Remote Monitoring for Patients With Inflammatory Bowel Disease: Current Status and the Future of the Field

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Abstract: As a direct result of the COVID-19 pandemic, many advances in telehealth have been made that save time and reduce travel costs for patients. Telehealth, specifically video visits, was especially embraced by patients with inflammatory bowel disease (IBD). However, remote clinic visits are only one part of the equation for remote IBD care. Patients with Crohn's disease or ulcerative colitis have a significant testing burden, and many strides still need to be made to improve all aspects of their care, including remote monitoring (testing at home) of biochemical markers (eg, C-reactive protein and fecal calprotectin) and drug concentrations. Remote monitoring has the potential to decrease the burden of chronic disease on patients through improved ease of access, both when patients are feeling well and when they are having an exacerbation of symptoms. Numerous technologies are available in other countries, are used in other disease states, or are in the animal or early human testing phases. These innovations in home testing have the potential to improve testing adherence, disease control, and monitoring of IBD for all patients, and will have a particularly significant effect on those living in rural communities. This article reviews the current modalities for remote monitoring of patients with IBD as well as the methods in development to make monitoring of IBD easier for patients.

Keywords
Crohn's disease, inflammatory bowel disease, monitoring, remote, rural, ulcerative colitis

As a result of the COVID-19 pandemic, patients, providers, and health care as a whole had to evolve to meet the needs of patients. With stay-at-home orders in place and clinics seeing only urgent patients in person, there was a rapid shift to virtual care. Technology was behind, spirits were low, and organizations turned to remote care purely out of necessity. However, as web-based conference and meeting platforms quickly evolved to become virtual providers' offices, what started as necessity developed into a rapid advancement of the field. Video visits

are now part of routine clinical practice, although this change is only the beginning of remote management of chronic disease.

Inflammatory bowel disease (IBD) comprises Crohn's disease (CD) and ulcerative colitis (UC). As treatment paradigms evolve for the management of patients with IBD, the importance of proactive monitoring toward a treat-to-target approach is gaining momentum.[1,2] Although this shift toward proactive (treat inflammation before symptoms develop) and away from reactive (treat symptoms when they occur) management has consistently been shown to improve outcomes,[3] it requires additional testing for patients. This testing increases the burden of disease management above and beyond the overall effect of chronic disease.[4] In particular, this burden may disproportionately affect patients living in rural regions, who typically do not have easy access to laboratories, clinics, or hospitals.

Two of the mainstays in biochemical markers of inflammation in IBD for proactive monitoring include C-reactive protein (CRP) and fecal calprotectin. Data from the CALM trial evaluated the necessity of this approach by examining how tight monitoring with fecal calprotectin and CRP affected disease outcomes. CALM demonstrated that using fecal calprotectin (<250 μg/g) and CRP (<5 mg/L) as targeted objective endpoints was effective at helping patients reach their goal of remission based on endoscopic and clinical outcomes. Furthermore, this strategy of monitoring with tight control resulted in fewer flares, surgeries, and hospitalizations in patients who had early CD. It also resulted in initiating a biologic agent earlier in the disease course.[5] Currently, these tests are obtained through in-person visits and travel to a laboratory, a clinic, or the hospital. Blood tests are the most ordered yet most refused test by patients with IBD.[6] Similarly, research suggests that one-third of fecal calprotectin laboratory orders are not completed, with distance to the testing laboratory being one of the most common reasons for nonadherence.[7] Offering patients the option to monitor their IBD at home may make monitoring more convenient, thereby improving patient adherence and providers' ability to proactively change or escalate therapies while maintaining a high quality of care.

