A SUPPLEMENT TO GI & HEPATOLOGY NEWS®

GASTROENTEROLOGY DATA TRENDS 2022

aga American Gastroenterological Association

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Official newspaper of the AGA Institute

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GI&Hepatology News

Produced in collaboration with the **American Gastroenterological Association**.

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Common Abbreviations

CRC, colorectal cancer; **CRP,** c-reactive protein; **CT,** computed tomography; **FDA,** US Food and Drug Administration; **FIT,** fecal immunochemical test; **GALAD,** gender age AFP-L3 AFP DCP; **GERD,** gastroesophageal reflux disease; **GI,** gastroenterology; **HCC,** hepatocellular carcinoma; **IBD,** inflammatory bowel disease; **IL,** interleukin

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The Impact of COVID-19
on Colorectal Cancer Screening Programs

Rachel B. Issaka, MD, MAS

Even before the pandemic, CRC screening was underutilized, despite clear evidence that CRC screening by colonoscopy and stool-based tests was cost-effective and saved lives.[1] On March 18, 2020, national agencies and health organizations made necessary initial recommendations to delay nonurgent surgeries and medical procedures, thus causing unprecedented disruptions in CRC screening.[2] These delays also risked exacerbating persistent racial and ethnic disparities in CRC screening and outcomes, which had been narrowing.[3]

COVID-19's impact on CRC screening was not a singular event. Members of racial and ethnic minority groups, those with limited income, and other historically medically underserved populations were inordinately affected by the disease itself. These populations had the greatest morbidity and mortality from COVID-19,[4] and they were understandably more reluctant to return to care,[5] including CRC screening.

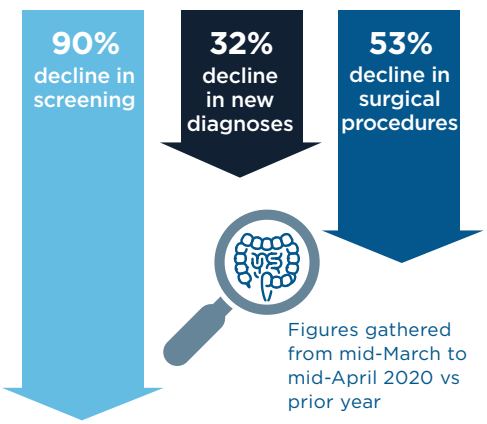
Since the onset of the pandemic, at home stool-based tests, including FIT, have emerged as promising alternatives for CRC screening due to low cost, ease of completion, and preference in low-resourced settings where CRC mortality is high.[6,7] In an integrated health system, a FIT-based CRC screening program increased screening participation[8] and nearly eliminated Black-White mortality differences over a 10-year period.[9] Yet, COVID-19 demonstrated that even small disruptions in such organized programs could have substantial consequences in detecting and preventing CRC.[10]

Mailed-to-the-home, stool-based CRC screening tests, including FIT, offer promise for increasing screening rates,[11] but must be implemented as part of a broader CRC screening program to realize maximal benefit.[12] For example, to ensure that mailed FIT programs do not exacerbate racial and ethnic disparities in CRC outcomes, abnormal results must be followed by a colonoscopy.[13] Thankfully, gastroenterology societies including the American Gastroenterological Association, in partnership with federal agencies and advocacy organizations, are leading the way by providing models that can improve screening and follow-up of abnormal results.[14]

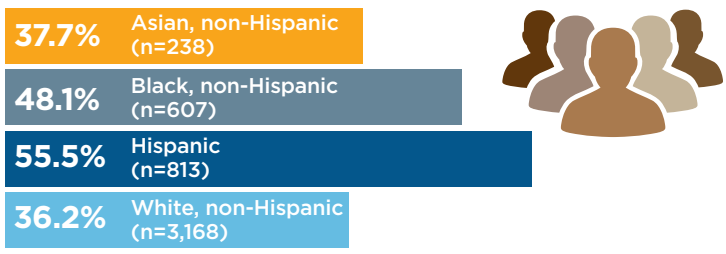
The COVID-19 pandemic has provided our specialty with a clear mandate: To develop long-term solutions that lead to consistent, effective, and trustworthy care for groups who have been historically medically underserved. CRC screening is a valuable way to accomplish this goal.[3,15] Doing so is critical for 2 reasons: (1) to maintain momentum in addressing persistent health care disparities, and (2) to guide efforts toward achieving health equity where gaps in care remain.

Avoidance of Care and Declines in CRC Screening

CRC screening during COVID-19[2]



Avoidance of care by race/ethnicity[5]

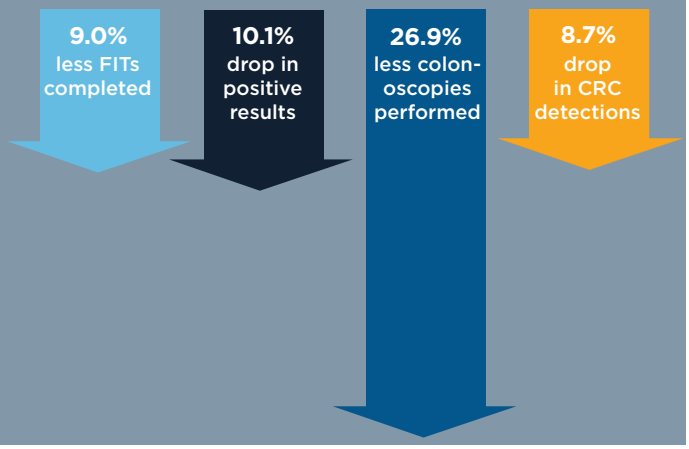


A survey of 4,975 US adults taken weeks after the pandemic started revealed that while most (92.0%) had insurance, **42.3% of them did not seek medical care** of any kind during that time.[5]

Small Temporal Disruptions, Big Consequences[8,10]

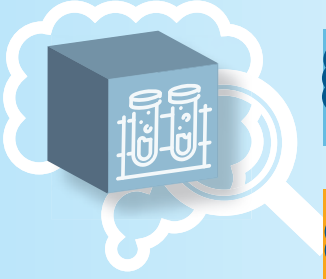
Kaiser Permanente Northern California began a mailed **FIT program** in the early 2000s. Through organized screening, CRC screening rates increased from 38.9% in 2000 to 82.7% in 2015, with similar rates for Black and White insured subscribers and a near-elimination of Black-White mortality differences. **When the pandemic began, Kaiser stopped FIT mailings in mid-March 2020 and resumed a few weeks later.**

Declines from 2019 to 2020



Colonoscopy After Positive FIT Result Leads to Longer Life[13]

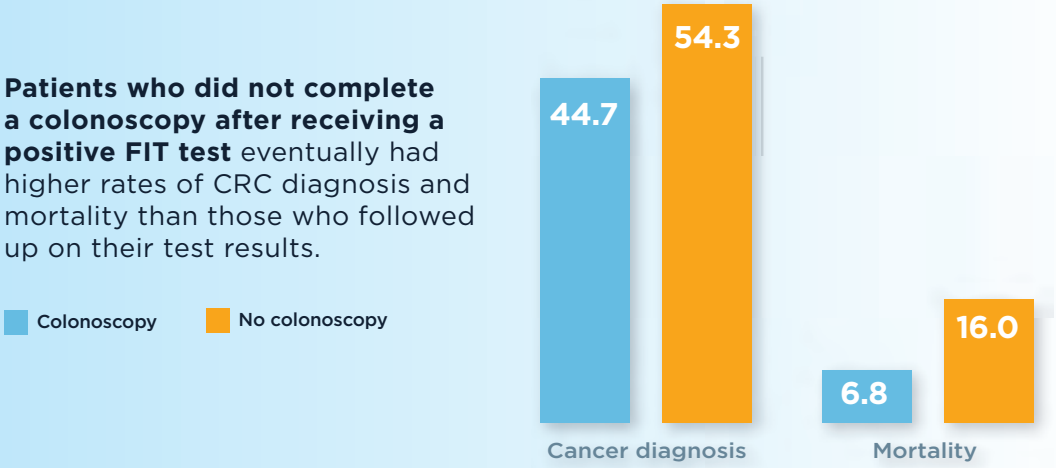
10-year cumulative CRC results



88,013 patients with positive FIT received a colonoscopy

24,410 patients with positive FIT did not undergo a colonoscopy

Patients who did not complete a colonoscopy after receiving a positive FIT test eventually had higher rates of CRC diagnosis and mortality than those who followed up on their test results.



