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GASTROENTEROLOGY DATA TRENDS 2025

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GI&Hepatology News

May 2025

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The Role of Bedside Intestinal Ultrasound in IBD Management

Bincy Abraham, MD, MS

Patients with inflammatory bowel disease (IBD) need accessible, timely, and noninvasive monitoring strategies. Bedside intraabdominal ultrasound (IUS) is a beneficial tool for diagnosing and monitoring patients with IBD, including both Crohn's disease and ulcerative colitis.[1,2] Integrating IUS can have a significant impact on decision-making and endoscopy use in a standardized care pathway for these patients, given that the benefits outweigh the risks and costs of other imaging modalities.

IUS is radiation free, and provides accurate point-of-care detection of bowel wall thickening and inflammation in individuals with IBD.[3] This imaging is effective for monitoring treatment response and guiding early interventions and is suitable for special populations (e.g., pediatrics and patients who are pregnant or obese).[1,2] IUS allows for medication adjustments without requiring urgent endoscopies or special preparations.[1] The small and large intestine can be visually monitored for IBD activity with IUS, with occasional exception regarding the rectum because of its deep location; however, a transperineal or transrectal ultrasound approach may be needed to view the rectum and perianal areas.[2,3]

Further, in 2024, AGA reviewed and provided guidance on the use of IUS in IBD care,[1] underscoring its growing importance and utility. IUS provides a noninvasive, cost-effective, and accurate method for IBD evaluation and monitoring.

Benefits of IUS[2,3]

Role and Effectiveness

- ✔ Real-time assessing and monitoring
- ✔ Noninvasive, radiation-free alternative to endoscopy

Clinical Benefits

- ✔ Treat-to-target approach that identifies treatment responses
- ✔ Improved access to indicators of disease activity

Comparative Value

- ✔ Comparable to MRI and CT enterography
- ✔ Effective for visualizing the small bowel and colon

Current efforts focus on training gastroenterologists to increase the adoption of IUS in clinical practice.[1,2] Future training of advanced practice providers, especially those primarily focused on IBD care,[1] could further benefit patients.

IUS Enhances Care for Patients With IBD: Study[4]

To assess how IUS, alone or in combination with in-clinic sigmoidoscopy, affects clinical decision-making and reliance on endoscopy, 158 patients with **Crohn's disease (78%), ulcerative colitis (11%), or new/suspected IBD (11%)** were evaluated.

IUS detected...

- Active inflammation | **65%**
- Strictures | **14%**
- Median fecal calprotectin levels
  - *Without inflammation:* **50 µg/g**
  - *With inflammation:* **270 µg/g**

How results informed clinical decisions...

- Acute change in IBD-specific medications | **57%**
- Avoidance or delay of urgent endoscopy | **85%**
- Urgent surgical consultation | **3%**

Using point-of-care IUS during a clinical flare significantly enhances the management and delivery of care for patients with IBD, often reducing the need for urgent endoscopy by effectively informing therapeutic decisions.[4]

Evaluating Bowel Wall Thickness, IBD Severity in Children[3]

A 2024 study aimed to evaluate the diagnostic performance of bowel wall thickness (BWT) measured by IUS vs endoscopic disease activity in children suspected of having IBD. A total of 174 bowel segments from 33 children were examined.

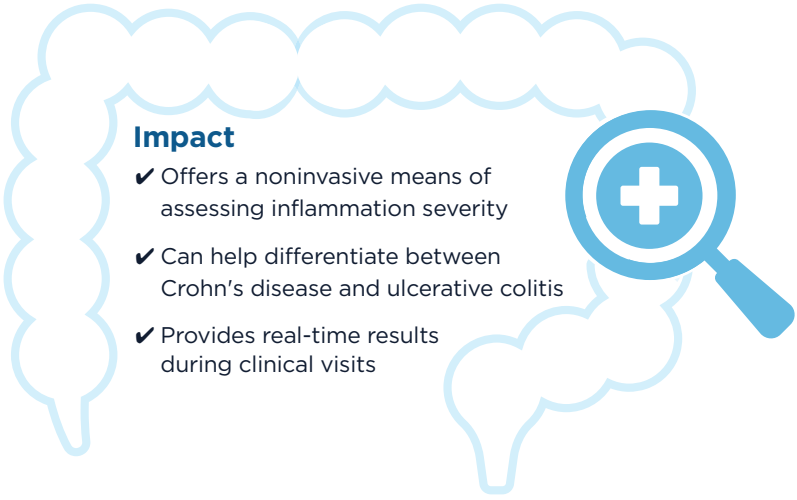
Bedside IUS was effective in visualizing **more than 85% of bowel wall segments.**

Elevated median **BWT was significantly associated with increased bowel-segment disease severity.**

Diagnostic Performance

- Cutoff Value | **1.9 mm BWT**
- AUROC | **0.743**
- Sensitivity | **64%**
- Specificity | **76%**

AUROC, area under the receiver operating characteristic curve



Impact

✔ Offers a noninvasive means of assessing inflammation severity

✔ Can help differentiate between Crohn's disease and ulcerative colitis

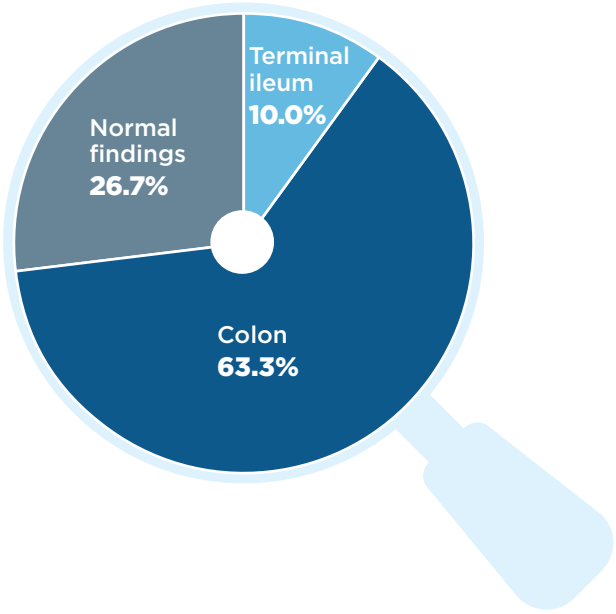
✔ Provides real-time results during clinical visits

Correlations Between BWT and Inflammatory Markers[5]

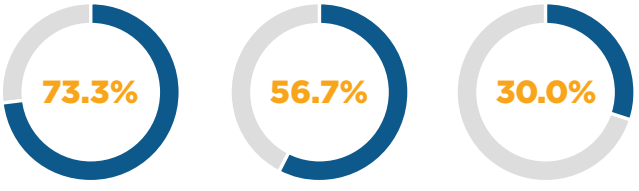
Lastly, a small study of patients with IBD (ulcerative colitis, n = 21; Crohn's disease, n = 9) sought to determine correlations between BWT and wall stratification, color Doppler signal, and inflammatory markers (i.e., hemoglobin, ferritin, C-reactive protein [CRP], and fecal calprotectin).

Key Findings

Lesion Locations



Ultrasound Findings



Increased wall thickness (≥ 3 mm)

Loss of bowel wall stratification

Mesenteric fat hypertrophy

Positive, Significant Correlations with Markers:

- Ferritin | **r = 0.60**
- CRP | **r = 0.49**
- Fecal calprotectin | **r = 0.84**

Obesity Management in the Era of GLP-1 RAs:

The Role of GLP-1 RAs

Michael Camilleri, MD, MPhil, DSc

Since 2022, glucagon-like peptide 1 (GLP-1) receptor agonist (RA) use has increased by more than 100%, whereas other obesity interventions, such as bariatric surgery, have decreased.[1] There is an ongoing debate on the gastroenterologist's role in treating obesity.[2] Obesity has a profound impact not only on diabetes and cardiovascular and neurologic disease, but also on gastrointestinal (GI) conditions and liver health.[2] Thus, obesity is a significant risk factor for other diseases like metabolic dysfunction-associated steatotic liver disease, inflammatory bowel disease, and gastroesophageal reflux disease.

