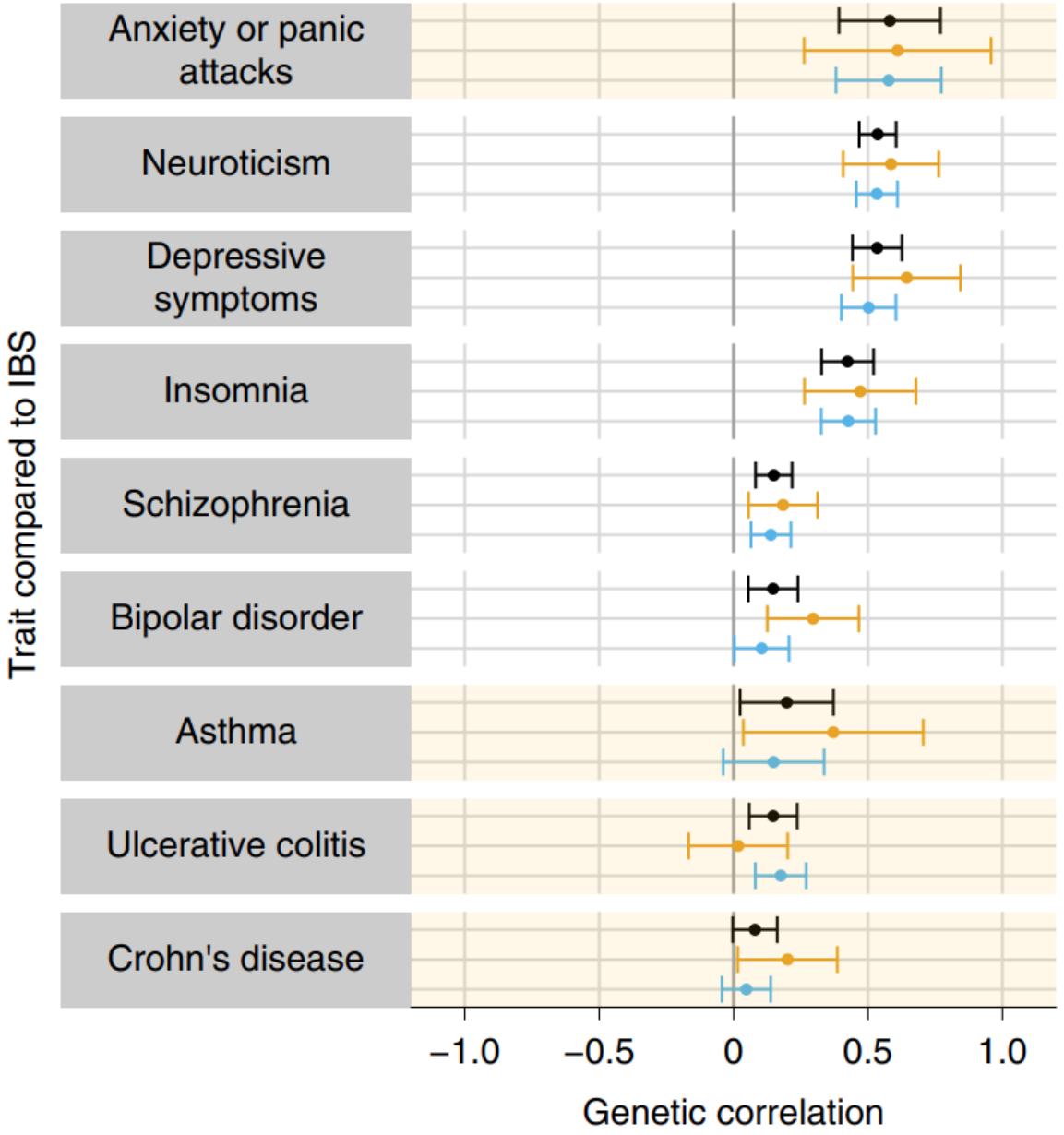
Drossman DA, Tack J, et al. *Gastroenterology.* 2018 Mar;154(4):1140-1171.e1.

IBS and psychological disease: chicken or egg?