Early Onset Colorectal Cancer:
Trends in Incidence and Screening

Aasma Shaukat, MD, MPH, AGAF

The literature calls early-onset CRC a "distinct disease," because of its molecular characteristics, challenges in diagnosis, and often poor prognosis.[1] Patients with early-onset CRC often have a close family member with colon cancer, yet often ignore symptoms like abdominal pain. Among individuals with a first-degree relative with colon cancer, those younger than age 50 years are half as likely to have undergone a colonoscopy as those 50 years and older.[2] When symptoms do appear, the average time to diagnosis is 128 days for those younger than 50 vs 79 days for those older than 50.[3]

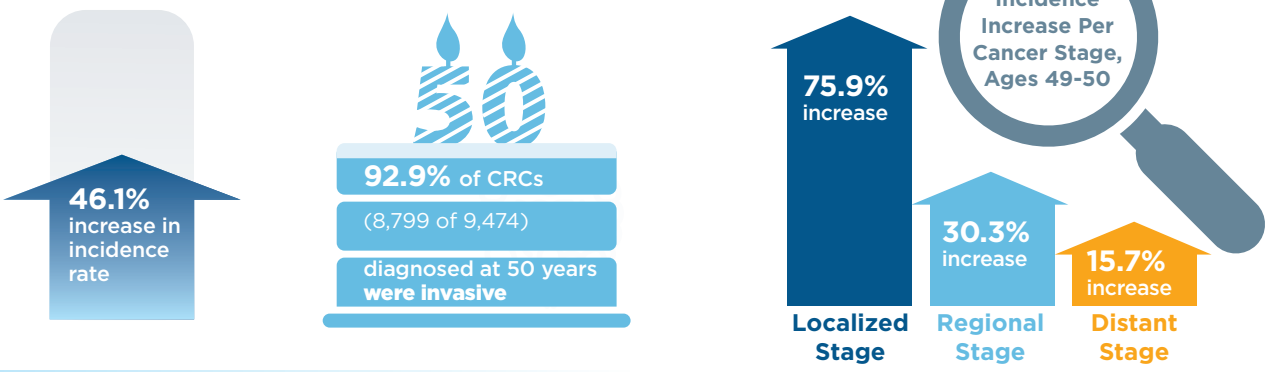
What is important to consider is the life stage in which these patients find themselves. A cancer diagnosis in a patient's 40s—accounting for about three-quarters of early-onset cases[4]—comes in the middle of a career, of raising a family, of living a full life. Therefore, noninvasive screening is so important for those at risk of early onset CRC: An easier screening procedure takes less time than a colonoscopy procedure can consume.

CRC screening rates remain suboptimal, even among persons aged 50 and older. As of 2020, approximately 30% to 35% of adults older than 50 in the United States had never been screened for colorectal cancer.[5] Strategies to improve CRC screening rates include organized outreach programs and use of noninvasive CRC screening tests. These tests do not replace colonoscopy but complement them.

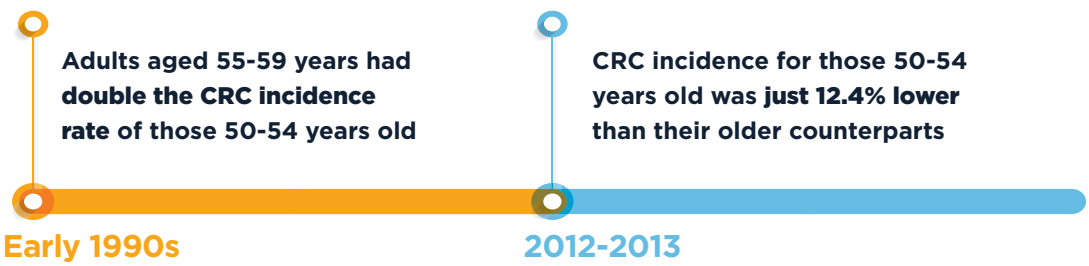
Acceptance of FIT is high and can reduce CRC incidence and mortality.[6] Industry has been working on devising other noninvasive options, which in their newer iterations are starting to show diagnostic relevance.[7] These options may help all individuals due or overdue for CRC screening.

Incidence of Early-Onset CRC Based on Surveillance, Epidemiology, and End Results (SEER) 2000-2015 Registries[8]

Notable changes in those diagnosed at 49-50 years over a 15-year span



To put these data in perspective...[2]



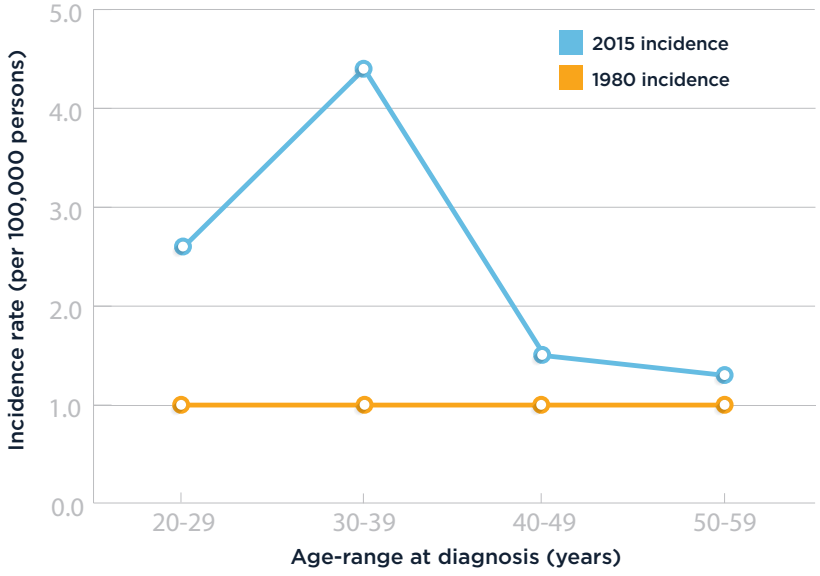
Red Flags for CRC Risk[9,10]

Signs and symptoms might be the same in CRC diagnosis at any age.

Common symptoms include:

- **Rectal bleeding**
- **Change in bowel habits**
- **New-onset or unexplained anemia**

Age of Early-Onset CRC Diagnosis Based on SEER Cohort (1980-2016)[3,a]



[a]Based on rectal cancer numbers. **CRC,** colorectal cancer; **SEER,** Surveillance, Epidemiology, and End Results.

Risk Factors of Early-Onset CRC[10]

Odds ratios represent probability of developing CRC compared to those without these risk factors.

1.41 Male Caucasian

4.13 Family history

1.33 Sedentary lifestyle

1.52 Alcohol use

1.42 Obesity

3.20 IBD

Noninvasive CRC Screening[11-13,a]

FIT, which tests blood in stool, is appropriate for assessment of the lower intestines.[12]

FIT-DNA goes 1 step further and looks for altered genetic material in the colon.[13]

A colon capsule endoscopy involves swallowing a large pill that contains a camera that can take video of the intestines.[12]

FIT

Sensitivity[a] **79%**

Specificity **94%**

Pros/Cons
- No bowel prep
- Sensitivity drops for advanced adenomas

FIT-DNA

Sensitivity[a] **92.3%**

Specificity **94%**

Pros/Cons
- Better than FIT in detecting CRC and advanced lesions
- Higher false-positive rate than FIT

Image screening

CT colonography (adenomas) ≥6mm[b]

Sensitivity[a] **73%-98%**

Specificity **89%-91%**

CT colonography (adenomas) ≥10mm

Sensitivity[a] **67%-94%**

Specificity **96%-98%**

Pros/Cons
- Radiation can accumulate over years
- False-positive rate increases with age

[a]Data determined by pooled studies.
[b]Covers smaller and larger polyps.

Diversity in the Gastroenterology Workforce

and its Implications for Patients

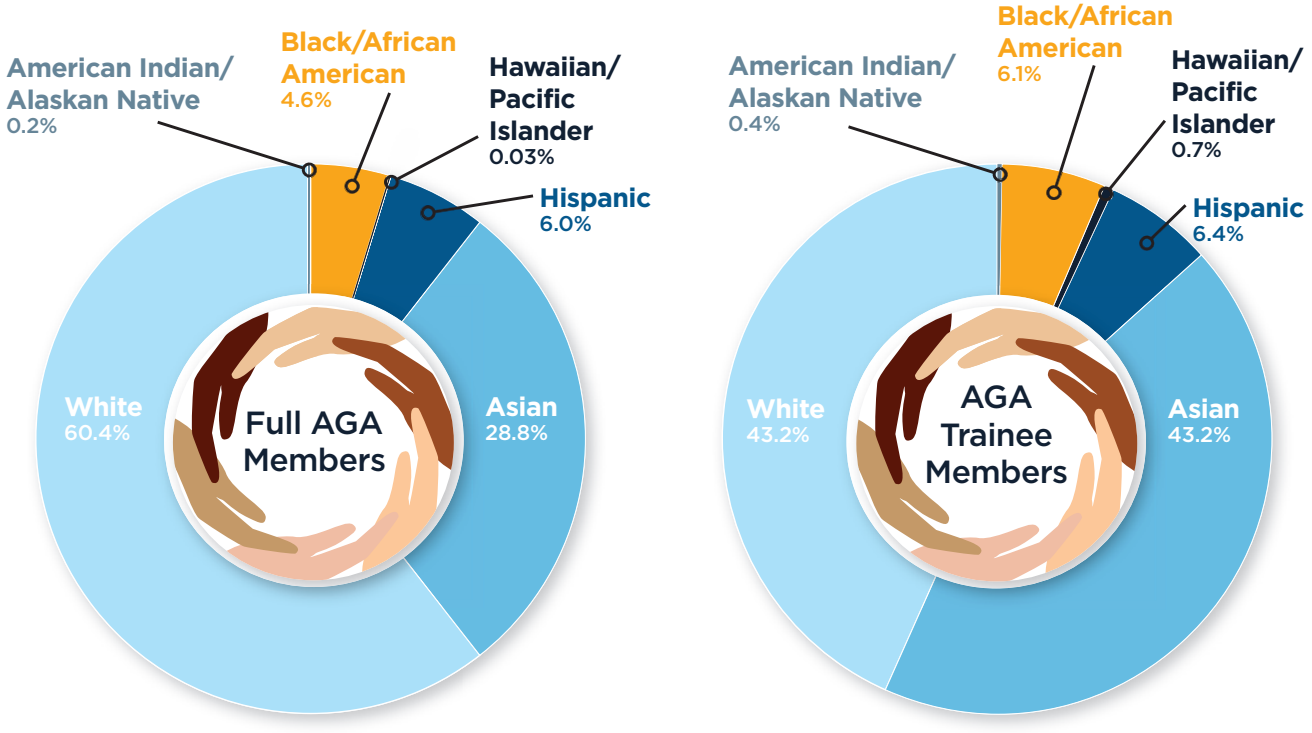
Sandra M. Quezada, MD, MS, AGAF

As the US population has become more diverse, the medical community has advocated for students, faculty, and curricula to reflect these changes. Understanding and addressing a patient's culture and socioeconomic situation is vital to their well-being, and physicians who share in the cultural backgrounds and lived experiences of their patients are more likely to bring this insight and understanding to medicine.[1] Yet over the last 2 decades, diversity among medical faculty is largely unchanged. One author recently wrote that students who are Black, Indigenous, and people of color (BIPOC) would be hard-pressed to find role models that look like them, as these populations are underrepresented among medical faculty.[2-4]