Although all patients can benefit from decreasing the burden associated with proactive management and treat-to-target, those living in rural or under-resourced regions have the greatest potential to benefit. Research suggests that patients with IBD who live in rural areas have higher rates of emergency department visits and hospitalizations, significantly increasing the overall cost of care.[8,9] Additionally, although patients with IBD in rural areas are interested in multidisciplinary, specialty IBD care (ie, care that includes mental health, nutrition, etc), geography is a barrier.[10] Remote technology, including virtual access to IBD specialists and in-home objective disease monitoring,[11] has the potential to ensure all patients have access to state-of-the-art health care and to transform the field as a whole. This article reviews the different modalities of remote monitoring in IBD, including novel blood, stool, and sweat tests that are currently being used or in development for future clinical use.

Current Modalities of Remote Monitoring for Inflammatory Bowel Disease

Stool

Modalities for home monitoring for fecal calprotectin that are currently on the market internationally include IBDoc (Bühlmann), QuantOn Cal (Preventis), and CalproSmart (Svar).[12,13] Although none are yet available in the United States, IBDoc has been used with success in Canada, the United Kingdom, Belgium, France, and Sweden in both adult and pediatric populations.[14-19] Patients receive an extraction device (test pin and tube) and a test cassette and are instructed to download an application onto their smartphone. The patient collects stool using a fecal collection paper sheet and sampling pin. The pin is placed into a tube and inserted into the test cassette to be analyzed digitally. Clinics have the option to make results available to patients (ie, phone notification of "normal," "moderate," or "high") or to display only whether the test was completed accurately.[19] The results are then registered into an electronic database, and an IBD home coordinator contacts the patient or patient's provider if needed.[19] Past studies of IBDoc have shown that its sensitivity, specificity, negative predictive value, and positive predictive value to predict a fecal calprotectin of greater than 300 μg/g by enzyme-linked immunosorbent assay (ELISA) were 89.8%, 95.5%, 91.4%, and 94.6%, respectively.[16] Head-to-head comparisons of all 3 fecal calprotectin tests and companion ELISAs showed that when concentrations are 500 μg/g or less, they agreed sufficiently, at 87%, 82%, and 76% for IBDoc, QuantOn Cal, and CalproSmart, respectively.[13] However, when results are greater than 500 μg/g with IBDoc, the agreement rate between IBDoc and standard ELISA was only 64% and needed to be confirmed by another method.[20] This may not matter practically, as these tests can be used in a more qualitative as opposed to quantitative manner.

Blood

During the COVID-19 pandemic, a home sampling device called the Tasso Serum Separator Tube (Tasso) was used to measure antibody titers in adults with IBD who received messenger RNA (mRNA) SARS-CoV-2 vaccination.[21] In addition, during strict public health restrictions

Table. Examples of Remote Monitoring Techniques Being Used in Specialties Outside of IBD

Specialty	Remote monitoring
Rheumatology	An upper arm self-sampling device called the Tasso Serum Separator Tube (Tasso-SST) and fingerprick testing were used to measure capillary blood for CRP levels and the presence of IgM rheumatoid factor and anti–cyclic citrullinated protein antibodies in patients with rheumatoid arthritis.[31] In addition, the Tasso-SST device was used to measure auto-antibody and CRP levels in patients with immune-mediated rheumatic diseases.[32]
Endocrinology	Patients used a point-of-care device called A1CNow with a small finger-prick sample. Home Hg A_{1c} measurement was followed by physician phone call and led to significant reductions in Hg A_{1c}.[33]
Infectious disease	Self-collection at home using the Tasso-SST device comparing patients with and without COVID-19 showed good correlations between the Tasso-SST device and matched serum samples for CRP and IL-6, but not D-dimer, IL-1β, and IL-1Rα.[34] The Tasso-SST device was also used to detect SARS-CoV-2 IgG antibodies.[35]

CRP, C-reactive protein; Hg A_{1c}, hemoglobin A_{1c}; IBD, inflammatory bowel disease; Ig, immunoglobulin; IL, interleukin.