Genetic correlation between IBS and anxiety

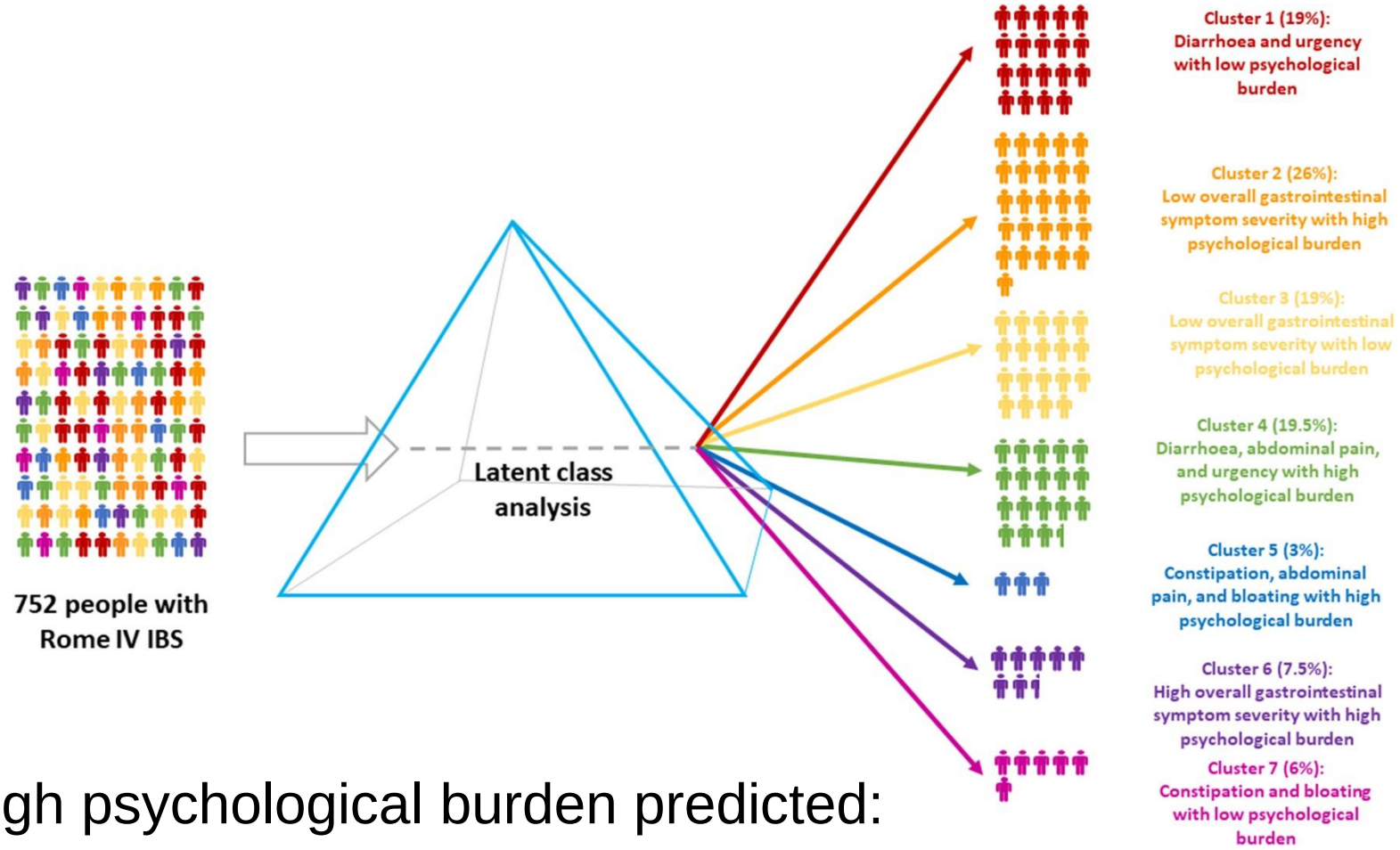
Association remained even after removing those with overlap

Suggests shared etiology rather than one condition causing the other



Eijsbouts C, Zheng T *et al. Nat Genet.* 2021 Nov;53(11):1543-1552.