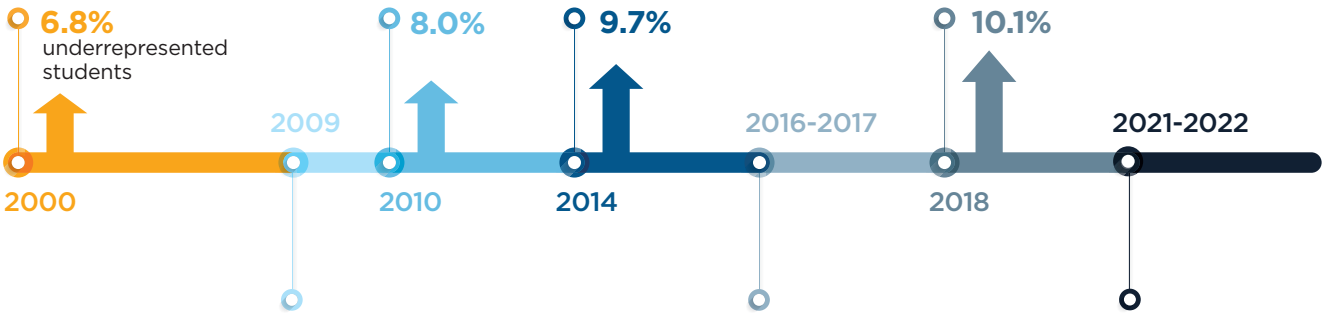
In 2020, the upsurge of the Black Lives Matter movement combined with the COVID-19 pandemic's exposure of health disparities prompted society to better acknowledge socioeconomic inequalities and health organizations to revisit these issues.[5,6] The AGA has introduced many crucial initiatives in collaboration with its Diversity Committee, including the AGA Equity Project – a multiyear strategic plan designed to: eliminate health disparities and inequities in access, support GI research that aligns with the realities of multicultural patient populations, and educate AGA members and staff about unconscious bias.[7]

Further diversification of the gastroenterology workforce will ultimately benefit all patients – perhaps most notably patients from diverse backgrounds and lived experiences. Diagnosis and treatment outcomes in multiple digestive-tract diseases are disparate across different races and ethnicities. The literature has demonstrated that patients are more comfortable discussing sensitive health issues and undergoing procedures in the care of doctors with whom they share a similar cultural background.[8,9]

AGA Member Demographics in 2020[6]



Within US medical schools, the proportion of racially/ethnically underrepresented students has increased at a minimal pace since the early 2000s.[3,10-12]



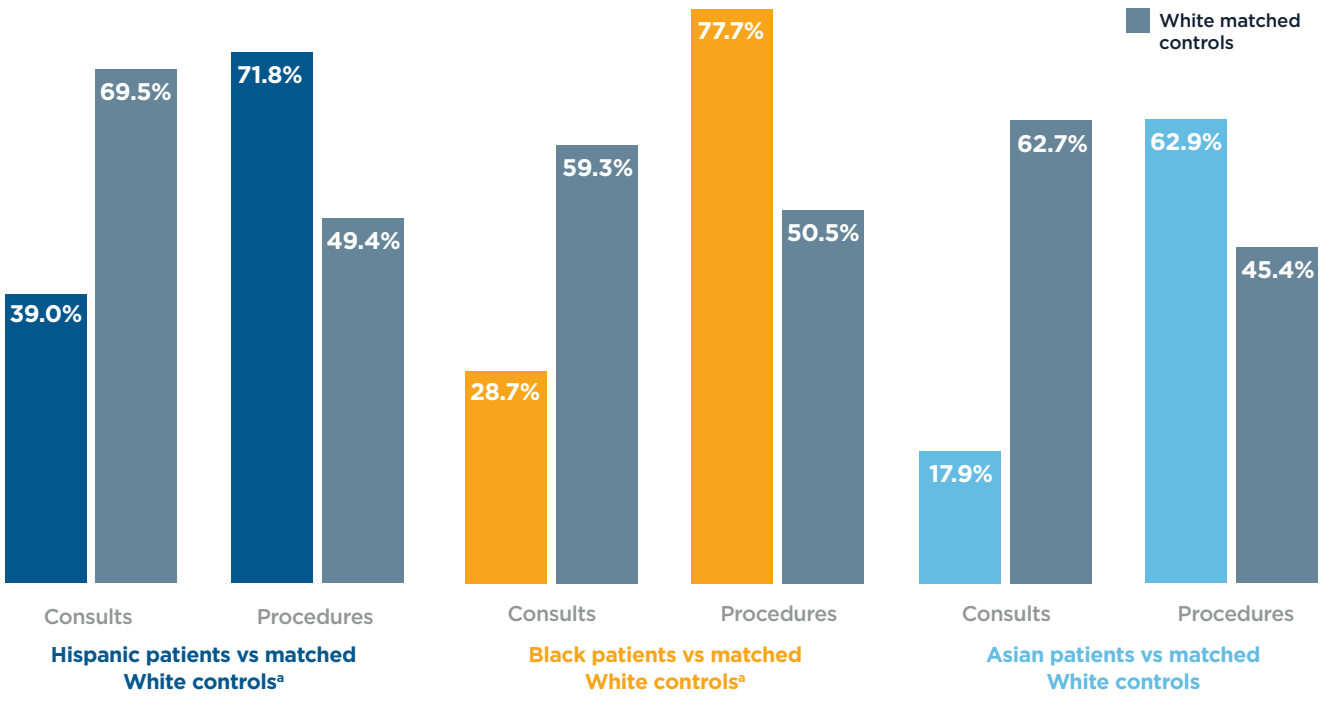
Association of American Medical Colleges (AAMC) establishes new guidelines for diversity accreditation

A survey of more than 28,000 medical students found that 17.7% reported a perceived lack of respect for diversity among school faculty

AAMC reveals that diversity among medical school enrollees is up 18% from the prior year, driving the need for increased representation and education among faculty

Outcomes in Diverse Patient Populations With IBS[13]

Lack of cultural training may lead to poor communication and less favorable outcomes for diverse patients. A 14-year study found that White patients received significantly more gastroenterology consults—and ultimately, fewer procedures—than their Hispanic, Black, and Asian counterparts.



[a]Highly significant, $P < .001$

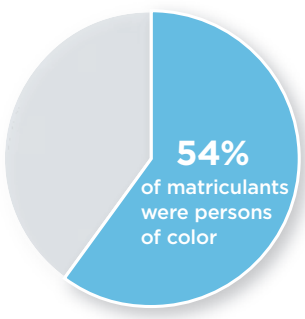
Diversity Pipelines: Mitigating Bias at Medical School Admission[14]

To recruit a more diverse group of students to enter the future physician workforce (including in gastroenterology), the University of Maryland School of Medicine implemented a multipronged approach in 2018 to mitigate bias and optimize equity in the selection process.

The plan's components:

- **Increase ethnic, gender, and racial diversity on the admissions committee**
- **Train committee members and interviewers to recognize and interrupt implicit bias**
- **Update recruitment materials to reflect a more diverse student population and establish stronger connections to undergraduate and graduate programs with diverse student populations**
- **Use holistic screening that de-emphasizes the Medical College Admission Test (MCAT)**
- **Change the interview process by blinding interviewers to candidate grade point averages and MCAT scores**

Results:



By comparison, over 60% of the surrounding Baltimore area identify as Black or African American.