As GLP-1 RA use increases, questions about the risk-benefit profile have arisen, especially among gastroenterologists who assess some of the treatment-related GI side effects. GLP-1 RA benefits extend beyond weight loss and diabetes control, improving cardiovascular and neurological outcomes as well.[3] However, challenges remain. GLP-1 RAs are associated with delayed gastric emptying, which, though generally manageable, raises concerns about rare complications such as aspiration during procedures.[3,4] Despite these concerns, a 2024 study indicates that delayed gastric emptying may normalize in patients over time and rarely, if ever, interferes with clinical practice.[3,4] Moreover, for patients with other GI side effects, such as nausea and vomiting, titration adjustments and slower escalation can be helpful.[5] According to a review of published data, even though there may be some food retained in the stomach at the time of gastroscopy, the risk for aspiration is extremely low and the examination can usually be completed satisfactorily without having to repeat the endoscopy.[3]

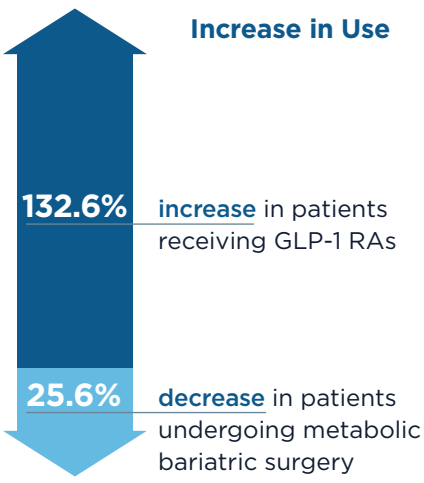
New multisociety guidelines were released in 2024 on the risk for aspiration in patients on GLP-1 RAs during the periprocedural period, emphasizing balancing benefits of obesity treatment with risks for delayed gastric emptying.[6] Although there are many benefits with GLP-1 RAs, questions remain about long-term safety, such as potential impacts on muscle mass and heart health, underlining the need for further research.

GLP-1 RAs vs Bariatric Surgery: Trends in Use[1]

In a study of 1.6 million patients **with obesity** and **without diabetes...**

81,092 patients **were prescribed GLP-1 RAs.**

5,173 patients **underwent metabolic bariatric surgery.**



... between the last 6 months of 2022 vs the last 6 months of 2023

Still, less than 6% of patients with obesity in this study received bariatric surgery or GLP-1 RAs, representing a large untreated population. It is unknown if the trend of decreasing bariatric surgery use will stabilize with the high cost and national shortages of GLP-1 RAs.

GI Side Effects: Delayed Gastric Emptying[4]

of all patients experienced **persistent gastric emptying delay.**

of all patients experienced **persistent gastric emptying delay.**

Of those who had a delay at week 5, **51% had persistent delay,** whereas **49% had normalization at week 16.**

Delayed gastric emptying and the risk for aspiration has been a concern in patients taking GLP-1 RAs. However, 2024 data show that **in most patients, gastric emptying is unaltered by the GLP-1 RA treatment,** or it normalizes over time. Factors that increase risk for delay and resolution remain unclear.

Clinical Guidelines for Perioperative GLP-1 RA Use[6]

The following guidelines have been issued jointly by the American Gastroenterological Association, the American Society for Metabolic and Bariatric Surgery, the American Society of Anesthesiologists, the International Society of Perioperative Care of Patients with Obesity, and the Society of American Gastrointestinal and Endoscopic Surgeons.

Risk Assessment and Management Decisions

- **Shared Decision-Making:** Use of GLP-1 RAs should be based on collaboration among the patient, anesthesia team, and prescribing care providers to balance the need for GLP-1 RAs with surgical risks.
- **Risk Factors:** Consider the potential causes of delayed gastric emptying and aspiration, such as escalation phase, higher dosing, weekly vs daily compound, presence of GI symptoms, and medical conditions that may delay gastric emptying.
- **Assessment:** Evaluate if GLP-1 RA use should be paused; current guidance recommends holding daily regimens on the day of surgery and weekly regimens one week prior to surgery.

Preoperative Preparations

- **Diet Modifications:** Patients should follow a liquid diet for at least 24 hours before the procedure.
- **Gastric Ultrasound:** Assess the risk for retained gastric contents on the day of the procedure.
- **Shared Decision-Making:** If risks are confirmed on the procedure day, options should be discussed with the patient.

Recommendations for the use of GLP-1 RAs in the perioperative period are based on clinical practice experience and may change based on expanded research of anti-obesity medications. Liquid diet for 24 hours before the procedure is particularly recommended and seems to have a positive impact in clinical practice. Gastric ultrasound may be clinically limited based on facility resources, interuser variability, and factors such as patient body habitus.

Ergonomics in Endoscopy

Amandeep K. Shergill, MD, MS

Endoscopy is a major component of the work of gastroenterologists, with 61% of gastroenterologists reporting spending more than 40% of their time performing endoscopic procedures.[1] Endoscopists are particularly prone to sustaining musculoskeletal injuries in their practice, given that current scopes were not designed to accommodate the range of physician hand sizes and strength.[2] In addition, the 2023 American Society for Gastrointestinal Endoscopy (ASGE) guidelines note that the endoscopy volume of the current-day endoscopist makes this a physically taxing career for many operators.[3]

The ASGE systematic review and meta-analysis found an overall endoscopy-related injury (ERI) rate of 57.7%, with survey results ranging from 39% to 89%.[3] These injuries, in some cases, start during fellowship, with 1 in 5 gastrointestinal fellows developing endoscopy-related pain and/or injuries.[4] Musculoskeletal injuries can occur as result of microtrauma caused by the repetitive motions, prolonged awkward postures, and sustained high pinch force used during endoscopy.[5] Additional risk factors for injury include higher procedure volume (> 20 cases per week), more time spent doing endoscopy per week (> 16 hours per week), and cumulative years performing endoscopy.[3]

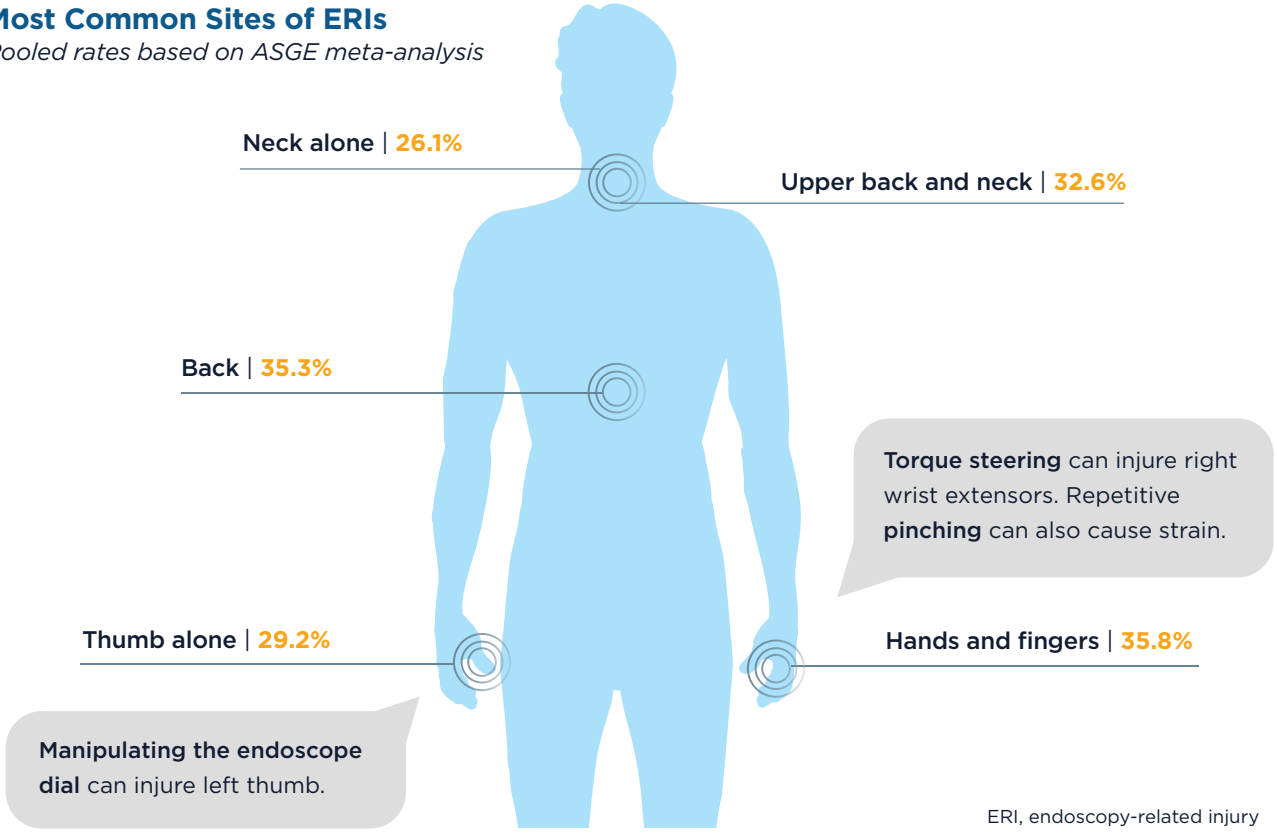
Overview of Endoscopy-Related Injuries[3,5]