Identifying IBS patient subtypes beyond stool form

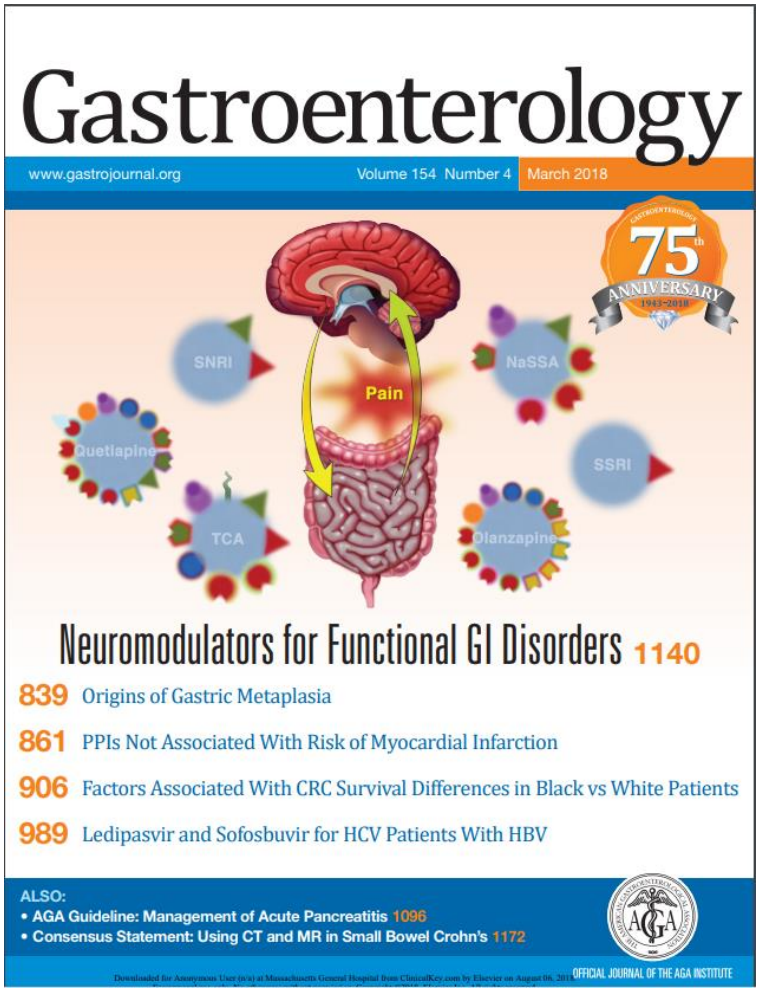


- High psychological burden predicted:
  - ↓ productivity, ability to work, and manage at home, engage in social activities
  - ↑ healthcare costs over previous 12 months

CJ Black, Ng C, *et al*. *Clin Gastroenterol Hepatol.* 2024 Feb;22(2):386-396.e10.

Use of neuromodulators in IBS

- Many patients have improved bowel frequency on laxatives, but bloating/abdominal pain remain
- Neuromodulators reduce global IBS symptoms and pain in IBS patients
- Potential benefits:
  - Reduction in pain/?bloating
  - Treatment of psychological distress and comorbid psychiatric disease
  - Leverage motility effects
  - Long-term treatment may reverse maladaptive brain-gut axis changes



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Sobin WH, Heinrich TW, et al. *Am J Gastroenterol*. 2017 May;112(5):693-702.
Drossman DA, Tack J, et al. *Gastroenterology*. 2018 Mar;154(4):1140-1171.e1.

Amitriptyline at Low-Dose and Titrated for Irritable Bowel Syndrome as Second-Line Treatment in primary care (ATLANTIS): a randomised, double-blind, placebo-controlled, phase 3 trial

THE LANCET

Alexander C Ford*, Alexandra Wright-Hughes*, Sarah L Alderson, Pei-Loo Ow, Matthew J Ridd, Robbie Foy, Gina Bianco, Felicity L Bishop, Matthew Chaddock, Heather Cook, Deborah Cooper, Catherine Fernandez, Elspeth A Guthrie, Suzanne Hartley, Amy Herbert, Daniel Howdon, Delia P Muir, Taposhi Nath, Sonia Newman, Thomas Smith, Christopher A Taylor, Emma J Teasdale, Ruth Thornton, Amanda J Farrin†, Hazel A Everitt†, on behalf of the ATLANTIS trialists‡

oa OPEN ACCESS

- Amitriptyline, self-titrated between doses of 10-30 mg qhs vs placebo
- Inclusion:
  - Active IBS of any subtype followed in primary care
  - Normal labs (Hgb, platelets, CRP, celiac serology)
  - Tried first-line treatments without success:
    - Dietary changes and lifestyle advice
    - Soluble fiber
    - Antispasmodics
    - Laxatives
    - Antidiarrheals

Ford AC, Wright-Hughes A, et al. *Lancet*. 2023 Oct 16:S0140-6736(23)01523-4.