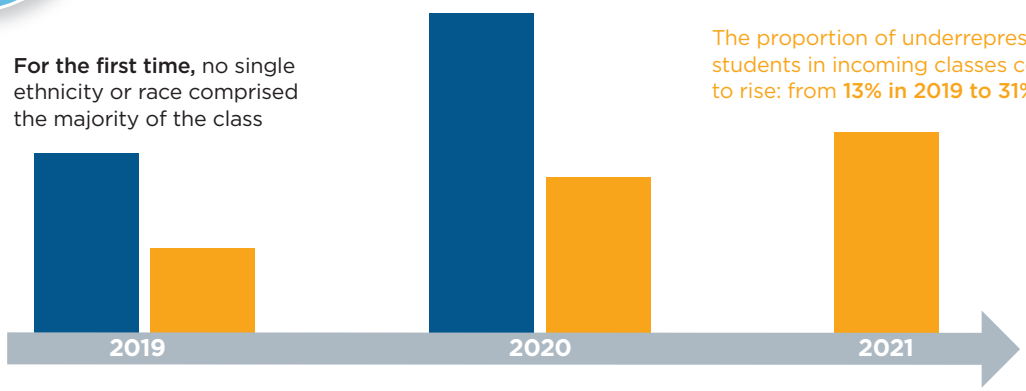
Accepted underrepresented students choosing to enroll

Proportion of underrepresented students in incoming class

The number of accepted underrepresented applicants who chose to enroll rose from **28% in 2019 to 49% in 2020.**

For the first time, no single ethnicity or race comprised the majority of the class

The proportion of underrepresented students in incoming classes continues to rise: from **13% in 2019 to 31% in 2021**



Trends in Surveillance and Management of Dysplasia in IBD

Joseph D. Feuerstein, MD, AGAF

The prevalence of IBD has nearly doubled worldwide since the early 1990s, with popularity of the Western diet and increased alcohol consumption both being implicated in this rise within the United States and other countries.[1-3] IBD serves as an important risk factor for developing colorectal cancer (CRC); risk of CRC rises from 2% 10 years after developing ulcerative colitis to 18% after 30 years.[4]

Successful bowel prep and highly skilled endoscopists are just some of the factors that affect screening results for CRC in IBD.[5,6] New technologies and drugs are changing the treatment paradigm. Endoscopic technologies and biologics for mucosal healing have elicited this shift to a treat-to-target approach.[7-9]

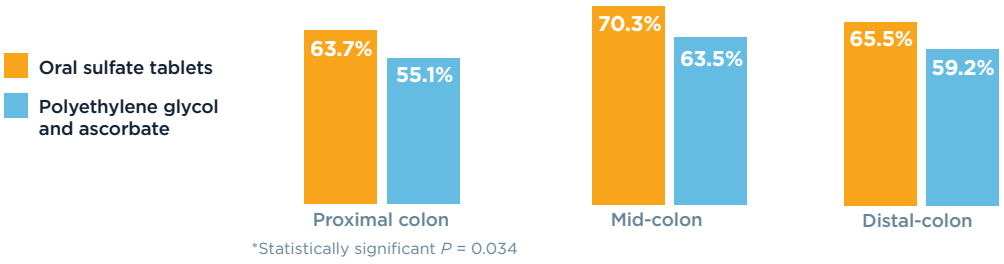
Because IBD is occurring in younger populations, earlier targeted treatment of the inflamed state caused by IBD also has been emphasized.[10] The earlier IBD is treated and put into remission, the less risk of CRC – with studies suggesting CRC rates for such patients may be comparable to that of the general population.[11] As IBD prevalence increases across age groups, races and ethnicities, and geographical locations, gastroenterologists need to consider IBD as a feasible diagnosis and take action early on to mitigate their patients' risk of developing colon cancer.[4,7]

Snapshot of AGA Best Practices for Endoscopic Surveillance and Management of Dysplasia in IBD[7]

1. Precancerous lesions in IBD should be described as polypoid (≥2.5 mm), nonpolypoid (<2.5 mm), or invisible (detected on nontargeted biopsy).
2. Factors that can be used to describe visible precancerous lesions can include size, morphology, clarity of borders, ulceration, location, presence in an area of colitis (past or present), completeness of resection, and special techniques used for visualization.
3. Patients with colonic IBD should receive colonoscopy screening for dysplasia 8-10 years after diagnosis; Take staging biopsies from multiple segments to assess disease activity and extent and guide surveillance intervals.
4. Optimize conditions and practices for dysplasia detection: Control of inflammation, use of high-definition endoscopes, bowel prep, careful washing and inspection of mucosa, and targeted sampling of irregularities.
5. Perform targeted biopsies on suspicious or inexplicably different mucosal findings.
6. Consider dye spray chromoendoscopy in patients with colonic IBD undergoing surveillance colonoscopy.
7. Virtual chromoendoscopy may also be used in patients with colonic IBD when using high-definition endoscopy.
8. Approximately 4 nontargeted biopsies every 10 cm should be taken in areas previously affected by colitis.
9. All clearly delineated dysplastic-appearing lesions without stigmata or submucosal fibrosis should be considered for resection.
10. Invisible dysplasia findings should lead to repeat examination using high-definition dye spray chromoendoscopy with biopsies in areas of prior dysplasia.
11. After a negative colonoscopy screening, colonoscopies should be preformed every 1-5 years based on risk factors for colorectal cancer.
12. Pouch surveillance should be preformed in those at high risk for dysplasia, as well as in those with moderate to severe pouchitis and pre-pouch ileitis.
13. Targeted biopsies of pseudopolyps is appropriate during colonoscopy. Removal and sampling of all lesions is not required. Surgery should be a last resort to manage colorectal cancer risk with pseudopolyps.
14. Optimal disease control with medical therapy is necessary for minimizing lifetime colorectal cancer risk.

Effective bowel prep is needed to carefully evaluate the mucosa for signs of dysplasia and to visualize polyps clearly.[5] New bowel prep methods have been explored to improve consumption of prep liquids for patients.[12] A study of 515 adults assessed the traditional prep compared with a new sulfate-based method.

Comparing Traditional Bowel Prep Methods to Sulfate-Based Methods[12]



*Statistically significant *P* = 0.034

Patients Achieving an "Excellent" Segmental Cleansing Rating

Along with a good cancer surveillance program for IBD, new technologies have fine-tuned treatment options and markers for healing.[8] Emphasis has been placed on mucosal healing in IBD, and newer endoscopic technologies have helped assess subtle dysplasia and allow for removal of precancerous dysplasia, avoiding major resection of the colon at a later date.[8] As well, new small molecules aim to target the inflammation of the GI tract mucosa caused by IBD.

New Technologies in IBD Dysplasia Detection Rate[8]

Technology Type	Dysplasia Detection Rate
• High-definition white light endoscopy (HD-WLE)	Improved dysplasia detection rate compared with non-HD-WLE
• Chromoendoscopy	Comparable to HD-WLE
• Artificial intelligence	Promising results for detecting inflammation, but similar to human reviewers

New Medications for IBD: Efficacy and Strengths[13-16]

- **SP1** (sphingosine 1-phosphate) receptor modulators: **34.0% mucosal healing at 8 weeks**
- **JAK** (Janus kinase) inhibitors: **34.7% mucosal healing at 8 weeks**
- **IL-23** (interleukin-23) p16 inhibitor: **45% clinical remission at 12 weeks**
- **TNF** (tumor necrosis factor)-alpha inhibitors: **48.6% mucosal healing at 1 year**
  - » The most commonly prescribed agents for IBD, the oldest treatment

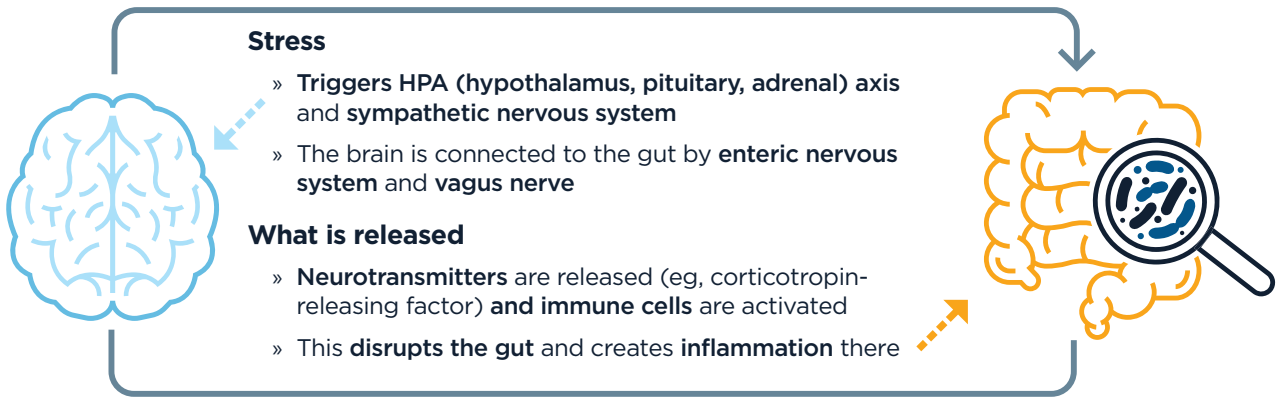
Environmental Factors in IBD:
Diet and Stress

Ashwin Ananthakrishnan, MBBS, MPH

A multitude of environmental factors affect the presentation, outcome, and treatment of IBD.[1] An expert consensus statement, published in April, discussed these environmental factors and provided guidelines in their management.[1] Of the many environmental factors examined, 2 commonly reported triggers were stress and diet. Stress-related mental health conditions are common in IBD, with 21.1% of patients with IBD reporting anxiety and 25.5% reporting depression.[2] Biologically, stress has been linked to changes in the gut microbiome, which may contribute to intestinal inflammation.[3] Modifying stress has also been shown to improve quality of life in patients with IBD and potentially decrease relapses.[4]

