

Integrating Intestinal Ultrasound into an Inflammatory Bowel Disease Practice: How to Get Started

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Intestinal ultrasound (IUS) offers a safe, noninvasive, point-of-care tool for diagnosing and monitoring disease activity in patients with inflammatory bowel disease (IBD). IUS is used widely in Europe and Canada for IBD, but it remains underutilized in the United States. Growing interest in IUS in the United States has prompted many IBD centers to train their faculty in IUS. This, however, raises questions about how to effectively use this new tool in the United States, which does not use a social medicine model like those implemented in Europe and Canada. Here, we provide a practical framework for incorporating IUS in an IBD practice in the United States, including training requirements, equipment, and protocols for implementing IUS in daily practice.

Lay Summary

Intestinal ultrasound (IUS) offers a safe, noninvasive tool for diagnosing and monitoring inflammatory bowel disease activity at office visits, but it is underused in the United States. Here, we provide practical tips for integrating IUS into clinical practice.

Key Words: Intestinal Ultrasound, Crohn's disease, ulcerative colitis, inflammatory bowel disease, practice management

Introduction

For patients with inflammatory bowel disease (IBD), STRIDE II guidelines on disease management goals recommend clinical response and remission as a short-term target and recommend endoscopic remission as a long-term target. The guidelines also include the consideration of transmural healing for Crohn's disease as a potential target. In assessing the mucosal healing target, colonoscopy is required to confirm endoscopic remission, but not all patients prefer to undergo the procedure due to time, cost, inconvenience, and comorbidities. Thus adjunctive assessments include laboratory biomarkers (eg, C-reactive protein, fecal lactoferrin, and fecal calprotectin (FC)) and imaging (eg, Magnetic Resonance Enterography (MRE) and Computed Tomography Enterography [CTE]). However, labs and imaging have to be ordered and scheduled and do not provide immediate access to results, so they do not provide an adequate alternative to endoscopy. Therefore, there is a clinical need to improve timely, easy, and accurate monitoring of IBD disease activity. Intestinal ultrasound (IUS) provides measurable clinical advantage in IBD management as a point-of-care testing and should be considered as a viable alternative for noninvasive, objective assessment of disease activity. Additionally, IUS can be used for long-term disease activity monitoring, especially due to the lack of correlation between symptoms and noninvasive objective markers of disease activity, allowing for prompt and early change in IBD treatment.² In what follows,

we briefly summarize the evidence for IUS's utility and provide a practical framework for implementing IUS in clinical practice in the United States.

Evidence Supporting IUS

Clinical Utility

Traditional methods for noninvasively evaluating disease activity consisted of clinical assessment in combination with inflammatory markers in blood or stool. However, reported symptoms do not reliably represent levels of mucosal inflammatory disease activity and biomarkers are correlative at best.³ Thus, there is a great clinical need to improve monitoring of IBD disease activity.

Endoscopy provides the most accurate morphologic assessment of inflammation, but it is invasive and is limited to evaluating only the intestinal mucosa. In contrast, IUS is non-invasive and evaluates the morphology of all layers of the intestinal wall while providing insight into mural stratification, bowel wall thickness, mesenteric fat, lymph nodes, and blood flow as assessed by doppler.² In stricturing disease, dilation of the proximal lumen can be seen in addition to conglomeration of loops, adjacent fistulas, and abscesses. Additional modalities, such as doppler ultrasound or contrast-enhanced ultrasound, can be used to examine intramural blood flow and differentiate between active inflammation and fibrotic mucosa.⁴⁻⁷ As such, IUS can often serve as an efficient,

clinically effective tool for assessing disease activity, along with biomarker/clinical assessment and endoscopy as needed. Current evidence indicates that the diagnostic accuracy of IUS in patients with ulcerative colitis depends on the disease site, with the highest sensitivity being in sigmoid/descending colonic disease and the lowest for rectal disease because the rectum is harder to visualize in a trans-abdominal IUS.⁸ With additional advanced training, physicians can use perianal ultrasound to better assess disease activity in the rectum in ulcerative colitis and in Crohn's disease for perianal fistulae/ abscesses.