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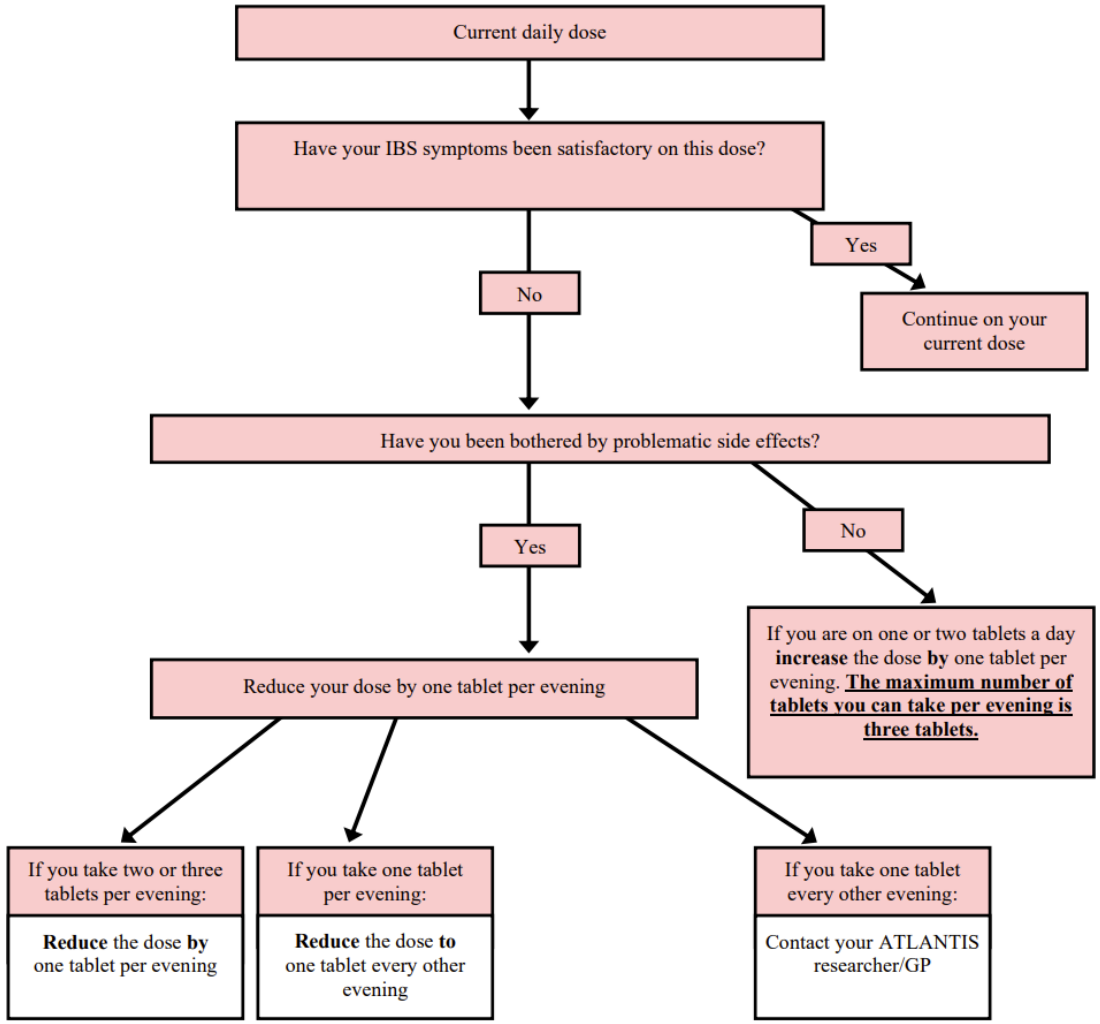

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Outcomes	Mean scores		Between-group difference (95% CI) at 6 mo	
	Amitriptyline	Placebo		
IBS-SSS†	170.4	200.1	-27.0 (-46.9 to -7.1)	
	Event rates		RBI (CI)‡	NNT (CI)‡
Relief of IBS symptoms§	61%	45%	32% (10 to 52)	7 (5 to 24)
Amitriptyline increased treatment-emergent adverse events (mean ASEC‖ scores) at 3 mo (9.9 vs. 8.4, $P = 0.013$) but not at 6 mo (9.3 vs. 8.7, $P = 0.68$).				