Among the various dietary factors examined, both individual macronutrients or micronutrients and broad dietary patterns such as a Mediterranean diet can positively influence both IBD symptoms and inflammation. In addition to nutritive content, the consumption of processed foods may also play a role in the development of IBD. In prospective cohorts, a diet high in ultraprocessed foods was associated with an increased risk of IBD.[5,6] Along with assessing dietary changes, studies examined how a patient feels his diet affects his symptoms.[7] As for technology, apps have been developed that help patients track their dietary and lifestyle behaviors and aim to improve IBD symptoms.[8] Overall, environmental factors such as these play an important role in IBD etiology, presentation, and treatment, highlighting the importance of more comprehensive approaches that incorporate dietary and psychological interventions in the management of IBD.[1]

Stress and IBD: From the Brain to the Gut[3]



Effects of Psychological Intervention on IBD Symptoms and Quality of Life[4]

8-Session Psychological Intervention: Covers psychoeducation, coping skills, stress management, emotion regulation, and problem-solving skills

Decreases in stress
pre to post (intervention group)
» Disease-related Stress Scale: change from **45.7 to 40.6** in the intervention group (*P* = 0.000)
» Perceived Stress Scale (PSS): change from **28.0 to 25.1** in the intervention group (*P* = 0.001)

Increases in quality of life
pre to post (intervention group)
» Quality of Life in IBD (IBDQ): change from **164.2 to 176.2** in the intervention group (*P* = 0.001)

Decreases in relapses
between intervention and control
» Relapses per patient: intervention **0.3 vs control 0.7**
» Relapses per month: intervention **0.03 vs control 0.07**

Effect of Mediterranean Diet on IBD Symptoms and Biomarkers[5]

- **Decrease** in inflammatory biomarkers, C-reactive protein, and fecal calprotectin
- **Decrease** in BMI
- **Reduced** liver steatosis

- **Improved quality of life**

Effect of Ultraprocessed Foods on IBD Symptoms[6]

- Patients who eat the highest amounts of ultraprocessed foods are at a **1.7× increased risk of Crohn's disease**

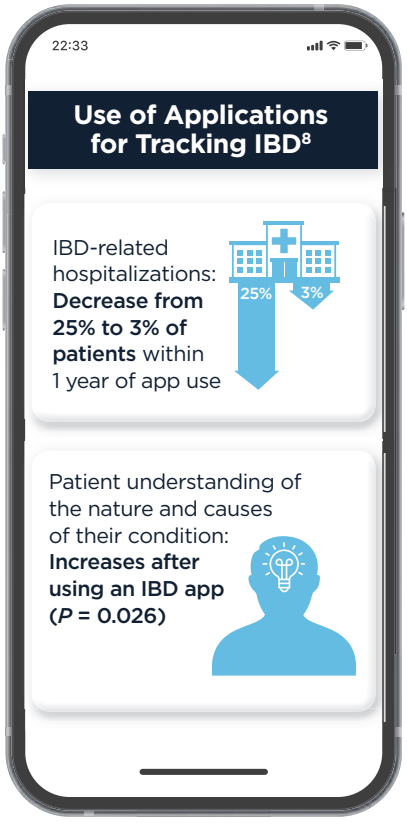
1.7x

- Ultraprocessed breads and breakfast foods, frozen ready-to-eat foods, cheese, spreads, and gravies **result in the strongest risk of Crohn's disease**

Mobile device applications are being developed to track behaviors and symptoms in IBD. In a small study, the effect of the apps was tracked across different patient outcomes.[8]

Patient Beliefs: Dietary Impact on IBD[7]

- **31%** believe diet initiated their IBD symptoms
- **37%** believe diet could trigger IBD relapse
- **59%** avoid dietary components to avoid relapse



Evolving Therapeutic Goals in Crohn's Disease Management

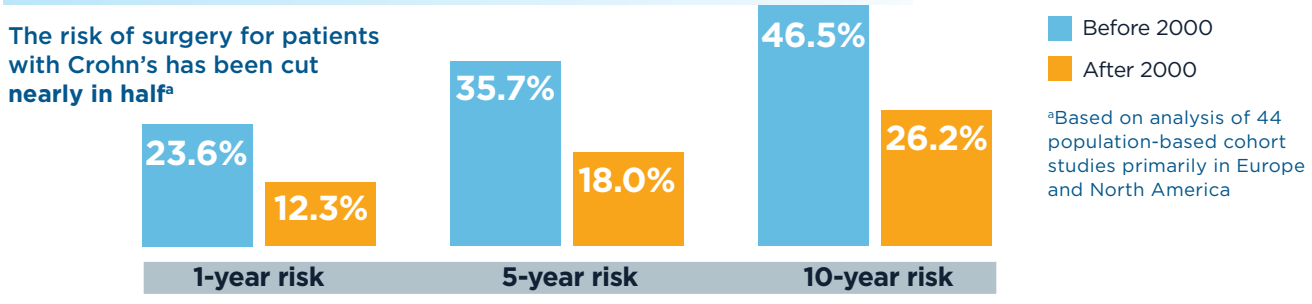
Ryan Ungaro, MD, MS

Over the last 2 decades, the armamentarium for Crohn's disease has expanded with the introduction of targeted biologic therapies. Beginning with the approval of infliximab by the FDA in 1998, the treatment options for Crohn's disease have greatly improved.[1] Although steroids are still prescribed too frequently, novel therapies now can limit the use of steroids in these patients.[2] In addition to anti-tumor necrosis factor alpha (anti-TNF-alpha) biologics, new therapies that target integrins, interleukin (IL)-12/23, and IL-23 have also demonstrated efficacy in inducing and maintaining clinical and endoscopic remission of Crohn's disease.[3]

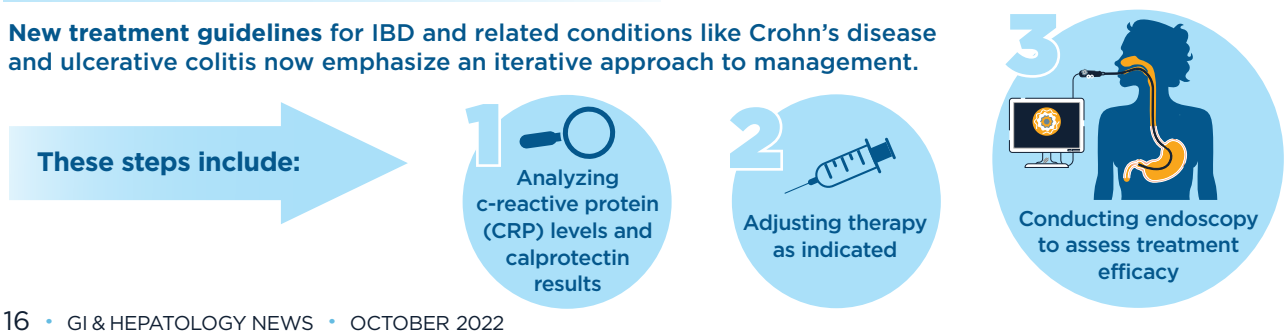
Other studies have shown what consistent therapeutic control can do for patients with Crohn's disease. Effective therapies can maintain remission and even halt progression to complications if the disease is identified and treated in its early stages.[4,5] Since the early 2000s, a significant drop in risk for surgery among patients with Crohn's has also been observed because of improved management.[6] Of course, patient acceptance and adherence to their regimens is critical. Patients who understand they need on-time treatment, have access to appropriate treatment, and get their questions answered in a timely fashion will be more adherent than those who do not.[7] A key advance in management is the adoption of a treat-to-target strategy in which the therapeutic goal has evolved beyond symptom improvement to include the achievement of objective metrics of remission, in particular endoscopic healing.[8]

These successes are juxtaposed against Crohn's disease incidence and prevalence figures, which are rising mostly everywhere.[9] In 1999, 1.8 million adults in the United States had the disease; in 2015, that figure was 3.1 million.[10] Crohn's disease, usually considered a younger adult disease, is also growing in incidence in adults older than 60 years.[9] While the underlying causes of this disease are not well understood, its development involves environmental factors, dysregulated innate and adaptive immune systems, and genetic predisposition.[11] With increasing investigation focused on understanding the disease's initial triggering events and how environmental factors, like diet, affect Crohn's disease, there is hope these research findings will lead to better management and treatment options.[12]

Benefits of Effective Disease Management[6]



Making Treatment Decisions[8]



Clinical Assessment[13,14]

With Crohn's disease, a decrease in symptoms is not necessarily indicative of a decrease in objective inflammation.