ERIs are musculoskeletal injuries caused by repetitive microtrauma to muscles, tendons and nerves. Biomechanical forces that contribute to ERIs include repetitive, high-force loads in non-neutral postures.

The overall rate of ERIs in female endoscopists is **62.4% compared with 45.5%** in male endoscopists.

Most Common Sites of ERIs

Pooled rates based on ASGE meta-analysis



ERI, endoscopy-related injury

Avoiding the Hazards of Endoscopy: Ergonomics as a Guide[6-8]

Preventing disability and facilitating a long and successful endoscopic career involves taking proactive measures that enhance well-being, and ergonomics plays a significant role.

Acknowledge pain—then intervene

- ✔ **Early stage**: Aching, fatigue during work
- ✔ **Intermediate stage:** Symptoms begin earlier and persist at night, possibly reducing work capacity
- ✔ **Late stage:** Persistent symptoms may affect sleep and light tasks

Use the hierarchy of controls

1. **Hazard elimination**
   (e.g., redesign endoscopes to reduce strain)
2. **Engineering controls**
   (e.g., adjustable workstations to fit different users)
3. **Administrative controls**
   (e.g., ergonomic training, scheduling adjustments)
4. **Personal modifications**
   (e.g., individual technique adjustments)

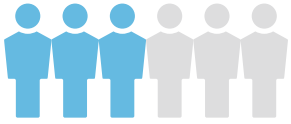
Optimize Suite Setup: Think MYSELF

- **M** - **monitor** -Place monitor directly ahead, 15 to 25° below eye height
- **人** - **(upside down) Y stance** - neutral body posture; straight neck and back, feet shoulder/hip width apart
- **S** - **scope** - check scope/equipment to ensure optimal performance
- **E** - **elbows** - set bed height 0 to 10 cm below elbow height; neutral elbow and shoulder posture
- **L** - **lower extremities** - foot pedals in easy reach, use supportive footwear and antifatigue mats
- **F** - **free movement of scope** - place processor directly behind in line with the orifice to be scoped

Take a break

Schedule breaks during full endoscopy days. **Microbreaks** during procedures reduce pain and improve performance. Incorporate **stretching and exercises** between cases, including routines tailored for endoscopists.

Aging isn't for the frail



50% of gastroenterologists are age ≥ 50 years. Regular exercise can help counteract sarcopenia and maintain strength.

Optimize workstations

- ✔ Maintain neutral, upright posture
- ✔ Adjust chair height for 90° hip and knee flexion
- ✔ Ensure back support
- ✔ Position monitor slightly below eye level
- ✔ Adjust mouse and keyboard for neutral wrist and elbow positioning

Microbreaks and Macrobreaks[3]

Microbreaks

30-second to 2-minute breaks

➤ Result in **31% lower odds** of ERIs

Targeted Stretching Microbreaks

1.5-minute stretching breaks at 20- to 40-minute intervals

➤ Has shown **improvement** in post-procedure pain, physical performance, and mental focus for surgeons

Macrobreaks

15- to 45-minute scheduled breaks throughout the day

➤ Result in **28% lower odds** of ERIs

Incorporating ergonomic breaks into endoscopy practice can significantly reduce the risk for injuries. Evidence supports the use of microbreaks, targeted stretching, and scheduled macrobreaks to reduce the risk for ERIs, alleviate pain, enhance focus, and improve physical performance for endoscopists.

Optimizing the Delivery of GI Care
in Transgender and Gender-Diverse Communities

Kira Newman, MD, PhD

Overall, 1.3% of US adults identify as transgender or gender-diverse (TGD), with a higher prevalence of TGD-identified people in younger generations.[1,2] This finding suggests that all clinicians will provide care to TGD patients.[1,2] TGD individuals are more likely to experience health care discrimination than cisgender individuals, resulting in reduced access to and utilization of care.[2,3] It is important for health care providers, including gastroenterologists and hepatologists, to create a welcoming and gender-affirming environment—offering single-occupancy handicap-accessible bathrooms, displaying nondiscrimination policies, using inclusive intake forms, and providing training for clinicians to increase knowledge of TGD health needs and address biases.[3,4] This type of environment can help reduce negative outcomes for TGD patients seeking care.[3,4] Understanding the minority stress model and trauma-informed care approaches can also be useful for caring for TGD patients.[2,5] A recent study found that up to 51% of gastrointestinal (GI) providers are not at all familiar with trauma-informed care, highlighting the need for further education.[5]

High-quality research on GI conditions in TGD populations is limited, and potential proposed biological effects of gender-affirming hormone therapy (GAHT) are still theoretical. Studies have shown that the prevalence of inflammatory bowel disease (IBD) is similar between TGD and cisgender individuals, and that GAHT does not affect flare-ups of IBD, although the sample sizes have been small.[6,7] Hepatic conditions such as cirrhosis were shown to be more common in TGD communities, which may be largely due to preventable causes of cirrhosis (e.g., alcohol-associated or viral etiologies) and delayed diagnosis and treatment before progression.[8] More research is needed in TGD patients with GI conditions, and best practices for their design and conduct, such as partnering with TGD people, designing studies with cultural humility in mind, using rigorous research methods, and checking for implicit biases in studies, must be followed.[2]

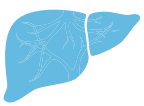
GI Conditions in TGD Patients[2,6-10]

IBD

IBD prevalence (**0.5%** TGD vs **0.6%** cisgender) and **flareups before vs after GAHT** (**53.3%** vs **60.0%**) show **no significant differences.**

Cirrhosis

- Prevalence is **twice as high** in TGD vs cisgender patients: **1,285 vs 561** per 100,000.
- TGD patients also have **higher rates of alcohol** (**57.5%** vs **51.0%**) **and viral** (**30.5%** vs **24.2%**) **etiologies** vs cisgender patients.



Cancers

- Incidence of **viral infection-induced cancers** is **2.3-3.3x higher** in TGD patients.
- **TGD women should be screened for anal cancer** at age 35 (with HIV) or age 45 (without HIV).

Other considerations

Although data on the impact of GAHT and other factors on GI and liver health in TGD patients remain limited, metabolic-associated steatotic liver disease, viral hepatitis, chronic abdominal and pelvic pain, and pelvic floor disorders are also significant concerns for these patients.

HIV, human immunodeficiency viruses

Minority Stress Model for Conceptualizing Care of TGD Patients[2]

TGD individuals are a diverse group with varying biopsychosocial factors and GI needs. **Understanding the complex experiences that TGD patients may experience can help clinicians provide more tailored, sensitive care.**

Stressors can be **structural** (e.g., lack of legal protections), **interpersonal** (e.g., discrimination), or **intrapersonal** (e.g., concealing one's identity).

These can also be **negatively or positively influenced by factors** such as:

- ✔ **Race/ethnicity**
- ✔ **Socioeconomic status**
- ✔ **Gender expression**
- ✔ **Social support**
- ✔ **Political discourse**

Biopsychosocial factors must also be considered.