over this period, some IBD patients used home-based low-volume intracapillary blood sampling that was mailed to central laboratories for testing biologic drug concentrations (therapeutic drug monitoring). This was accomplished by patients cleaning the surface of a finger, making a small cut into the skin with a stylet, and then collecting approximately 500 µL of blood. Blood samples were delivered to the laboratory at room temperature within 4 hours of collection. Samples were centrifuged and serum was aliquoted and frozen at –80°C until analysis. One study examined whether the use of patient-led remote intracapillary pharmacokinetic sampling (fingerPRICKS) was comparable to conventional venipuncture. The researchers found that their fingerPRICKS method was equivalent to venipuncture for measuring drug concentrations of adalimumab, infliximab, vedolizumab (Entyvio, Takeda), and ustekinumab (Stelara, Janssen), as well as for anti-adalimumab and anti-infliximab antibody levels. Additionally, a majority of patients found it easy (87% of patients) and preferred it to conventional venipuncture (69% of patients). The adherence rate was also relatively high, at 75.3%, permitting providers to successfully perform remote biologic therapeutic drug monitoring.[22] This makes this method noninferior to traditional routine clinical therapeutic drug monitoring, which has adherence rates ranging from 38% to 86%.[23,24]

Dried blood samples have also been used for remote biologic therapeutic drug monitoring for infliximab and adalimumab. In this technique, patients complete an at-home fingerprick with a lancet and place several blood drops on a filter card. Cards dry overnight and then are placed in a sealable plastic bag with a desiccant pack and mailed to a laboratory for extraction and analysis.[25] For both infliximab and adalimumab, dried blood samples from fingerpricks showed good correlation to levels from venipuncture.[26,27] The studies also found that this method allowed for a reduction in time in adapting infliximab and adalimumab dose or dosing interval.[26,27] Dried blood sample–based high-sensitivity CRP testing is also possible; it has been found to be both sensitive and specific at a cut point of 3.0 mg/L and is strongly correlated with serum CRP (r=.84-.98).[28-30]

Remote Monitoring in Other Specialties: Learning From Others

Because much of IBD care has been learned from the management of other chronic diseases, it is also possible to look to these populations and related practices for ideas involving home monitoring. Rheumatology, endocrinology, and infectious disease specialists also have been working in the space of remote monitoring. The application of these technologies can be leveraged in the home management of IBD. Examples are described in the Table.[31-35]

Future At-Home Modalities for Remote Monitoring for Inflammatory Bowel Disease

Colorectal Mucus

Colorectal mucus acts as the interface between colonic mucosa and bowel contents and can be a potential source of sampling in patients with IBD. One novel technique sampled the mucus-rich contents from the external anal area immediately after defecation.[36] The pilot trial instructed 141 participants with IBD or irritable bowel syndrome (IBS) and healthy controls to collect their colorectal mucus via self-swabbing the anal area twice after defecation and placing samples in cell-preserving buffer and smears on microscope slides for cytologic and mucin 2 (MUC2) analysis. MUC2 was measured using ELISA. A total of 96% of the participants rated this as a "good" or "adequate" self-sampling modality for assessment of

disease severity. Researchers found that MUC2 excretion is significantly increased in IBD patients vs those who have IBS or healthy controls.[37] In a follow-up study, the authors examined mucus calprotectin, eosinophil-derived neurotoxin (EDN), and protein S100A12 and found that patients who responded to IBD treatment demonstrated a steady decline of mucus calprotectin and EDN levels.[38] With further studies, mucus calprotectin and EDN could be used to remotely monitor response to IBD treatment, especially because patients preferred it to collecting stool.[36]

Saliva

Because CD affects the entire gastrointestinal tract, including the mouth, several groups have investigated the utility of salivary inflammatory markers to measure disease activity of CD. One study found that salivary inflammatory cytokine levels of tumor necrosis factor (TNF)-α, interleukin (IL)-1β, and IL-6 levels were higher in patients who had active CD (defined as having an active exacerbation based on their CD activity index) compared with patients who had inactive disease and controls.[39] Another group investigated the potential use of salivary calprotectin and found that it was reliably elevated compared with controls in 23 people who had UC or CD.[40] MicroRNA (miRNA) was also studied in the saliva of CD and UC patients, with miR-101 significantly overexpressed in CD; miR-21, miR-31, and miR-142-3p overexpressed in UC; and miR-142-5p significantly underexpressed in UC patients compared with healthy participants.[41] Although none of these salivary biomarkers have yet to be validated,[42] saliva has the potential to be a modality for home measurement because it is easier to obtain and handle compared with stool samples, resulting in the potential for higher testing adherence rates.