Symptoms include:

Mild

- Changing eating and drinking habits
- < 10% weight loss
- CRP levels above normal

Moderate

- Treatment for mild disease ineffective
- No obvious obstruction
- CRP levels above upper limit of normal (5 mg/l)

Severe

- High fever
- Obstruction or abscess present
- Symptoms persist despite extensive treatment
- CRP further increased

Medication Progression[15]

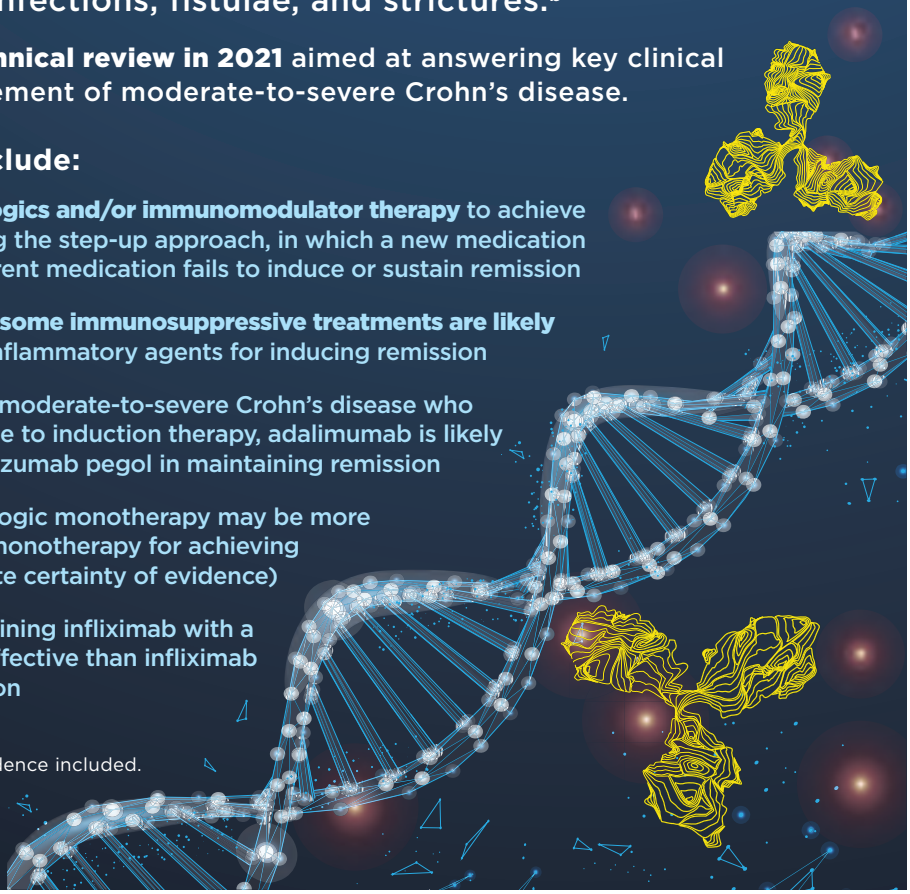
Patients with moderate-to-severe Crohn's disease are at risk for disease complications including surgery, hospitalization, dependence on corticosteroids, infections, fistulae, and strictures.[b]

The AGA released a technical review in 2021 aimed at answering key clinical questions in the management of moderate-to-severe Crohn's disease.

Recommendations include:

- **Early introduction of biologics and/or immunomodulator therapy** to achieve remission rather than using the step-up approach, in which a new medication is prescribed **after** the current medication fails to induce or sustain remission
- In biologic-naïve patients, **some immunosuppressive treatments are likely more effective** than anti-inflammatory agents for inducing remission
- In patients with quiescent moderate-to-severe Crohn's disease who have had an initial response to induction therapy, adalimumab is likely more effective than certolizumab pegol in maintaining remission
- In adult outpatients, a biologic monotherapy may be more effective than thiopurine monotherapy for achieving remission (low-to-moderate certainty of evidence)
- In adult outpatients, combining infliximab with a thiopurine is likely more effective than infliximab alone for inducing remission

[b]Only moderate certainty of evidence included.



Switching to Disposable Duodenoscopes:
Risks and Rewards

Rajesh N. Keswani, MD, MS

In 2013, the CDC warned the FDA that patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) were being infected with multidrug-resistant bacteria, and that the bacteria were likely coming from the duodenoscopes.[1] Subsequent changes to the instrument's cleaning protocols did not significantly improve infection rates.[2] Thus in 2019, the FDA urged endoscopists to abandon use of reusable, hard-to-clean duodenoscopes when performing ERCP.[3] The FDA wanted surgeons to adopt either single-use models or reusable tools redesigned with disposable tips.

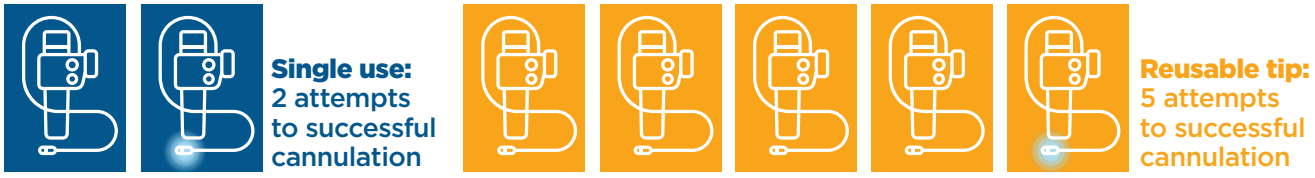
The FDA's request has created a lively debate among endoscopists.[4] While single-use instruments would, by definition, eliminate risk of infection and save time related to endoscope cleanings, the constant replacement costs and the environmental impact of their disposal have prompted much discussion.[2,4] The estimated amount of greenhouse gas emissions, for example, from manufacturing the single-use instruments is remarkably higher than for other instruments.[5]

Alternatively, a "hybrid" duodenoscope, a reusable instrument equipped with a one-time-use tip, has been available for a few years; its use has been shown to significantly reduce bacterial contamination.[6] However, that use has not entirely eliminated risk of microbial contamination despite adherence to high-level disinfection and reprocessing.[7]

Although the primary driver for disposable duodenoscopes has been reduction of infection risk from ERCP, other improvements are anticipated changes in ergonomic design for instrument operators with smaller hands, for example. A small case study has shown that expert endoscopists can finish ERCPs of different levels of complexity using disposable duodenoscopes.[8]

Single-Use Duodenoscopes Perform Comparably to Standard Duodenoscopes[9]

Based on a study in which >80% of procedures were of low complexity:



Endoscopic Technique Preferences[10]

There is a need for technique modifications and training to improve ergonomics and comfort in the endoscopic space. A survey of 107 gastroenterologists highlighted differences in techniques, primarily due to physical differences.

90% of female gastroenterologists hold the umbilical cord of the endoscope outside of their forearm

vs **50%** of male gastroenterologists

48% of female gastroenterologists use their right hand to turn the small wheel

vs **29%** of male gastroenterologists

Dimensions, Optics, and Scope Characteristics[11]	Field of view	Maximum diameter insertion portion with end cap attached	Bending capability (left to right)	Working length
Duodenoscope with Removable End Cap	**100°**	**13.5-14.9 mm**	**90°-110°**	**1,240-1,250 mm**
Disposable Duodenoscopes	**108°-130°**	**13.7-15.1 mm**	**90°-110°**	**1,240 mm**

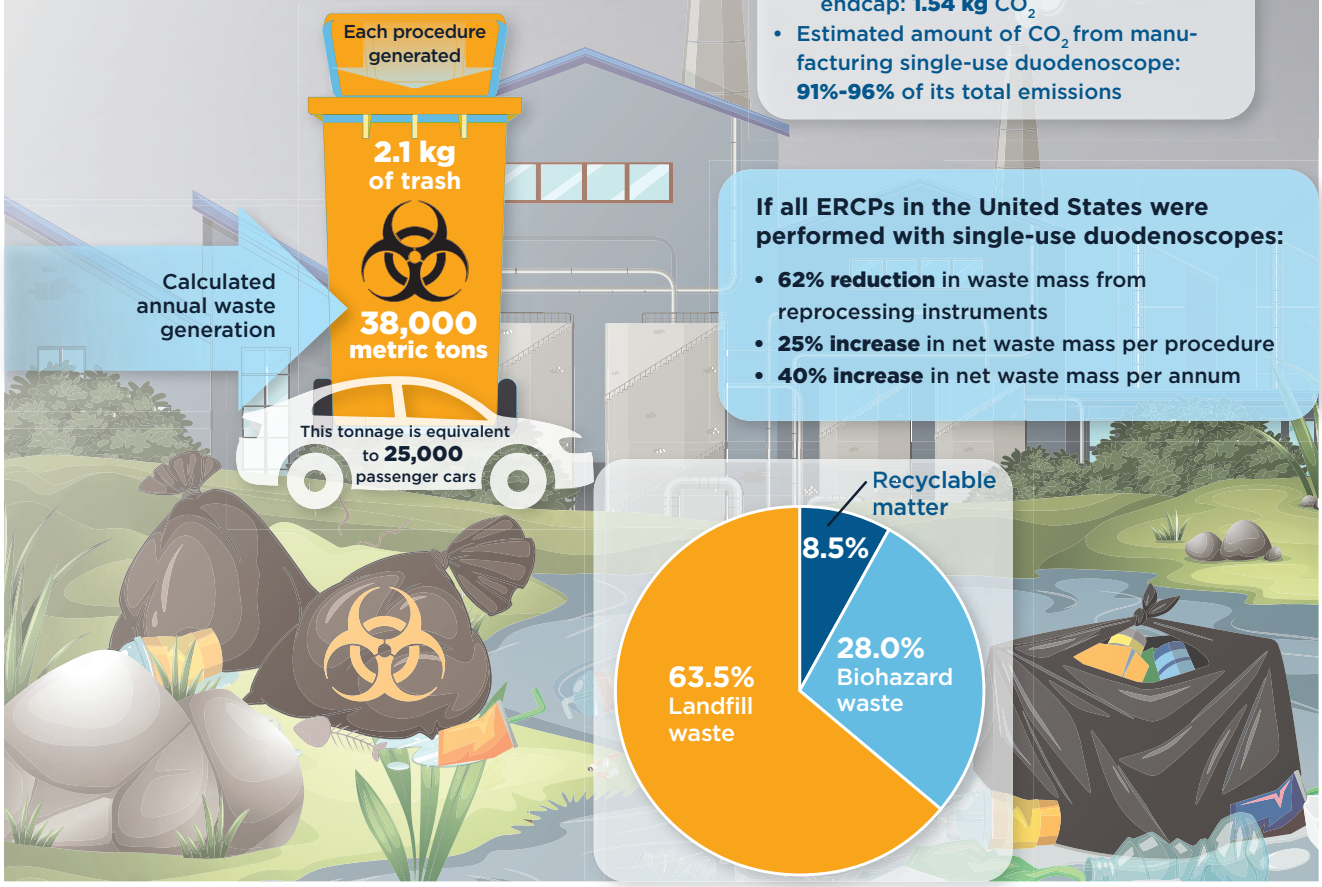
Possible Environmental Impact of Disposables[5,12]