When used in Crohn's disease, IUS has a high diagnostic sensitivity of 75%-94% and specificity of 67%-100% when compared to our gold standard of endoscopy. In ulcerative colitis, disease activity on IUS was also significantly associated with endoscopic activity (0.32; 95% CI, 0.14-0.49; P < .001), total Mayo score (0.31; 95% CI, 0.02–0.60; P = .036) but not FC (0.10; 95% CI, -0.01 to 0.21; P = .064) or clinical disease activity (0.04; 95% CI, -0.21 to 0.28; P = .768). A composite of IUS and FC showed the greatest association (1.31; 95% CI, 0.43-2.18; P = .003) and accurately predicted histological activity in 88% of cases (P = .007), with sensitivity of 88%, specificity 80%, positive predictive value 95%, and negative predictive value 57%.8 Current American Gastroenterology Association guidelines on the role of biomarkers in ulcerative colitis management recommend the use of FC to rule in active inflammation and help avoid endoscopic evaluation in patients with clinical symptoms suggestive of a flare. 10 Given the reported positive predictive value of 95% in the aforementioned study, IUS used in conjunction with FC could help to reduce the need for endoscopic evaluation in patients with a high pretest probability for active inflammation. Lastly, results from the METRIC trial and the development of the International Bowel Ultrasound Segmental Activity Score (IBUS-SAS) demonstrate low variability of IUS results between operators. 11-13 Specifically, in a group of 15 patients with CD evaluated by 6 experienced sonographers, all operators agreed on the presence/absence of CD lesions.¹³ There was a strong agreement between bowel wall thickness, bowel wall stratification, vascularization, lymph node presence, lesion location, fistulas, and presence of phlegmon. Poor agreement was observed for mesenteric adipose tissue alteration, lesion extent, and prestenotic dilation.¹³

Ultimately, IUS can provide useful point-of-care assessment data for decision-making in patients with IBD. In addition to its convenience, IUS can detect disease without sedation, bowel prep, or radiation exposure, conferring a large clinical advantage for its use in IBD. Also, IUS can easily assess transmural healing, which may be the next target after mucosal healing to be considered in STRIDE II guidelines; in contrast, colonoscopy cannot assess all layers of intestinal wall involvement.

Practical Utility

IUS is simply the performance of ultrasonography of the abdomen focusing on the intestinal wall and surrounding structures to assess for inflammation. Utilizing bowel wall thickness, which is the most specific assessment of inflammatory activity, additional activity parameters include examining mural stratification, Doppler flow activity, surrounding mesenteric fat, and lymph nodes. 14-16 Complications, such as

fistulas and strictures, can also be assessed in real-time. IUS does not have the same preprocedure requirements that colonoscopy or CTE/MRE imaging have, such as scheduling, fasting, bowel preparation, and oral contrast. Thus, IUS has the potential to reduce noncompliance-related inefficiencies and nonadherence, potentially replacing colonoscopies for assessing mucosal healing in the majority of the IBD population. This potential is specifically important in those that would have higher comorbidities/ higher risk to undergo a more invasive procedure, pregnant patients, for those that need frequent assessments due to disease severity. Also, IUS can be incorporated with little additional time, overhead, and labor requirements. It does not require sedation, postoperative patient monitoring, or specialized procedure rooms. Instead, it can be quickly performed within the same exam room as a clinical assessment. The value of these advantages may vary between practices, but cost savings can be estimated in a straightforward manner. Finally, real-time interpretation within the exam room by the gastroenterologist reduces associated personnel requirements and turnaround time compared to labs, other imaging modalities, or endoscopic biopsy, all of which depend on other departments and specialists. IUS provides considerable value through streamlined care and direct point-of-care patient education/communication.