Psychopathology:
Anxiety, depression, chronic stress

Behavioral detriments:
Sleep patterns, nutrition, fitness, drug or alcohol use

Pharmacologic/anatomic:
GAHT, surgery

Physiological:
ANS reactivity, inflammation, altered HPA axis, HPV, HIV, viral hepatitis

ANS, autonomic nervous system; HPA, hypothalamic-pituitary-adrenal axis; HPV, human papillomavirus

Clinical Guide for Providing GI Care to TGD Patients[2,3]

1. Use **preferred name and pronouns**, without making transgender identity the whole focus.

   "Thank you for sharing that you go by 'Quinn' and use 'they/them' pronouns. While your legal name may appear on some official documents due to government policies for billing, we'll do our best to ensure our team addresses you correctly."

2. **Only ask about gender-affirming care or gender identity if medically relevant** to the patient's chief complaint or preventive care. Consider using an organ inventory for data collection.

   "To provide the best care, I'd like to know which, if any, gender-affirming treatments or surgeries you've had, as they can sometimes affect pelvic floor function. I am going to review a list of the organs and ask if you have ever had surgery to remove or alter them. You can share as much or as little as you feel comfortable."

3. **Do not make assumptions** about mental health conditions, procedures, life experiences, or medications. Walk through potential causes with the patient, **allowing them the opportunity to disclose any pertinent information.**

   "There are many possible reasons for increased liver enzyme levels, including alcohol use, certain medications like testosterone or contraceptives, over-the-counter supplements, and fat buildup in the liver. Let's review your history and explore all potential causes together. I want to reassure you that we'll carefully consider our options before making any recommendations about your hormone therapy."

4. **Do not dissuade** the patient from receiving gender-affirming care. Rather, simply inform them of any known associated risks.

   "Currently, there isn't strong evidence about how estrogen affects IBD symptoms. However, from what we know, it doesn't appear to be harmful. I'll continue to keep you updated on the latest research to best support your care."

New Therapeutic Frontiers
in the Treatment of Eosinophilic Esophagitis

Evan S. Dellon, MD, MPH

Eosinophilic esophagitis (EoE) is a chronic, immune-mediated disease characterized by symptoms of esophageal dysfunction and dense eosinophilic infiltration. The prevalence of EoE continues to increase in the United States, with genetic, environmental, and microbiome factors contributing to its rise.[1] This condition manifests as dysphagia for solid food in adults and adolescents and can lead to esophageal remodeling if untreated; symptoms are non-specific in children. Diagnosis of EoE is per International Consensus Criteria.[2] Management options include proton pump inhibitors, elimination diets, topical steroids, and biologics.[1]

Recent advances in treatment include the US FDA approval of the swallowed topical steroid budesonide oral suspension and of a monoclonal antibody targeting interleukins (IL)-4/IL-13 (dupilumab).[3] The positioning of biologics continues to evolve but, as for other atopic conditions, they are mostly used as "step-up" treatment for more difficult-to-treat patients with EoE. The Index of Severity of Eosinophilic Esophagitis (I-SEE), developed in 2022, has been shown to be a promising clinical tool for assessing and following EoE severity that may ultimately help to better manage treatment modalities.[4,5] After prescribing treatment, careful assessment of symptomatic, endoscopic, and histologic outcomes is needed to determine response.[3] In addition, understanding of various inflammatory mechanisms has led to the ongoing development and evaluation of new biological drugs targeting the Th2 axis and fibrosis.[1,3] More studies are needed to determine the effects of these emerging therapies as well as the long-term outcomes of existing treatments for patients with EoE.

Prevalence and Cost of EoE in the US[6,7]

From 2009 to 2022, there was a **5-fold increase** in cases of EoE:

*From the MarketScan database

There has been a marked increase in EoE prevalence over the past 10+ years, in all age groups and sexes. Because the prevalence of EoE is particularly high in patients presenting with symptoms of dysphagia or food impaction, it is important to consider the diagnosis and perform esophageal biopsies during endoscopy for all patients with dysphagia regardless of the appearance and whenever EoE is on the differential diagnosis.

2024 By the Numbers

2:1 (male:female) prevalence

of patients with upper gastrointestinal complaints were diagnosed with EoE after endoscopy.

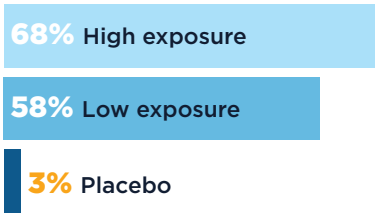
+$1.3 billion in healthcare costs

Recently Approved and Emerging EoE Treatments[8-14]

2024 FDA Approvals

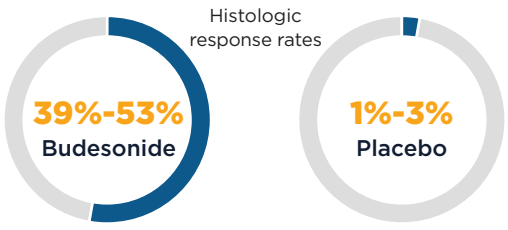
Dupilumab
Anti-IL-4/IL-13 mAb

- The EoE KIDS trial demonstrated **histologic remission in children aged 1 to 11 years** who did not respond to PPIs, leading to the January 2024 expanded FDA approval[a] in patients aged ≥ 1 year and weight ≥ 15 kg.



Budesonide oral suspension
Swallowed topical corticosteroid

- Two 12-week studies demonstrated **significantly improved histologic remission and patient-reported dysphagia** in patients aged ≥ 11 years, leading to FDA approval in February 2024.



[a]Based on the LIBERTY EoE TREET study, leading to the 2022 FDA approval in patients 12+ and 40+ kg.

Trials Underway

Cendakimab
Anti-IL-13 mAb

- A phase 3 trial of patients aged 12-75 with EoE who had not fully responded to ≥ 8 weeks of PPI treatment evaluated mean change in dysphagia days and eosinophil histologic response.
- The once-weekly group had **fewer dysphagia days** and a **higher eosinophil histologic response** vs placebo.
- Cendakimab shows promise in **improving both endoscopic and histologic features**, even in patients who were steroid inadequate responders or intolerant.

Tezepelumab
TSLP mAb

- The phase 3 CROSSING trial includes patients aged 12-80 years and focuses on **esophageal eosinophil count reduction and change in dysphagia symptoms**.
- The trial is **ongoing**, with results to be announced in the future.

Solrikitug
TSLP mAb

- A phase 2 trial includes patients aged 18+ and is evaluating the **reduction in esophageal eosinophil count and change in dysphagia symptoms**.
- The trial is **ongoing,** with results to be announced in the future.

Barzolvolimab
Anti-KIT antibody

- The phase 2 EvolvE trial includes patients aged 18+ and is evaluating **reduction of the number of mast cells** in the esophagus from baseline to week 12.
- The trial is **ongoing**, with results to be announced in the future.

mAb, monoclonal antibody; PPI, proton pump inhibitor; TSLP, thymic stromal lymphopoietin

The Index of Severity of Eosinophilic Esophagitis, I-SEE Tool[4-5]

Domains Assessed

✔ Symptoms and complications
✔ Inflammatory features
✔ Fibrostenotic features

Scoring System

Quantifies the severity of EoE on the basis of clinical symptoms, endoscopic findings, and histologic data

Application

Can be used at initial diagnosis and follow-up visits to track disease progression and guide treatment decisions.

Patient Population

I-SEE is designed for use in adult and pediatric patients with EoE.

The I-SEE tool, which is completed by the clinician, uses a standardized scoring system designed to assess and track the severity of EoE by evaluating various domains. I-SEE helps clinicians quantify disease activity and monitor progression over time, guiding treatment decisions and improving disease management.

