ADVANCES IN UPPER GI DISORDERS

Current Developments in the Management of Upper GI Disorders

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Point-of-Care Esophageal Mucosal Impedance Testing for Diagnosing GERD and EoE

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G&H What useful information does esophageal mucosal impedance testing provide?

MV Mucosal impedance (MI) testing assesses the integrity of the esophageal epithelium. Any condition that alters the esophageal epithelium will result in a signal in the MI testing unique to that medical condition. For example, patients who have gastroesophageal reflux disease (GERD) will have alteration of the distal esophageal epithelium. During endoscopy, one can then determine whether the distal esophageal epithelium is intact, and if that patient has reflux. Similarly, in patients with eosinophilic esophagitis (EoE), the esophageal epithelium is typically involved all along the esophagus, and MI can identify this pattern of injury during endoscopy and provide an accurate diagnosis. It is a very simple test that can help gastroenterologists decide whether the esophageal epithelium is altered from a variety of conditions, including GERD and EoE.

> As the endoscopist pulls back the endoscope with the MI device at the tip, measurements are taken along the esophagus to assess esophageal integrity.

G&H How simple is it to perform esophageal MI testing and interpret the results?

MV It is very simple to perform. This is a point-of-care test that can be completed during a routine upper endoscopy while the patient is sedated, adding only a few minutes to the examination time. The device fits onto the tip of an endoscope, which is then introduced into the esophagus. This avoids the drawbacks of having to either insert a catheter into the patient's nose or deal with a monitor for a wireless device. MI testing is capable of evaluating the entirety of the esophagus. As the endoscopist pulls back the endoscope with the MI device at the tip, measurements are taken along the esophagus to assess esophageal integrity. The device software creates an image of the interior contour of the esophagus, which appears simultaneously on the monitor, allowing the clinician to assess for alterations in real time and determine if it is normal, GERD, or EoE. Clinicians can then use that information to make the final diagnosis.

G&H Is esophageal MI testing for the general gastroenterologist or is it for tertiary care?

MV Like any new device that comes on the market, this test has been used initially in academic centers where studies are conducted to see its value, sensitivity, specificity, and positive/negative predictive value, and then it rolls into general gastroenterology practice. The device is approved by the US Food and Drug Administration and is purchasable. Many gastroenterologists in both tertiary care and private practice are currently using it.

G&H Will MI testing influence the performance of other tests for GERD? Where does it fit into the diagnostic process?

MV The answer is no. Esophageal MI testing does not impact anything else that the gastroenterologist may want to do for a patient. It simply indicates whether the esophageal epithelium is intact or has been altered by either reflux, EoE, or other inflammatory conditions. Currently, tests like pH monitoring with a catheter or wireless device are used to diagnose reflux, and biopsy is used to assess whether someone has EoE. MI testing does not alter this process. Essentially, MI testing can provide the same diagnosis in a point-of-care setting during endoscopy, as is obtained with some of those tests for reflux, but without having to wait for results of monitoring or biopsies, which can take a few days.

G&H Can it replace other tests?

MV In my opinion, MI testing should replace pH testing, impedance pH testing, or biopsies in EoE because it is potentially the next generation of how we diagnose reflux. The gastroenterology population of patients has changed over time. Currently, these diagnostic tests are performed in patients who have treatment failure or have partially responded to proton pump inhibitor (PPI) therapy, for example, in GERD. The role of the device is going to be to determine whether the patient's esophageal epithelium is normal or not. Point-of-care MI testing can provide an immediate answer to the question of whether there has been chronic acid or bile exposure in the esophagus and whether that has resulted in separation of the epithelium or alteration. I can see esophageal MI testing eventually replacing other tests as it is adopted more by gastroenterologists, but this will likely take time. It is exceedingly difficult to tell people to move away from what they have been doing for many years, and what they are used to doing. However, in my opinion, yes, at some point people will be using MI testing instead of the traditional tests currently being used.

In any patient currently being referred for pH testing, with either a catheter or wireless device, esophageal MI testing can be used.

G&H In which patients or clinical scenarios might esophageal MI testing be most helpful?