IUS cannot replace colonoscopies for colon cancer surveillance in patients with IBD who are at high risk (disease duration > 8 years in colon; or those with primary sclerosing cholangitis). IUS may not necessarily capture very mild mucosal disease where a colonoscopy or capsule endoscopy may be needed for assessment. Colonoscopy would also still be needed for the rapeutic maneuvers such as dilation of stricture or resection of polyps. IUS has limitations in patients with proctitis alone because it is difficult to assess the rectum unless one is trained in perianal ultrasound. High BMI may limit IUS assessment due to the need for the ultrasound to penetrate past layers of abdominal fat, limiting visualization and contributing to a suboptimal exam in some patients. Although, in our recent study on the utility of IUS in clinical management, we demonstrated that there was not a statistically significant difference in IUS findings between BMI subgroups of obese, overweight, normal, and underweight.² There is no set BMI limit as clarity of images can vary between patients even with similar BMI. If the exam is not adequate, this limitation should be included in the report. On the other hand, IUS can also replace costly MRE and radiation exposure from CTEs, especially if the findings are straightforward and correlate with the overall clinical picture. However additional imaging such as MRE/CTEs can still be used if patients have complex anatomy due to multiple surgeries or complex fistulas that need to be assessed in a larger cross-sectional view.

Patient Impact and Preference

Point-of-Care IUS testing avoids several key patient-side burdens associated with other diagnostic tools. Colonoscopy requires extensive personal planning: Taking a full day off from work, and having a driver for the procedure that often requires a friend or family member to also take time off work or add childcare, bowel prep, and sedation requirements together present pre- and postprocedural challenges. Also, patients may not remember discussions with the gastroenterologist postprocedure due to residual effects of sedation and Abraham et al 3

must also wait several days for pathology processing. CTE and MRE require prior planning, scheduling, and wait times associated with separate departments and specialists. Fecal marker labs require the need to handle stool, and have the potential for additional trips to pick up a stool kit and then return it which can add to delay in obtaining results or perhaps reducing adherence to completing the test. These results are not immediate and do not indicate specific disease location. Interpreting the results of each of these diagnostic tools requires a separate follow-up appointment or interaction with the gastroenterologist. By contrast, IUS is seamlessly integrated into existing appointments, allows meaningful real-time engagement between the patient and the physician, and provides immediate clinical data that guide a shared decision-making process.

It is inarguable that patient satisfaction with IUS is high. In a systematic review of 10 studies assessing IBD patients' acceptance of and satisfaction with various IBD monitoring methods, 9 studies reported a patient preference for noninvasive monitoring tools, and GI ultrasound scored highest for patient acceptability and satisfaction.¹⁷ IUS brings demonstrable advantages in clinical utility, practical utility, and patient preference; therefore it makes sense that incorporating and implementing this modality in IBD patient care is worthwhile for the effort in training and cost of purchasing equipment.

Implementing IUS

Initiating the use of IUS in an IBD practice entails an initial investment of time and cost associated with personnel training and the purchase of equipment, as well as adjustment to clinic scheduling to accommodate the procedure. Nonetheless, once established as a routine assessment tool, IUS will provide immediate assessment for IBD management in a safe manner that patients appreciate. It is a simple, yet powerful tool that can optimize and revolutionize patient care.

Training

For physicians interested in obtaining training, official certification from the International Bowel Ultrasound Group (IBUS) is highly recommended. Courses for certification can be found at https://ibus-group.org/. Certification occurs over 3 modules organized as follows:

- Module 1 (3 days): Intensive, introductory, hands-on workshop on IUS.
- Module 2 (~4 weeks): Hands-on training at a certified IBUS training center.
- Module 3 (1 day): Advanced workshop and final exam.

Prospective participants must apply for the certification course. Once accepted, participants initiate module 1, a 3-day course that teaches the fundamentals of IUS and provides hands-on training on simulators as well as on patients at a center/facility. Before moving on to module 2—typically 4 weeks of training at an IBUS-certified site—IBUS recommends that participants prove they have already bought IUS equipment. Since most physicians in the United States cannot take 4 weeks at a time away from their practice, IBUS accommodates them through flexible scheduling and by allowing physicians to complete the module in shorter sessions over time. The

final module is a 1-day extended training during a major national/international conference, such as European Crohn's and Colitis Organization/ Digestive Disease Week. The final exam and certification are provided at the end of module 3.