The US health care system now generates 8% of this country's total greenhouse gas emissions. A 5-day audit of 2 academic health centers recorded the following findings:

278 endoscopies performed during the study period

Estimates of greenhouse gas emissions from 1 ERCP procedure:

- Single-use duodenoscope releases **36.3-71.5 kg** of CO_2 equivalent
- This is 24-27 times more than:
  - » Traditional duodenoscope: **1.53 kg** CO_2
  - » Duodenoscope with disposable endcap: **1.54 kg** CO_2
- Estimated amount of CO_2 from manufacturing single-use duodenoscope: **91%-96%** of its total emissions

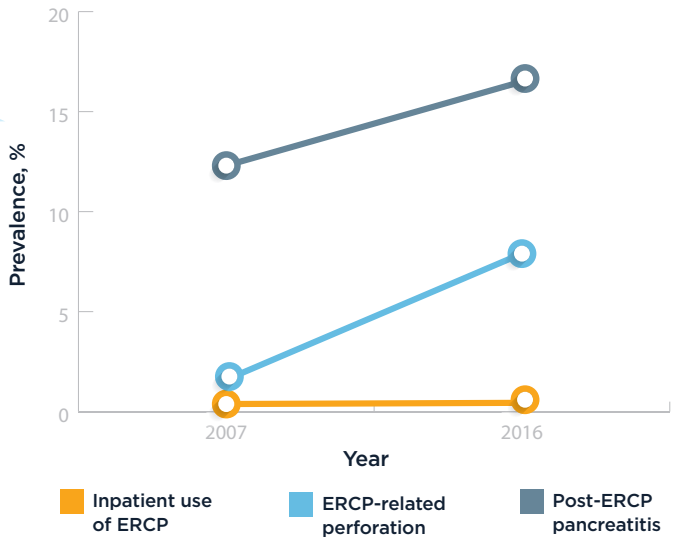


If all ERCPs in the United States were performed with single-use duodenoscopes:

- **62% reduction** in waste mass from reprocessing instruments
- **25% increase** in net waste mass per procedure
- **40% increase** in net waste mass per annum

More Procedures, Less Reimbursement[13,14]

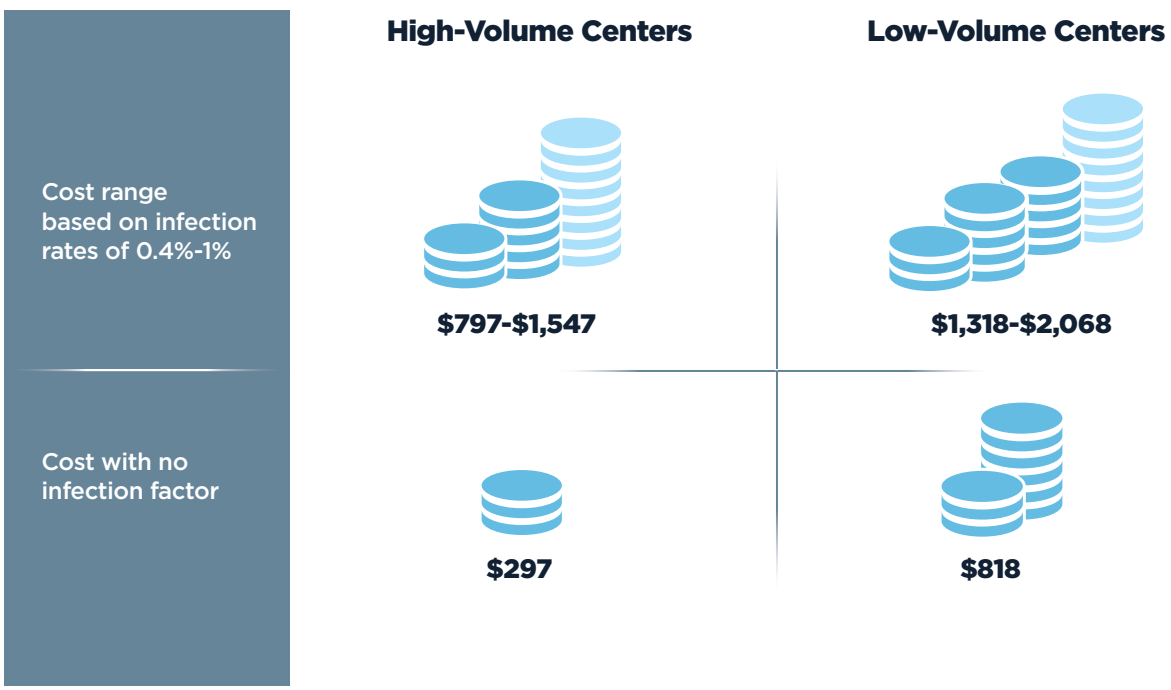
Data from the Nationwide Inpatient Sample showed a small increase in ERCP utilization (from 0.38% to 0.44%), along with an increase in related adverse events such as pancreatitis and perforation.[10]



[a]Adjusted odds ratio.
ERCP, endoscopic retrograde cholangiopancreatography.

Dollars and Cents[15]

Estimated costs of single-use duodenoscopes, based on hospitals performing high and low volumes of ERCP.



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Increasing Surveillance Programs
and Expanding Treatment Options in HCC

Amit Singal, MD, MS

The incidence of HCC has increased over the last 10 years, with more than 1 million cases projected by 2025.[1,2] Although mortality rates—which have risen over the past decade—appear to be leveling out, improved surveillance and screening efforts are still critical for decreasing mortality.[3] More intensive, multifaceted interventions—such as increasing patient and provider education, which are currently underutilized in clinical care—are needed, as well as the start of earlier screening for HCC.[4] The use of new imaging and biomarker, GALAD, and liquid biopsy techniques is also being explored, although these techniques still require validation prior to routine use in clinical practice.[5-7] The current ultrasound screening methods alone are not ideal, with sensitivity as low as 47% for detecting early-stage HCC.[8]

Generally, multidisciplinary care has also been emphasized in the treatment process, using oncologists, radiologists, hepatologists, and surgeons working together to improve clinical outcomes.[9] Recent treatment advances have been reported for early-, intermediate-, and late-stage disease. For early-stage HCC, surgical resection and transplant criteria have been expanded through downstaging techniques.[10] For intermediate-stage HCC, radioembolization has been incorporated as another therapy, beyond transarterial chemoembolization.[11,12] For late-stage HCC, treatment is moving toward immunotherapy, which has generated longer survival than older therapies.[13] While HCC remains a cancer of concern, new interventions, tools, and treatments on the horizon can help expand screening and improve treatment outcomes.

Effect of Various Educational Programs on HCC Screening[4]

Primary Care Provider Educational Program: increase in the proportion of HCC detected by surveillance **from 34.8% to 55.3%**

Nurse-based Surveillance Protocol: increase in one-time abdominal imaging **from 74.4% to 93.2%**

Mailed Outreach Program: increased one-time screening **from 24.3% to 44.5%**

Electronic Medical Record (EMR) Alert Reminder: increase in adequate HCC surveillance among patients with cirrhosis **from 18.2% to 27.6%**

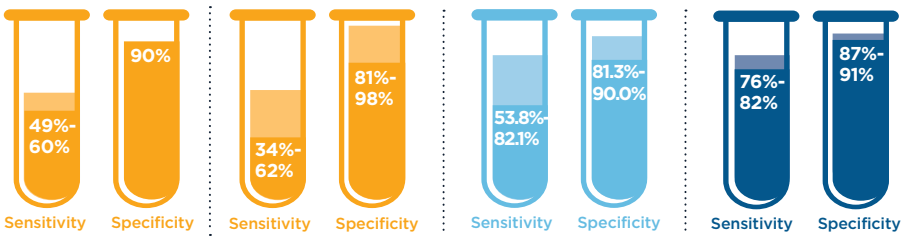
Pharmacist-led Program: increase in adequate HCC surveillance among patients with cirrhosis **from 22.8% to 81.7%**

New Biomarker, GALAD and Liquid Biopsy Panels and HCC Outcomes[5-7,14]