ASEC = Antidepressant Side Effect Checklist; IBS = irritable bowel syndrome; IBS-SSS = Irritable Bowel Syndrome Severity Scoring System; other abbreviations defined in Glossary. Primary outcome indicated by boldface.
†Score range, 0 to 500 (more severe symptoms). Negative between-group difference favors amitriptyline.
‡RBI, NNT, and CI calculated from placebo event rate and odds ratio in article.
§Self-report of symptoms being at least somewhat relieved on the subjective global assessment.
‖Score range, 0 to 63 (worst).

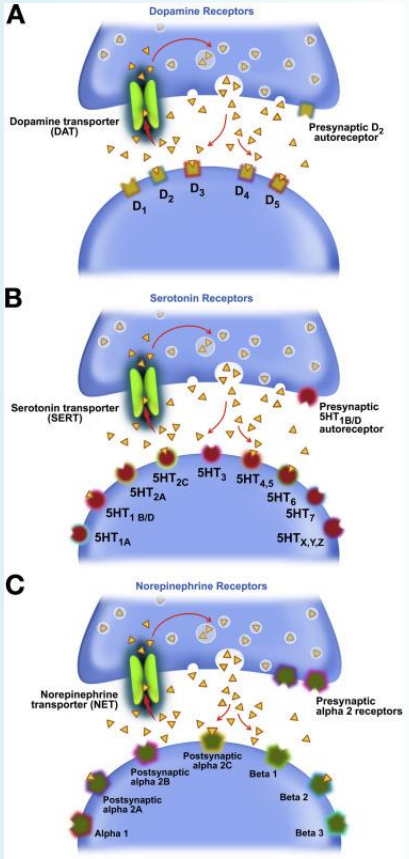
Bottom line:
In primary care patients with IBS, second-line therapy with amitriptyline vs. placebo reduced symptoms at 6 months.

- Amitriptyline increased treatment-emergent AEs at:
  - 3 months (9.9 vs 8.4, *P*=0.013)
  - But not 6 months (9.3 vs. 8.7, *P*=0.68)
- AEs mostly anticholinergic
- Most aside effects mild and these pts still completed 6 months of treatment

Ford AC, Wright-Hughes A, et al. *Lancet*. 2023 Oct 16:S0140-6736(23)01523-4.
Gupta T, Cash BD. *Ann Intern Med*. 2024 Feb;177(2):JC15. doi: 10.7326/J23-0122.

Prescribing antidepressants in IBS smartly

- Overall efficacy[1].
  - TCAs more effective than SSRIs for pain
  - SSRIs should be a second-line agent or a first-line agent in pts w/ comorbid anxiety, depression, social anxiety
  - SNRIs extensively studied for fibromyalgia and diabetic neuropathy but can be useful in IBS-C or in those who failed TCA trial
- Leverage side effects to correct patient's motility
  - TCAs in IBS-D (use anticholinergic side effects)
  - Emerging data for pregabalin (?IBS-M)[2].



SNRI, serotonin norepinephrine reuptake inhibitors; SSRI, selective serotonin reuptake inhibitors; TCAs, tricyclic antidepressants.

Sobin WH, Heinrich TW, *et al. Am J Gastroenterol. 2017 May;112(5):693-702*

Saito YA, Almazar AE, *et al. Aliment Pharmacol Ther.* 2019 Feb;49(4):389-397.

Image: Drossman DA, Tack J, et al. *Gastroenterology.* 2018 Mar;154(4):1140-1170. e1.