Choosing the Right Ultrasound Equipment

There are many types of ultrasound machines available. Since it is a requirement to have an ultrasound machine to apply for IBUS training, if feasible, it is recommended that the provider has a chance to review multiple machines before the purchase. Choosing the optimal equipment should be based on several factors, but primarily: (1) The type of ultrasound machine already used at their institution, which may have service contracts in place and would require no further negotiation for future services, and (2) the ultrasound machine they are most feel comfortable using, in terms of image clarity, ease of controls, and customer support. Several companies make high quality ultrasound machines that are highly suitable for intestinal ultrasound, including the Canon (Canon Medical Systems, Otawara, Tochigi, Japan), GE (General Electric, Chicago, Illinois, United States), Philips, Samsung (Samsung, Seoul, South Korea), (Koninklijke Phillips N.V., Amsterdam, Netherlands), and Siemens (Siemens AG, Berlin, Germany).

A minimum of 2 probes are recommended: One linear and one convex. Convex probes have a wider view and lower frequency (3.5-6.5 MHz) but are capable of deeper penetration to provide an overall view of the bowel. This includes haustrations and loops of bowel deeper into the pelvis. Linear transducers are higher frequency probes (6-11 MHz) with a rectangular beam that are excellent for high resolution and quality images to assess details of diseased areas of the bowel wall, especially near the abdominal surface. Microconvex transducers are similar to convex but have a smaller curve. These can be used for perianal assessment but are not required. Additional transducers may be bought as needed, so there is no need to purchase everything upfront. Costs vary based on the manufacturer. If the machine will be used for perianal assessment, a disposable sheath should be used for simple and sanitary clean-up. In addition to the machine and probes, ultrasound gel is needed to transmit the sound waves.

Although handheld and portable ultrasound machines offer more portability and are less expensive, physicians should be cautious in choosing these as the primary machine for assessment, as they must be able to view intestinal walls with good resolution to detect abnormalities. Studies evaluating the benefit of these machines are required before they can be recommended for IUS.

To choose among the variety of options, we recommend contacting multiple vendors to bring in their ultrasound machines. They should be notified that the machine will be used to image the intestinal wall, and have them bring the most appropriate probe (curved, low frequency and linear, and high frequency) options for testing. We recommend testing the vendors within 1–2 days on the same patient or volunteer to compare image clarity, ease of use, settings, and options. Having 2 or 3 rooms set up to take patients from one machine to another to assess image quality can be beneficial. It is also prudent to take images and compare them after reviewing all machines to confirm your decision regarding the best equipment for your practice. It is important to trial different equipment on patients with varying BMIs to determine that you can optimize images regardless of the BMI range

in your practice. A representative should also be present to assist with image optimization for bowel. Many representatives have previous experience as ultrasound technicians, so take advantage of their wealth of knowledge. Immediately afterwards, write out a list of pros and cons for each machine, including prices, services, and contract differences.

After careful consideration of the differences amongst vendors in image quality, ease of use, services offered, contracts via your institution on existing ultrasound machines, and pricing, contact the manufacturer's representative to initiate the purchase.

Clinic Schedule and Protocol

Establish a protocol for using intestinal ultrasound in IBD practice. Schedule specific dates/times (to allow for additional time) or consider using it for all in-person clinic visits.

Clinical staff, such as a medical assistants or clinic nurses, can be included in basic training of cleaning the machine, ensuring cords remain off the ground, and probes are placed securely in their holders. Towels for patients during the exam and for cleaning should be available and staff should be trained on having adequate ultrasound gel on hand.

The ultrasound machine, including keyboard and probes can be easily cleaned with antiseptic wipes. Monitors and screens may require a different cleaner. It is recommended to discuss options with the manufacturer. With routine care, the ultrasound machine can last many years.

Time for procedures

The time needed to complete an IUS evaluation varies based on operator experience, history of prior surgeries, presence of significant inflammation, body habitus, and complications such as fistulas/abscesses that require careful assessment of the anatomy. A unremarkable IUS in a patient with normal BMI and no prior surgeries may be as fast as 10 to 15 minutes. On the other hand, if a patient has significant inflammation in the small intestine or colon, along with complications such as fistulas or abscesses that require careful measurement of details, IUS can take up to 30 minutes or longer. Starting out, plan for a minimum of 30 minutes per IUS, then increase or decrease that time based on your growing experience and comfort level. Additional time may be needed if there are trainees at your center learning this technology.