Sweat

Sweat inflammatory markers have also been examined. One group studied the multiplexed SWEATSENSER (EnLiSense) to monitor IL-1β and CRP using the US Food and Drug Administration–approved PharmChek patch (PharmChem). The patient wears the sensor on their lower arm, similar to a smartwatch. Their device showed good agreement between measured IL-1β and CRP levels using sweat compared with standard methods, thereby demonstrating proof-of-feasibility that a wearable device that measures multiplexed cytokine and inflammatory markers using passively expressed eccrine sweat can be utilized toward management of IBD.[43]

Swallowed Wireless Capsules and Pills

Capsule endoscopy is frequently used to monitor for small bowel inflammation in patients with CD. This procedure typically requires a patient to come in person to a gastroenterology clinic or endoscopy center. However, there is now a capsule endoscopy device that can be used at home, decreasing barriers to this testing, particularly for patients who need to travel many hours to a testing center. CapsoCam Plus (CapsoVision), a capsule endoscopy modality that stores images within the capsule, was studied in 94 patients who had indications for capsule endoscopy owing to gastrointestinal bleeding. Patients administered capsule endoscopy independently at home. A capsule retrieval kit was provided to every patient along with the capsule endoscope, and patients were instructed to record the time and date of capsule ingestion and excretion. Retrieved capsules were returned via courier service to the clinic.[44] Using this technology to monitor endoscopic healing in IBD has the potential to be a compelling future application.

In addition, although not yet studied in humans, one group has developed an ingestible microbial biosensor that has been used in the gastrointestinal tracts of small and large animal models. This device includes genetically modified bacteria that luminesce after encountering inflammation-related signals such as NO, H_2O_2, thiosulfate, and tetrathionate. The luminescence is converted to electrical signals that have successfully detected colitis in mouse and pig models.[45]

Remote Monitoring in Special Populations

Rural Populations

Rural patients often have poor access to clinics and laboratories, which has downstream effects on their IBD care as well as their ability to participate in research. However, these patients deserve the same level of care as patients living in urban settings in terms of frequency and quality of biochemical parameter measurements, access to an IBD provider, and the option to participate in research. Many of the devices previously described, paired with virtual visits, could pave the way for tighter monitoring of inflammation and drug levels; they could also open avenues to participation in clinical trials and increase diversification of research cohorts through the inclusion of rural patients.

Pregnant Patients

In pregnant patients with IBD, tight control using remote monitoring is crucial. Some studies have shown that some biochemical parameters such as CRP are less accurate in determining disease activity, especially in later trimesters, and endoscopy may be less comfortable/less feasible for pregnant IBD patients.[46] However, fecal calprotectin remains an accurate marker of inflammation in pregnant patients with IBD.[47] IBDoc was used successfully in Canada in pregnant patients with UC and CD, with all

survey respondents strongly preferring the IBDoc home fecal calprotectin measurement compared with standard laboratory measurement and stating that they would use it again at home in the future.[48]

Practicality and Potential Drawbacks of Remote Monitoring for Patients and Providers