New and Emerging Treatments for MASLD/MASH

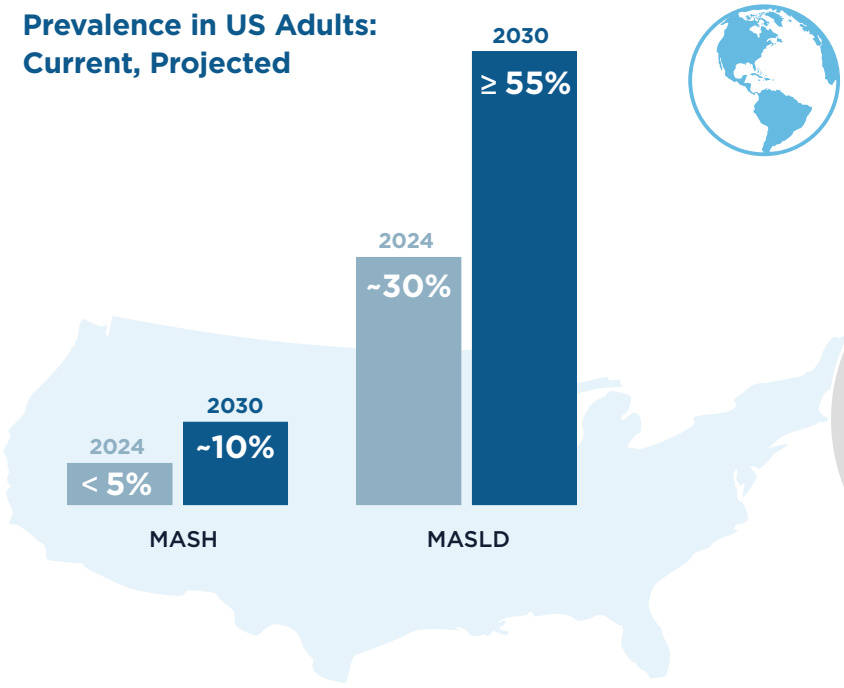
Naim Alkhouri, MD

With the global rise in metabolic dysfunction-associated steatotic liver disease (MASLD), the lack of approved medications is striking.[1,2] Fortunately, during the past year, significant advancements have been made in the US treatment landscape for MASLD. Recent insights into the heterogeneous nature of MASLD have spurred the discovery of novel therapeutic agents and the repurposing of drugs (e.g., semaglutide) available for type 2 diabetes and obesity.[1,3]

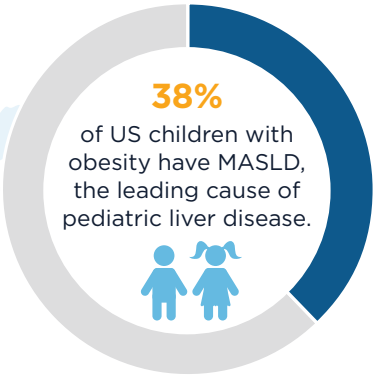
Although lifestyle modifications like diet and exercise remain the cornerstones of treatment,[1,2,4] effective pharmacologic options have been elusive. Numerous phase 3 trials are under way, and more promising therapies will likely become available within the next few years. In 2024, the FDA conditionally approved resmetirom, a thyroid hormone receptor-β selective drug, for treating non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced fibrosis.[4] Although this condition is highly underdiagnosed,[5] combination therapy may improve outcomes,[1,3,6] with greater efficacy for metabolic treatments initiated in the early stages and for liver-targeting drugs initiated in the advanced stages.[3]

MASLD/MASH Burden[5,7-12]

Prevalence in US Adults: Current, Projected



1 billion adults globally are affected by MASLD, the most common liver disorder in the world.



The economic burden of MASLD/MASH in the United States is projected to grow substantially, to over $1 trillion by 2034, highlighting the growing need for improved diagnostic and treatment strategies (and for encouragement of patient lifestyle changes) to effectively manage MASLD and MASH.

4 Main Pathways of MASLD Therapies[1,13-15]

1 Address the link: MASLD and type 2 diabetes

- Incretins
- Thiazolidinedione insulin sensitizers
- SGLT2 inhibitors

2 Reduce liver fat and metabolic stress

- PPAR agonists
- De novo lipogenesis inhibitors
- FGF21/19 analogs
- Bile acid-FXR regulators

3 Address fibrotic changes

- Belapectin (galectin 3 inhibitor)
- Cilofexor (nonsteroidal FXR) + firsocostat (allosteric acetyl CoA carboxylase inhibitor)
- Antioxidants/chemokines and cytokines regulators
- Immune modulators

4 Modulate gut-liver axis

- Probiotics
- Fecal microbial transplantation
- Bariatric surgery
- IMM-124e
- Solithromycin

CoA, coenzyme A; FGF, fibroblast growth factor; FXR, farnesoid X receptor; IMM-124e, hyperimmune bovine colostrum enriched with IgG anti-LPS; PPAR, peroxisome proliferator-activated agonist; SGLT2, sodium-glucose cotransporter 2; TNF, tumor necrosis factor

Promising Phase 3 Trials[2,6,16-20]

Drug/Class	Phase 3 Trials	Primary Endpoint: Status Met?	Designation
Resmetirom **THR-β selective agonist**	MAESTRO-NASH	Improvement in liver fibrosis and MASH resolution at week 52: **Yes** *Accelerated FDA approval, March 14, 2024	Non-cirrhotic MASH with moderate to advanced fibrosis
	MAESTRO-NASH Outcomes	Time to first occurrence of all-cause mortality/ liver-related events: **Ongoing**	MASH with compensated cirrhosis (F4)
Efruxifermin **Bivalent Fc-FGF21 analog/ FGF21 analog**	SYNCHRONY-Outcomes	Fibrosis regression without worsening of MASH after 96 weeks of histology-based treatment: **Ongoing**	MASH with compensated cirrhosis (F4)
	SYNCHRONY-Histology	One-stage improvement in fibrosis and resolution of MASH after 52 weeks: **Ongoing**	Pre-cirrhotic MASH (F2/F3)
	SYNCHRONY-Real World	Assess safety and tolerability: **Ongoing**	Noninvasively diagnosed MASH/MASLD
Lanifibranor **Pan-PPAR agonist**	NATiV3	MASH resolution and improvement in fibrosis by ≥ 1 stage: **Ongoing** *Fast Track and BTD from the FDA for MASH, October 12, 2020	Biopsy-proven non-cirrhotic MASH and F2/F3 fibrosis
Pegozafermin **GlycoPEGylated analog of FGF21**	ENLIGHTEN-Fibrosis	≥ 1 point improvement in fibrosis with no worsening of MASH, and MASH resolution with no worsening of fibrosis at 52 weeks: **Ongoing**	Noncirrhotic MASH with fibrosis (F2/F3)
	ENLIGHTEN-Cirrhosis	Regression of fibrosis from F4 to an earlier stage of fibrosis at 24 months: **Ongoing** *FDA BTD for MASH, September 21, 2023	Compensated cirrhosis (F4)
Semaglutide **GLP-1 RA**	ESSENCE	Liver fibrosis improvement and steatohepatitis resolution with no worsening of liver fibrosis at week 72: **Yes**	Type 2 diabetes, obesity, CV risk reduction Noncirrhotic MASH with fibrosis (F2/F3)
Survodutide **Glucagon/GLP-1 RA**	LIVERAGE	Improve MASH/fibrosis at week 52: **Ongoing**	MASH and moderate or advanced fibrosis (F2/F3)
	LIVERAGE-Cirrhosis	4.5 years or time to first occurrence of all-cause mortality/**liver-related** events: **Ongoing** *FDA BTD, October 8, 2024	MASH and compensated cirrhosis (F4)

BMI, body mass index; BTD, Breakthrough Therapy Designation; CV, cardiovascular; FDA, Food and Drug Administration; FGF, fibroblast growth factor; GLP-1, glucagon-like peptide-1; MASH, metabolic dysfunction-associated steatohepatitis; MASLD, metabolic dysfunction-associated steatotic liver disease; pan-PPAR, pan-peroxisome proliferator-activated receptor; RA, receptor agonist; THR, thyroid hormone receptor

Advances in Screening for Barrett's Esophagus and Esophageal Adenocarcinoma

Joel Rubenstein, MD, MS

Barrett's esophagus (BE) is a metaplastic transformation of the esophageal lining and the sole known precursor to esophageal adenocarcinoma (EAC), a malignancy with a 20% 5-year survival rate and about 16,000 new cases per year.[1-3] Despite a lack of high-quality evidence supporting screening, guidelines suggest screening and focus heavily on endoscopy for individuals with gastroesophageal reflux disease (GERD) and other risk factors.[1] Barriers to screening include reliance on GERD symptoms (given only 50% of individuals with EAC report prior GERD symptoms), provider lack of knowledge about guidelines, and the invasive nature of endoscopy.[4,5] Fewer than 20% of EAC cases are detected as part of screening and surveillance.[6] As many as 85% of individuals with EAC also had at least 1 missed opportunity where screening endoscopy could have been offered earlier.[6]

Predictive algorithms incorporating factors like age, GERD, obesity, and smoking history (e.g., Nord-Trøndelag Health Study [HUNT], Kunzmann, Kettles Esophageal and Cardia Adenocarcinoma predictioN [K-ECAN] tools) have been developed to better identify at-risk populations who should undergo screening.[5,7,8] New screening modalities are also being developed. Non-endoscopic tools, such as EsoCheck with EsoGuard and Cytosponge, offer minimally invasive alternatives for detecting BE.[9,10] Future efforts should focus on enhancing risk stratification, improving the referral process to screen appropriate populations, and integrating new technologies to enable earlier diagnosis and intervention, potentially improving survival outcomes for EAC.