Other factors to consider, especially if your center is well established, is the number of faculty who are trained in IUS,

the number of ultrasound machines available, and whether IUS is performed in conjunction with the clinic visit or done for another colleague as a procedure visit alone. All these factors will influence scheduling and allotting time for IUS evaluation.

Documentation

As with any procedure, appropriate documentation is necessary to provide details on the exam findings, as well as for billing and communication. The IUS note should outline the indications for performing an intestinal ultrasound, who performed the procedure, the findings, the quality of the images, and the interpretation of the results. Full details on documentation can be found in the ECCO-ESGAR Review and will also be taught in module 1 of the IBUS course. Integration into the electronic medical record system is recommended with notes set up in the Imaging section and integrated into an imaging software such as PACS. This can make exam findings easily accessible to your team and to other providers.

Cost

The general cost of the ultrasound machines, including at least 2 transducer probes, will vary depending on the brand, model, buying new versus used. After the initial investment, the system can last many years with proper care and maintenance. Routine (at least annual) updates through the manufacturer are recommended. It is important to understand the servicing costs per year based on institutional or individual contracts. Ultrasound gel and personal protective equipment are the only other minor renewable costs. The ability to fully pay off the machine will be based on reimbursement per patient, number of patients seen, and insurance. There are training costs to the provider for certification courses, as well as indirect costs to the institution from the provider being offsite for training for 4 weeks. Although the initial time needed to learn, buy, and utilize the system is well worth it for patient care, one must educate department leadership and administrators on the value provided to patients and the organization.

Reimbursement for IUS

Unfortunately, there is no CPT code for intestinal ultrasound in the United States yet. One can bill under an unlisted CPT

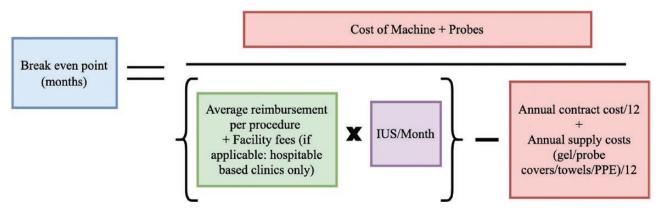


Figure 1. Overall time to break even calculated by dividing the fixed costs by variable costs per month subtracted from revenue per month.

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code (76999), but this may not be covered by most insurance providers. On the other hand, utilizing codes for limited abdominal ultrasound (CPT 76705) can provide some reimbursement. If utilizing Doppler flow (to assess inflammatory activity), a limited Doppler code (CPT 93976) can be added. These codes can be used for reimbursement and to obtain RVUs in an academic setting which translates to 0.59 RVUs for a limited abdominal ultrasound, and 0.80 wRVUs for a limited Doppler totaling 1.39 RVUs per each IUS done. For those working at a hospitalbased clinic, facility fees may also be billed based on your institution. If, in the future, a CPT code is created and approved for intestinal ultrasound, we may be able to obtain higher reimbursement for the time spent conducting IUS. Requirements for billing include capture of images, as well as documentation of the procedure that includes indication, examination findings, and impression/interpretation as explained above.

Time to Break Even

The time needed to "break even" after buying ultrasound equipment can vary based on factors ranging from cost of the equipment, contracts to reimbursement based on insurances, CPT code billing, as well as any facility fees involved. Nonetheless, this simple formula in Figure 1 can help provide an estimate of the time in months.

Conclusion

This framework guides a physician in setting up IUS by acquiring certification through IBUS, setting up a streamlined workflow to incorporate IUS in IBD clinic, and navigating billing and documenting to make use of this point-of-care tool. IUS provides valuable information with positive patient preference and is a safe, effective, noninvasive tool to manage IBD. Practices seeking to implement IUS should consider the financial benefits for patients, long-term benefits for payors, and the developing reimbursement landscape of using IUS for IBD treatment in the United States. Future analysis should consider the downstream benefits of implementing IUS, determining whether immediate diagnostic assessment, enhanced patient education, and streamlined physician communication can demonstrably correlate to improved patient compliance and diagnostic decision-making.

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Conflict of Interest

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Data Availability

No new data were created or analyzed for this manuscript.

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