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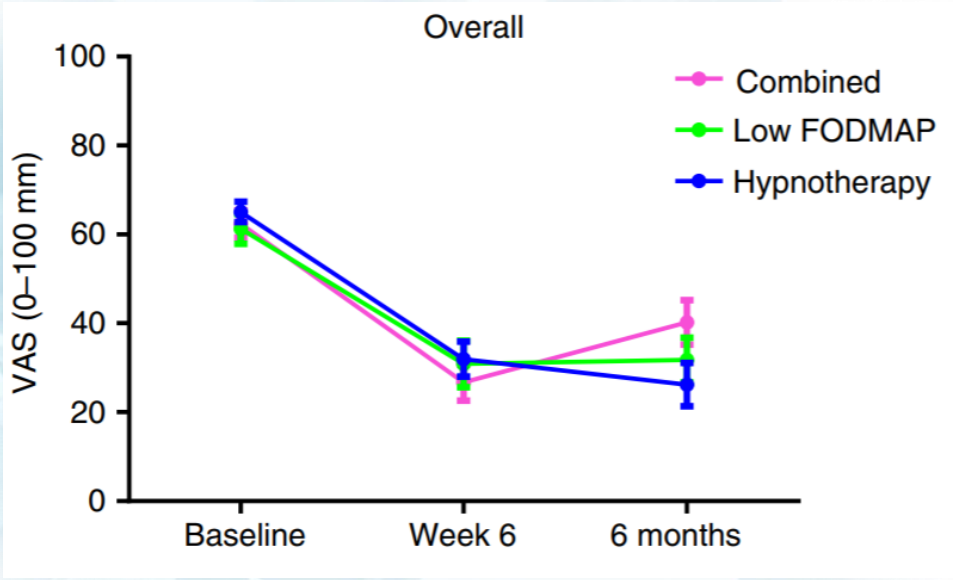
Psychological therapies improve IBS symptoms

- Psychosocial therapies have been shown to be effective in improving IBS symptoms
  - Cognitive behavioral therapy (CBT)
  - Hypnotherapy:
    - Recent positive data from a multicenter RCT with 6 sessions of group or individual treatments
    - Benefits up to 12 months
- Use limited by lack of skilled therapists in managing IBS



Flik CE, Laan W, *et al. Lancet Gastroenterol Hepatol.* 2019 Jan;4(1):20-31.
Peters SL, Yao CK, *et al. Aliment Pharmacol Ther.* 2016 Sep;44(5):447-59.

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There's an app for that

Cognitive Behavioral Therapy

Study type:
Randomized, comparative effectiveness trial (6)
- TAU vs TAU + phone-based CBT vs TAU + web-based CBT
- n = 558, divided in 3 groups

Primary outcome(s):
Improvement in IBS-SSS; WSAS

Key results:
Improvement in both CBT groups as compared with TAU alone:
- IBS-SSS ($P < 0.001$, $P = 0.002$)
  WSAS ($P < 0.001$, $P = 0.001$)

Prescription; max out-of-pocket = $90

Mahana

Study type:
Randomized, crossover (8)
- Immediate access (n = 62)
- Waitlist control (n = 59)

Primary outcome(s):
Improvement in IBS-QoL; GI symptom rating scale-IBS

Key results:
Improvement in:
- IBS-QoL ($P < 0.001$)
- GI symptom rating scale-IBS ($P < 0.001$)
- Fear of Food Questionnaire ($P = 0.001$)
- Visceral Sensitivity Index ($P < 0.001$)
- Depression Anxiety Stress Scale ($P = 0.016$)
- PHQ-9 ($P = 0.002$)

$19.49/mo or $154.99/yr

Zemedy

Gut-directed Hypnotherapy

Study type:
Randomized, comparative effectiveness trial

Primary outcome(s):
Reduction in abdominal pain

Key results:
Unpublished results:
- No difference in Regulora vs muscle relaxation
- Improvement in abdominal pain intensity
- Improvement in proportion of stools with normal consistency compared with baseline

Prescription; maximum out of pocket = $75

Regulora

Study type:
Observational cohort study reported as an abstract (10)

Primary outcome(s):
Improvement in symptoms

Key results:
- Improvement in VAS ($P < 0.001$)
- Improvement in abdominal pain, bloating, dissatisfaction with stool consistency, flatulence, and nausea

$79.99 for 3 mo

Nerva

Saleh ZM, Chey WD, *et al. Am J Gastroenterol*. 2023 Mar 20.