Alpha-fetoprotein (AFP) + abdominal ultrasound (US):
Only approved biomarker

63%
Sensitivity

84%
Specificity

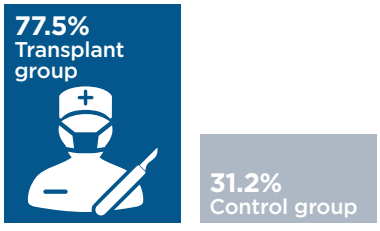


New treatment strategies have been developed for **early-, intermediate-, and late-stage HCC** that lengthen survival, despite the increasing mortality and incidence worldwide.[10-13]

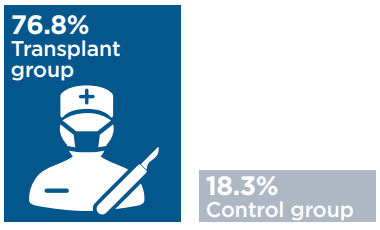
Early Stage

Downstaging and Survival Rate in Early-Stage HCC and Tranplantation[10]

5-year survival rate



5-year tumor event-free survival



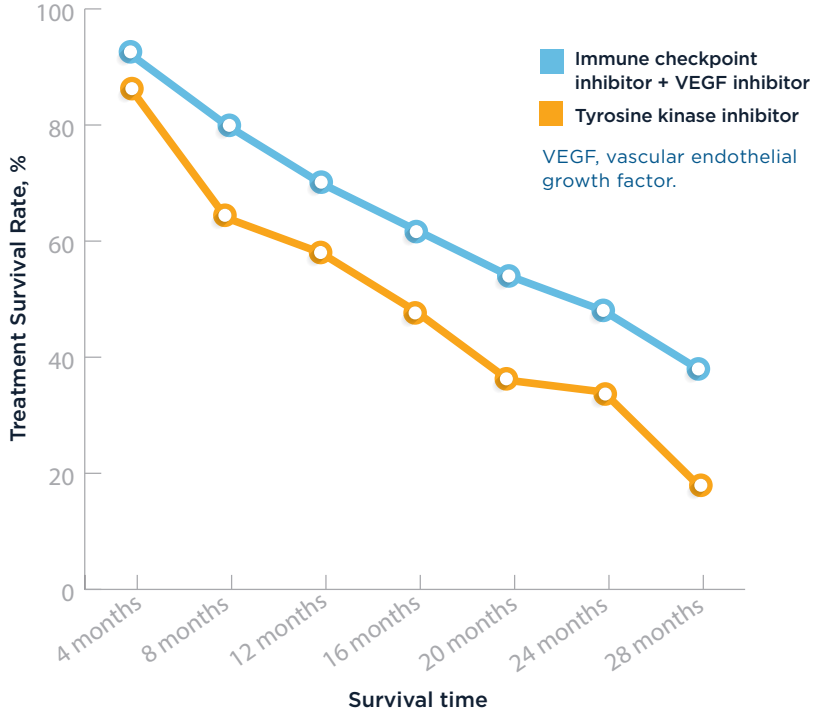
Intermediate Stage

Use of Radioembolization for Intermediate-Stage HCC [11,12]

- **Eastern Cooperative Oncology Group 0: 60.5%** after use of therapy
- **Medium tumor size:** 2.7 cm (vs. 8 cm before)
- **Served as neoadjuvant therapy for transplant or resection: 21%**
- **3-year survival rate:**
  - All patients: **86.6%**
  - Resected or transplant patients: **92.8%**

Late Stage

Survival Rates for Immune Therapies vs. Tyrosine Kinase Inhibitors for Advanced-Stage HCC[13]



Achalasia Remains a Challenging Disorder
for the Community Gastroenterologist

Benson T. Massey, MD

Considerable advances in our understanding of esophageal achalasia have been made in the 21st century, accompanied by new diagnostic and treatment modalities. Indeed, about half of the available citations for the term *achalasia* in PubMed have been published in the past 20 years.[1] These developments have increased awareness of this condition among practicing gastroenterologists. But because achalasia is a rare disorder in which the available treatments are palliative, it continues to present a challenge for the community gastroenterologist to diagnose and manage.[2]

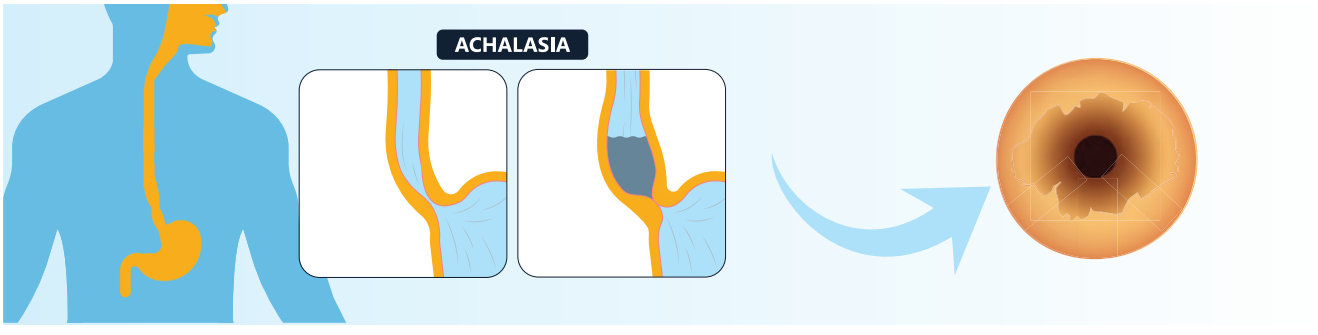
The first problem for diagnosis concerns the rarity of the condition combined with lack of specificity of the presenting symptoms, particularly early in the disease course. Because the prevalence of troublesome GERD (18,000/100,000) is easily 1,000-fold greater than that of achalasia (just 15/100,000), a patient presenting anew with any constellation of esophageal symptoms is far more likely to have them result from GERD than achalasia.[3,4] Further, the classic features of achalasia—massive esophageal dilation with retained contents—are often absent on endoscopic or radiographic evaluation early in the disease.

When initial testing shows no findings confirming a GERD diagnosis and symptoms fail to respond to GERD therapy, or testing identifies late-stage morphologic features suggesting an achalasia diagnosis, the next step in evaluation is esophageal high-resolution manometry (HRM). This test is currently the standard of care for an achalasia diagnosis.[5] Community gastroenterologists are increasingly incorporating HRM into their practice, and likely discovering that the learning curve for generating high-quality studies and accurate interpretations of HRM findings is steep, particularly if they have had no training with this technology during their fellowship.[6-8]

The findings on HRM are characterized into 3 different motor phenotypes, per the Chicago Classification, which have implications for treatment approach and prognosis. Manometric findings always must be considered within the context of the patient's entire clinical picture, to avoid misdiagnosis of achalasia and subsequent inappropriate treatment decisions. Other diagnoses, such as opiate-induced dysmotility, "pseudoachalasia" due to cancers, and end-stage esophageal dysfunction in systemic sclerosis, can have findings on HRM that mimic those of idiopathic achalasia.[9-11]

All definitive treatments for idiopathic achalasia (pneumatic dilation, laparoscopic myotomy, peroral endoscopic myotomy [POEM]) have the goal of irreversibly disrupting abnormal smooth muscle function causing outflow obstruction at the esophageal outlet or spastic contractions in the esophageal body. When applied to the appropriate achalasia motor phenotype, all offer reasonable palliation of symptoms in most, but not all, patients, with a small but immediate risk of serious complications.[2] The best choice often depends on the degree of locally available expertise for the different treatment options, which in the case of pneumatic dilation is unfortunately declining in the United States. While increasing percentages of patients are being treated with POEM, the high rate of postprocedure reflux has uncertain implications for these patients in the future.[2]

Because no treatment can return esophagus function to normal, patients require ongoing follow-up to monitor for signs and symptoms of disease progression or new complications. Patients need to be counseled regarding the risks of esophageal pill injury, imprudent eating habits (eg, excessive consumption), excessive weight gain, and neglecting new-onset GERD symptoms.



Monitoring for Persistent or New Symptoms in Achalasia

Etiologies of Persistent Symptoms Immediately After Definitive Treatment[2]

- Incomplete disruption of abnormal motor activity
- Treatment resulting in new-onset GERD
- Procedural complications (eg, paraesophageal hernia)
- Improper eating habits (eg, excessive consumption)
- Esophageal hypersensitivity/ hypervigilance
- Incorrect diagnosis of idiopathic achalasia

Etiologies of Late Developing Symptoms After Successful Treatment[5]

All of those persistent symptoms, plus:

- Progressive esophageal dilation/ sigmoid esophagus
- Medication injury
- Peptic stricture
- Excessive weight gain
- Development of a new problem (eg, esophageal cancer)

Comparison of Durable Treatment Options for Achalasia

	Pneumatic dilation	Surgical myotomy	POEM
Eliminates outflow obstruction from LES dysfunction	++	+++	+++
Eliminates spastic esophageal body contractions	+/-	+	+++
Beneficial for Chicago Classification Type			
I	+	++	++
II	+++	+++	+++
III	+	+	++
Requires general anesthesia	0	+++	+++
Requires hospitalization	0	+++	+++
Complication requiring invasive intervention	+	+	+
Requires repeat treatment	++	+	+
Post-treatment GERD	+	++	+++
Total costs	+	+++	+++

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