MV This is an important question. In any patient currently being referred for pH testing, with either a catheter or wireless device, esophageal MI testing can be used. Currently, impedance or wireless devices are being used in patients with reflux who have partial response or no response to treatment, or who have been referred for surgical fundoplication to prove objectively that reflux is present. Esophageal MI testing would be used in that population. If testing a patient off PPI therapy, the patient would be taken off PPIs for 7 to 14 days prior to esophageal MI testing, and the test performed off therapy in the same way—as a point-of-care test during endoscopy. If one is interested in knowing what is going on in the esophagus on therapy, esophageal MI testing can be performed that way as well. The device can be used off or on therapy in patients who are either partially responsive or nonresponsive to PPI therapy to see if their symptoms continue to be reflux-related. The test could be performed similarly in patients with EoE to see if there is EoE pretherapy and then used posttherapy to follow patients to see whether the implemented therapy has resulted in normalization of the epithelium.

G&H Are there any limitations to the testing?

MV The limitation of it is more about what we are currently using and what we are comfortable with. For example, in pH testing, we are accustomed to seeing if patients have predominantly upright reflux during the day or supine reflux at night. Esophageal MI testing does not determine whether there is acidity during the day or at night; it is looking at the consequence of a chronic inflammatory process on the epithelium. A patient may have reflux one day but not the next; likewise, a pH test may be normal one day, but abnormal the next. For the gastroenterologist who is trying to determine whether a patient is refluxing at night or day, esophageal MI testing is not going to provide that information. It is not the same as pH monitoring.

G&H What is the current consensus on the use of esophageal MI testing in the diagnosis of GERD?

MV I think that it will take time for consensus among gastroenterologists as they have more experience with the test and can see the benefit of it. Have the societies recommended use of this test over our current traditional methods? The current answer is no because esophageal MI testing is new, and we have not had enough experience

with it yet in that sense. As someone who has developed it over the past 10 to 15 years and has used it clinically, I can see where it could go, and hopefully soon, societies agree with this assessment.

G&H How might new evidence from studies evaluating esophageal MI testing help clarify its role in clinical practice and in diagnosing GERD, specifically?

MV Anytime something new comes along, one of the questions people ask is, how easy is it to use? Esophageal MI testing is much easier than putting a catheter in a patient's nose. From the patient's perspective, it removes that discomfort because it is done during endoscopy when patients are sedated. The other advantage is not having to purchase expensive monitors required for wireless devices and then having to wait for the device to be returned in order to interpret the results. The interpretation of esophageal MI testing happens at the point of care during endoscopy. Another question is what its clinical benefit is over what is currently being done. As I mentioned, this device has a very high sensitivity, specificity, and positive and negative predictive value in EoE, and its performance in GERD seems to be better based on recent studies, when looking at the gold standard, which is presence of inflammation in the esophagus. Preliminary studies, including a recent study on PPI use and pH monitoring, suggest that esophageal MI testing may perform better than pH monitoring in patients with GERD. Another recently published study assessed the value of MI testing after surgery in determining the success of surgical fundoplication. These results are promising, but more independent validation and robust data are needed.

G&H Does the test have a role in the diagnosis of EoE?

MV Yes, it definitely does. Currently, EoE, by name, suggests that there are eosinophils in the esophagus, which means that biopsy results show the presence of eosinophils. I think we need to look beyond just counting eosinophils because not only is there a high level of variability in the number of eosinophils and variability on where biopsies are taken, but establishing an eosinophil count is tedious and increases the pathology assessment time. This device, being that it can be done at point-of-care diagnosis, has very high potential; however, overcoming the current practice will require time, as well as increased use and comfort level among clinicians.

G&H What further research is needed?

MV Outcome studies are the most important, but other types of research are also needed. In clinical practice, there are many applications for esophageal MI testing, and it is currently being evaluated for additional clinical utility. For example, for patients with Barrett esophagus who have high-grade dysplasia and typically receive ablative therapy followed by high-dose acid suppression, esophageal MI testing could potentially be useful in determining whether that medicine is working, whether there is alteration from reflux, or whether that patient's reflux is under control. It could be useful in patients who are being considered for fundoplication to see if they have reflux, and after fundoplication, in patients who have either return of symptoms or other symptoms, to rule out reflux or to see whether there is any continued reflux or changes. Further research from other institutions in addition to our institution's studies will help define its utility. Overall, it would be wonderful to have more published studies evaluating esophageal MI testing for reflux testing, whether it be off or on therapy (PPI or fundoplication), postablative therapy in Barrett esophagus, or pre- or posttreatment of EoE, so that the device can become more widespread, and clinicians feel more comfortable using it.

Disclosures

Dr Vaezi is a coholder of a patent for the MI testing device and concept (Diversatek) and is a consultant for Bayer, Diversatek, Ironwood Pharmaceuticals, ISOThrive, Medtronic, Phathom Pharmaceuticals, and Sanofi.

Suggested Reading

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