Current Screening Guidelines for BE[1,11-13]

Society (Year of Latest Update)	**Screening Recommendation**
American College of Gastroenterology Guideline (2022)	Screening endoscopy is suggested for patients with chronic GERD and ≥ 3 risk factors: male sex, age > 50 years, White race, tobacco smoking, obesity, or family history of BE or EAC. Nonendoscopic capsule with biomarker can be used.
American Gastroenterological Association Clinical Practice Update (2022)	Screening endoscopy should be considered for patients with ≥ 3 risk factors: male sex, age > 50 years, non-Hispanic White race/ethnicity, history of smoking, chronic GERD, obesity, or family history of BE or EAC. Nonendoscopic cell collection devices can be used.
American Society for Gastrointestinal Endoscopy Guideline (2019)	Screening endoscopy is suggested for patients who have family history of EAC or BE (high risk) or who have GERD and ≥ 1 other risk factor (moderate risk).

Predictive Algorithms for Identifying At-Risk Patients[5,7,8,14,15]

Kunzmann Tool (2018)

- **Based on:**
  - Age, sex, body mass index (BMI), smoking status, history of diagnosis or treatment for esophageal conditions
- **Development Study AUROC**
  - EAC = **0.80**
- **Validation Studies AUROC**
  - Neoplastic BE = **0.76**
  - Incident EAC or gastric cardia adenocarcinoma = **0.76**

HUNT Tool (2018)

- **Based on:**
  - Age, sex, GERD symptoms, obesity, tobacco smoking
- **Development Study AUROC**
  - 5-year risk of EAC = **0.82**
- **Validation Studies AUROC**
  - EAC 10-year-risk = **0.71**
  - EAC 15-year risk = **0.84**
  - Neoplastic BE = **0.80**
  - Incident EAC or gastric cardia adenocarcinoma = **0.77**

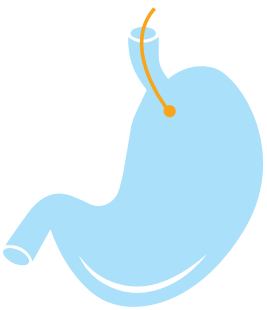
K-ECAN Tool (2024)

- **Based on:**
  - Machine learning to analyze multiple factors and patterns throughout electronic medical records
- **Development Study AUROC**
  - EAC and gastric cardia adenocarcinoma = **0.85**

AUROC, area under the receiver operating characteristic curve

Screening rates for BE and EAC remain low, but predictive strategies can better identify high-risk patients for early detection strategies, including minimally invasive approaches.[5,8,14] Artificial intelligence and machine learning have the potential to further refine risk prediction by integrating vast clinical datasets, but further validation is needed.[8] In clinical studies, other machine learning algorithms have shown similar AUROC (0.84) to K-ECAN.[8,16]

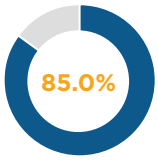
New Screening Modalities for BE and EAC[9,10,17]



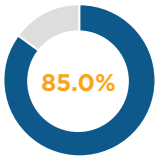
59% of patients who had an endoscopy after a positive Cytosponge screening were diagnosed with BE or esophago-gastric cancer.

EsoCheck with EsoGuard:[10]

Inflatable balloon (EsoCheck) with a 2-gene methylated DNA biomarker panel (EsoGuard)



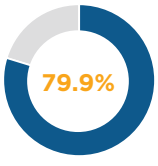
Sensitivity



Specificity

Cytosponge-trefoil factor 3 (TFF3):[17]

Non-endoscopic cell collection device coupled with immunohistochemical staining for TFF3 biomarker



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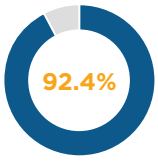


Specificity

EsoCheck with EsoGuard and Cytosponge can be used in the primary care setting to screen patients for BE and EAC.[9,10] These tools are also less invasive and faster than sedated endoscopy, with EsoCheck requiring as little as 3 minutes to collect a sample for testing.[10]

Alagille Syndrome:

Epidemiology and Management of a Rare Genetic Disease

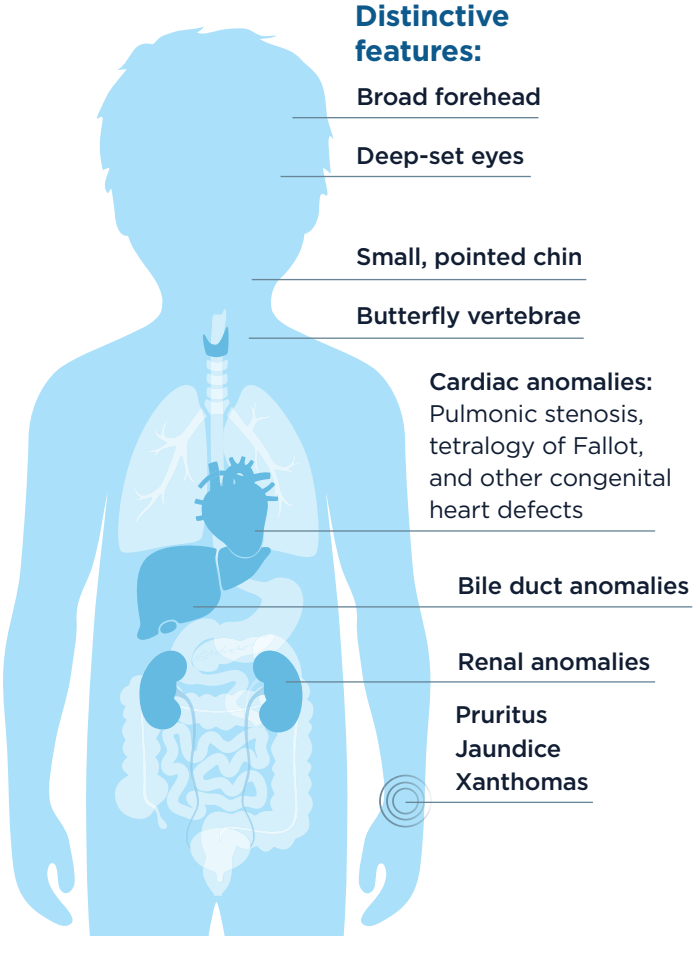
Alisha Mavis, MD

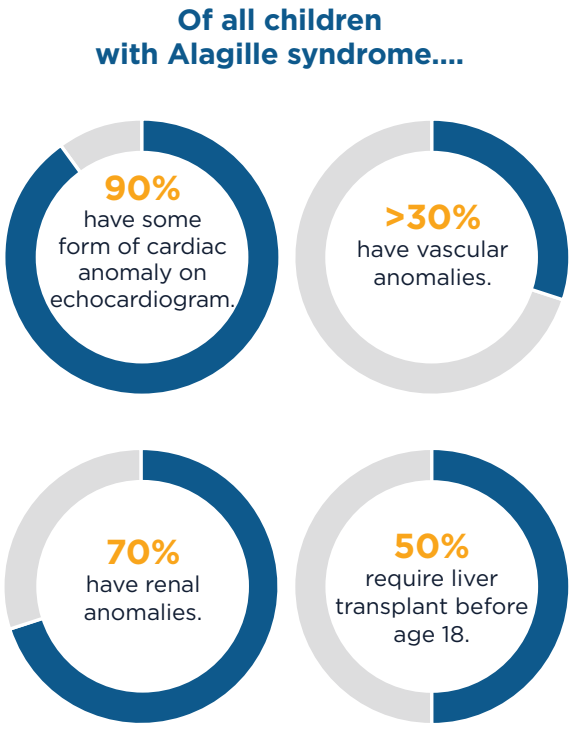
Alagille syndrome (ALGS) is a rare, genetically inherited multisystem disorder that typically presents in early childhood.[1] The condition is attributed to pathogenic variants in the Notch Homolog 2 (*NOTCH2*) and jagged canonical Notch ligand 1 (*JAG1*) genes.[1,2] The incidence of ALGS is estimated to be between 1 in 30,000 to 1 in 1,000,000 individuals.[1]