Before home-based self-administered tests can be considered a mainstay of IBD care and implemented for IBD patients across the United States, many considerations need to be examined. For example, one study examined adherence to remote monitoring modalities, and found that patients with a higher disease burden were more adherent than patients who were deemed by the study to have a better health-related quality of life.[49] Another study found that in patients with IBD who were offered a home fecal calprotectin test, only 35% of them performed it, with primary reasons for nonadherence being forgetfulness, lack of perceived benefit, constipation, and refusal to handle feces.[50] However, many of these factors that led to nonadherence are still present in the laboratory setting, so it may be prudent to look to other specialties and how they incentivize patients to check their biochemical markers even when they are feeling well. In the pediatric IBD population, one study found that a majority (61%) of parents were dissatisfied with IBDoc owing to difficulties with the smartphone application and problems with the test hindering accurate measurements (different from ELISA).[51] This may not be the same case in adult patients, who manage this quite well in regions where the test is available commercially.[12-14] Furthermore, devices such as the continuous sweat monitor have the potential to increase patient anxiety owing to the occasionally falsely elevated levels that are available to them in real time.

Additional considerations such as access to at-home Internet and digital health literacy in aging patients with IBD should also be examined. It has been shown that telemedicine offers a comparable alternative to in-person visits that is convenient, low cost, and does not compromise the quality of care for older patients obtaining gastrointestinal care.[52] With adequate teaching about new home technologies, it could be reasonably extrapolated that the use of home-monitoring technologies for IBD patients of all ages could be a high-quality and convenient way to stay on top of their gastrointestinal care. Although this trend of home technologies removes the burden of travel for some, it is important to keep in mind that it could make access to care for others (such as those without reliable home Internet) more difficult. Prior research has shown that upwards of 24% of rural adults say access to high-speed Internet is a major problem in their local community,[53] and many of these new technologies require access to the Internet to upload data.

For clinicians, the ability to obtain data at regular intervals would be greatly beneficial for optimizing a patient's IBD care, possibly reducing the need for urgent visits and/or hospitalizations. However, clinicians also have the potential to receive increased calls or messages from patients who now have regular, immediate access to a wealth of data. Further, if appropriate testing intervals are not clearly established, some patients may become hypervigilant about monitoring their disease, thereby increasing stress and/or anxiety and reducing IBD-related quality of life. In these cases, it is possible that working collaboratively with mental health providers specializing in IBD could mitigate some of this anxiety and reduce unnecessary clinic contacts or testing.[54] In addition, many remote monitoring technologies, such as IBDoc for fecal calprotectin and fingerprick for therapeutic drug monitoring, although successful in other countries, are not yet approved for use in the United States. Before integration of these tools into clinical practice, it will be critical to better understand optimal testing intervals, implementation processes, and management of the change in patient flow. Optimally, insurance companies would provide reimbursement for interpretation and discussion of results collected through these remote technologies.

The future of remote monitoring of IBD demonstrates burgeoning potential for monitoring at home, but these modalities need further study before being integrated into clinical practice. Researchers and clinicians need to collaboratively test these tools to ensure they are comparable to current gold standard tests and should focus on equitable access for patients who already have health care barriers, such as those living in rural regions. Just as important as understanding the test characteristics of these new modalities will be leveraging implementation science to identify the best approaches for incorporation into routine clinical practice. If performing the testing is not easy for patients and providers, it will not be used. Integration of a provider's order for these novel tests as well as entering the subsequent results into electronic medical records will be required, and user support for patients will need to be available. Furthermore, insurance coverage of these tests is an important consideration for patients. Any saved travel costs should not be replaced by increased prices of at-home tests.

Conclusion

With advancements in technologies, patients will likely soon have the option to monitor their biochemical parameters of IBD in the comfort of their own homes. At-home monitoring of fecal calprotectin and therapeutic

drug levels have already been successfully used in other countries, and saliva, colorectal mucus, and sweat-based modalities are in development. This convenience can be offered to all patients and can save time and money, with a clear advantage for rural patients living far from any laboratory. At-home monitoring has the opportunity to increase therapeutic monitoring for patients with IBD, resulting in earlier detection and more rapid treatment of IBD exacerbations.

Disclosures

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