How I explain IBS

- Visceral hypersensitivity
  - Normal gut sensations improperly amplified in PNS and CNS
  - Abnormal sensory response to normal physiologic processes
- Treatment is a “3-legged stool”
  1. Motility agents (speed up/slow down)
  2. Dietary and ?microbiome changes
  3. *Leverage the brain-gut connection

  Neuromodulators Cognitive behavioral therapy
  Gut hypnotherapy
- Investing time up front can pay dividends later on

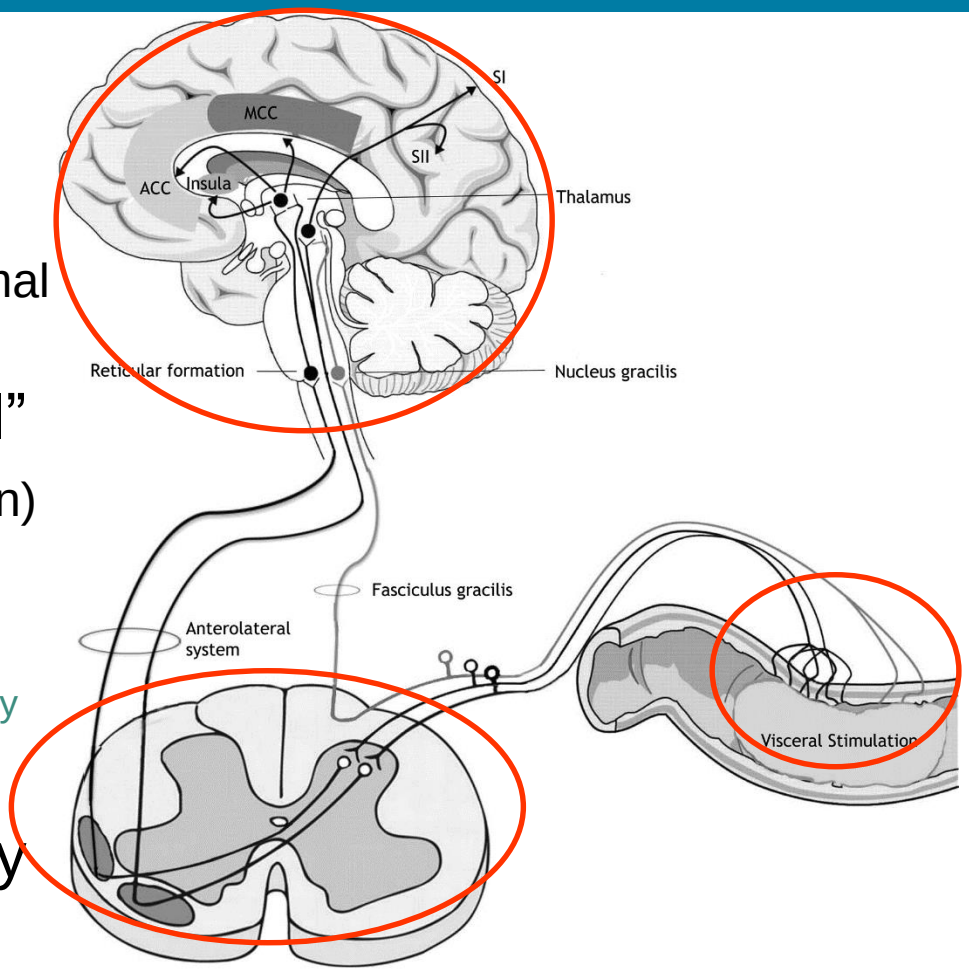

Figure adapted from Keszthelyi D, Troost FJ, *et al. Am J Physiol Gastrointest Liver Physiol.* 2012 Jul 15;303(2):G141-54.

Summary

1. IBS has a specific definition: use it
2. Most IBS does not need a colonoscopy, but know the IBS mimickers
3. The low-FODMAP diet is a powerful, patient-centered tool but has limitations
4. Evidence for FMT is still limited
5. Brain-gut behavioral therapies are now available digitally
6. IBS is fundamentally a disorder of brain-gut interaction; neuromodulators can and should be used early

Thank you

Helpful references:

- IBS overview: Camilleri M. *JAMA.* 2021 Mar 2;325(9):865-877.
- IBS and mental health management: Staudacher HM, Black CJ, *et al*. *Nat Rev Gastroenterol Hepatol.* 2023 Sep;20(9):582-596.
- Using neuromodulators: Sobin WH, Heinrich TW, Drossman DA. *Am J Gastroenterol*. 2017;112(5):693-702.