This condition is characterized by a range of symptoms and anomalies, most notably cholestasis, which can lead to severe liver disease.[1] These anomalies can include renal anomalies, cardiac abnormalities, vascular malformations, bone deformities, eye irregularities, and developmental delays.[1,3] Genetic testing and diagnostic imaging are key in diagnosis.[1] Treatment includes medication to address symptoms—especially pruritus—and liver transplant is not uncommon in these patients.[2]

The Global Alagille Alliance (GALA) Study comprises more than 100 physicians, surgeons, scientists, and research coordinators from 32 countries around the world. This study aims to produce several significant findings regarding ALGS that contribute to a better understanding of the condition and help improve clinical decision-making and patient care.[3,4]

Symptoms and Affected Systems[1,3,5]



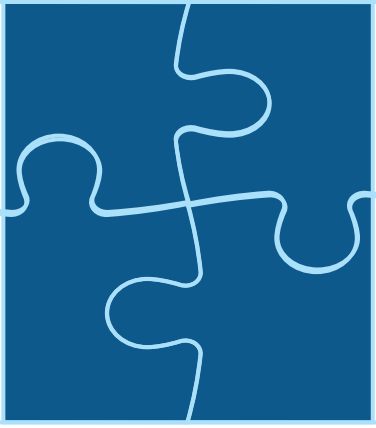


Key Components for Diagnosis and Treatment[1,2,5,6]

Screening for ALGS

Clinical Evaluation
Physical exam
Assessment of clinical features (facial, liver function, cardiac and skeletal anomalies)

Genetic Testing
Helpful for diagnosis
Sequencing *JAG1* and *NOTCH2* genes to identify pathogenic mutations/variations (via blood test or other tissue samples)



Imaging Studies
Echocardiogram
Abdominal ultrasound
Liver biopsy (to assess the extent of organ involvement)
X-ray (to evaluate for butterfly vertebrae)

Laboratory Tests
Blood tests (to measure liver function, cholesterol levels, and other biomarkers)

Managing and Treating ALGS

✔ **Nutritional Support**
High-calorie diets and vitamins (especially fat soluble vitamins: A,D,E,K) for malabsorption issues

✔ **Medications**
Pruritus: cholestyramine, rifampin, ursodeoxycholic acid, antihistamines
Bile acid transport inhibitors: maralixibat, odevixibat

✔ **Liver Transplantation**
For patients with severe liver disease or those who do not respond to medical management

✔ **Cardiac Care**
Monitoring and management of cardiac anomalies (may include medication or surgical intervention)

✔ **Renal and Vascular Anomalies**
Regular check-ups and appropriate interventions

Managing and treating ALGS involves a **multidisciplinary approach** to address the various organ systems affected by the condition.

The GALA Study: Significant Findings[6-9]

Event-Free Survival With Maralixibat
Patients on maralixibat had **substantially improved outcomes.**
HR 0.305 (95% CI, 0.189-0.491; *P* < 0.0001)

Surgical Biliary Diversion (SBD)
SBD may indicate severe hepatic phenotypes and is associated with a **2.5x increased risk** of liver transplantation or death.

Natural History of Liver Disease
Total bilirubin < 5.0 mg/dL in those between 6-12 months of age is associated with **better long-term hepatic outcomes.**

Specialized Monitoring
Disease-specific charts help **monitor growth and development.**

Serum Bile Acids (SBA)
Higher SBA levels are associated with poorer native liver survival. Patients with median SBA levels above 102 µmol/L in the first 3 years had **lower native liver survival** at 8 years of age.

IBS: Mental Health Factors and Comorbidities

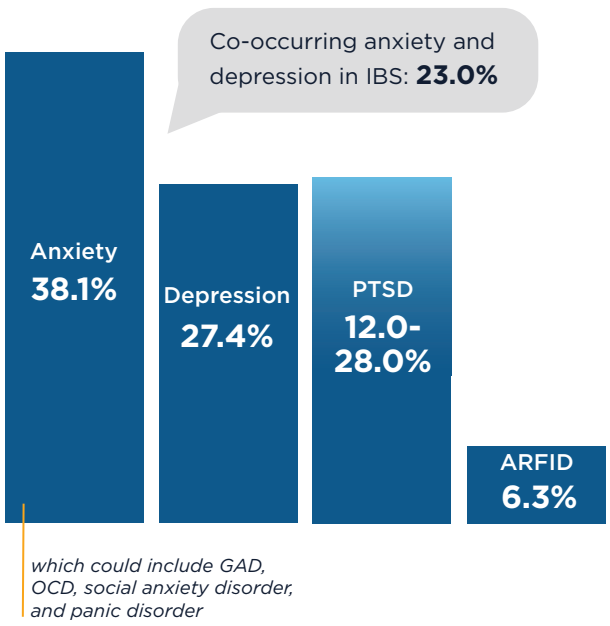
Lin Chang, MD, and Laurie A. Keefer, PhD

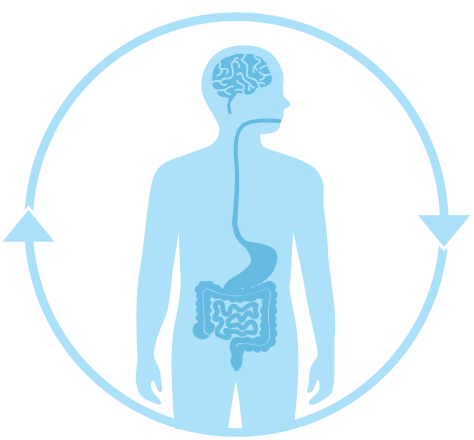
Irritable bowel syndrome (IBS), a disorder of gut-brain interaction, affects up to 10% of the global population.[1] Psychological symptoms often are associated with IBS, increasing its burden and affecting quality of life.[1-3] About one third of patients with IBS experience anxiety or depression.[1] Multidisciplinary care, involving gastroenterologists, psychologists, and dietitians, is crucial to address both physical and emotional symptoms in patients with IBS.[1]

Effective clinical pathways vary by patient profile. Some patients may have maladaptive cognitive processes that affect coping with IBS (e.g., avoidance behaviors and symptom-related anxiety) but do not meet criteria for a psychiatric disorder.[2] For these patients, referral to brain-gut behavior therapy (BGBT) is advised.[2] BGBTs can include cognitive behavioral therapy (CBT), gut-directed hypnotherapy, and mindfulness-based interventions, among others.[3] These approaches can improve not only mental health symptoms and symptom-related stress but also gastrointestinal (GI) symptoms.[4] For patients with psychiatric illnesses, referrals to psychiatrists or psychologists specialized in the patient's specific comorbid condition are recommended.[2] It is also helpful for GI professionals to familiarize themselves with a few antidepressant medications for symptom-specific anxiety or mood symptoms when a psychiatrist is unavailable.[5,6] Some antidepressants, called central neuromodulators, also improve IBS symptoms.[5,6]

Access to integrated IBS care remains a challenge. The number of GI psychologists is limited. Most digital applications aiming to bridge this gap have limitations, such as nonpersonalized approaches and problems with engagement.[7] Other options to provide care for patients with IBS and psychological symptoms include support groups or nurse-led self-management programs, education, patient advocacy organizations, and placement of educational material in clinic waiting areas.[3]

Prevalence of Mental Health Conditions in IBS[1,8,9,a]



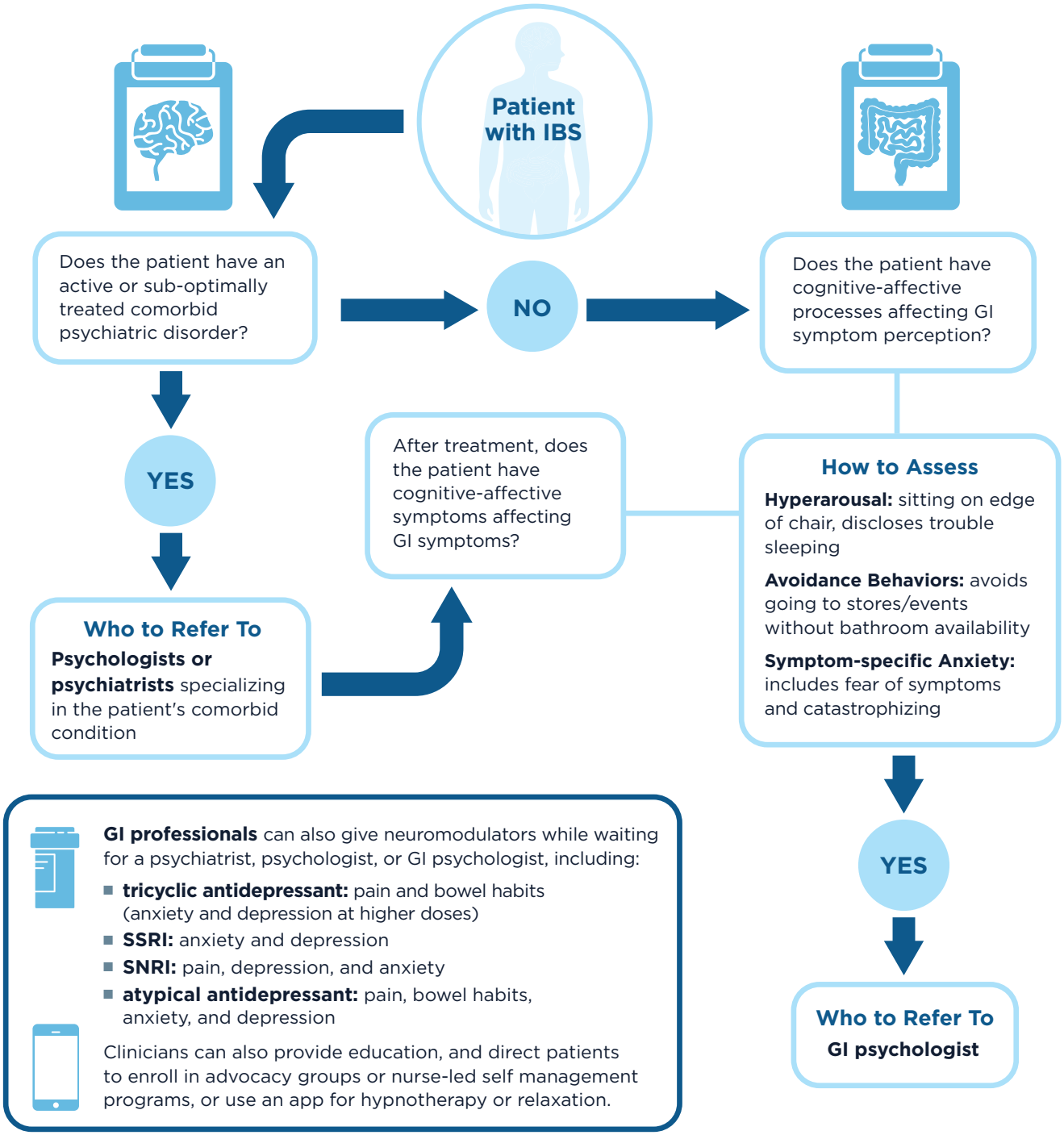


Many patients with IBS have comorbid mental health conditions, and many patients with mental health disorders have gut symptoms.[1] **This bidirectional relationship is attributed to shared biological pathways along the gut-brain axis.[1]**

[a]GI symptom-related anxiety is also common in IBS and is not the same as GAD.

ARFID, avoidant restrictive food intake disorder; GAD, generalized anxiety disorder; OCD, obsessive-compulsive disorder; PTSD, post-traumatic stress disorder

Treatment Framework for IBS With Mental Health Features[1-3,6,7,10,11]



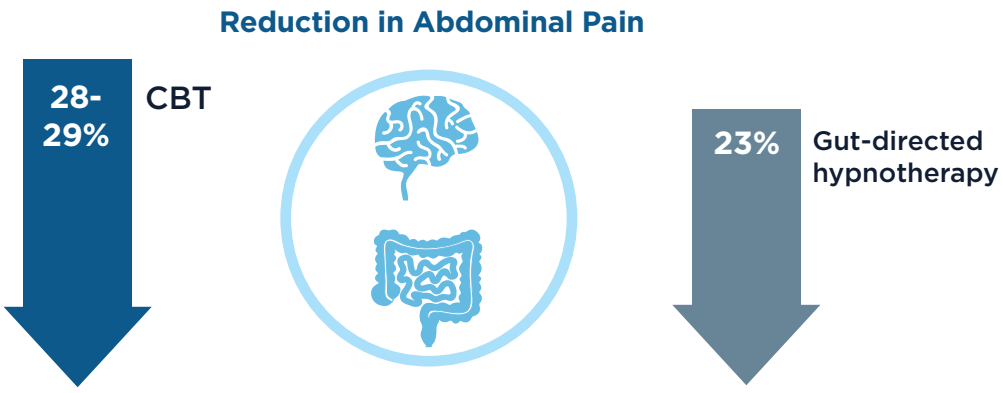
SSRI, selective serotonin reuptake inhibitor; SNRI, serotonin-norepinephrine reuptake inhibitor

Patients with IBS may have a comorbid psychiatric disorder and/or cognitive-affective symptoms related to GI symptoms.[3] The clinician should assess which is the predominant issue.[2] The clinician can prescribe neuromodulators or antidepressants to treat IBS and mood if indicated.[6] If the patient is seeing a psychiatrist, the clinician should work with the patient's psychiatrist about medication changes.[6]

Types of BGBTs and Uses[3,7]

Type of BGBT	Description
Mindfulness-based interventions	Strategies to cultivate nonjudgmental awareness of the present moment
Relaxation training	Diaphragmatic breathing, progressive muscle relaxation, guided imagery
CBT	Reframing unhelpful thoughts about symptoms and their consequences, promoting self-efficacy to manage unpleasant symptoms or situations
Gut-directed hypnotherapy	Physical and emotional regulation of the gut-brain axis, changing the interpretation of symptoms arising from the gut at the level of the brain
Exposure-based therapies	Building courage, testing hypotheses in the real world, managing fear, and tolerating unpleasant symptoms to reach other goals

BGBT Effect on Abdominal Pain[4]



BGBT can address both mental health and GI symptoms. In a meta-analysis of 42 randomized controlled trials (RCTs) in IBS, BGBTs were associated with improvements in abdominal pain.[4] BGBTs appear most effective for patients who accept their diagnosis, understand the gut-brain connection, and are motivated to change.[4] For future RCTs, a suggested focus is an existing behavioral treatment development model that has iterative progression, as in the drug development model, and includes BGBT nuances.[12]

Resources for Patients and Providers[13-18]

- Rome Foundation's website to find GI psychology providers and participate in professional trainings (romegipsych.org)
- Gipsychology.com to find community providers
- *Mind Your Gut* by Kate Scarlata and Megan Riehl
- *Gut Feelings: Disorders of Gut Brain Interaction* by Douglas A. Drossman and Johannah Ruddy
- Tuesday Night IBS
- Nerva (gut-directed hypnotherapy app)
- International Foundation for Gastrointestinal Disorders (IFFGD)

References

The Role of Bedside Intestinal Ultrasound in IBD Management

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