ISSUE 2 // SPRING 2012

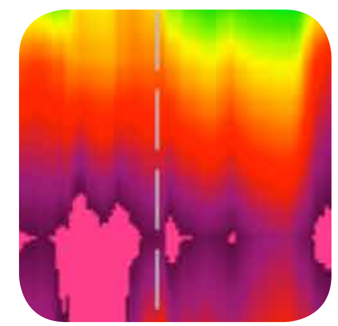
Givensight

HIGH RESOLUTION MANOMETRY: The Next Generation

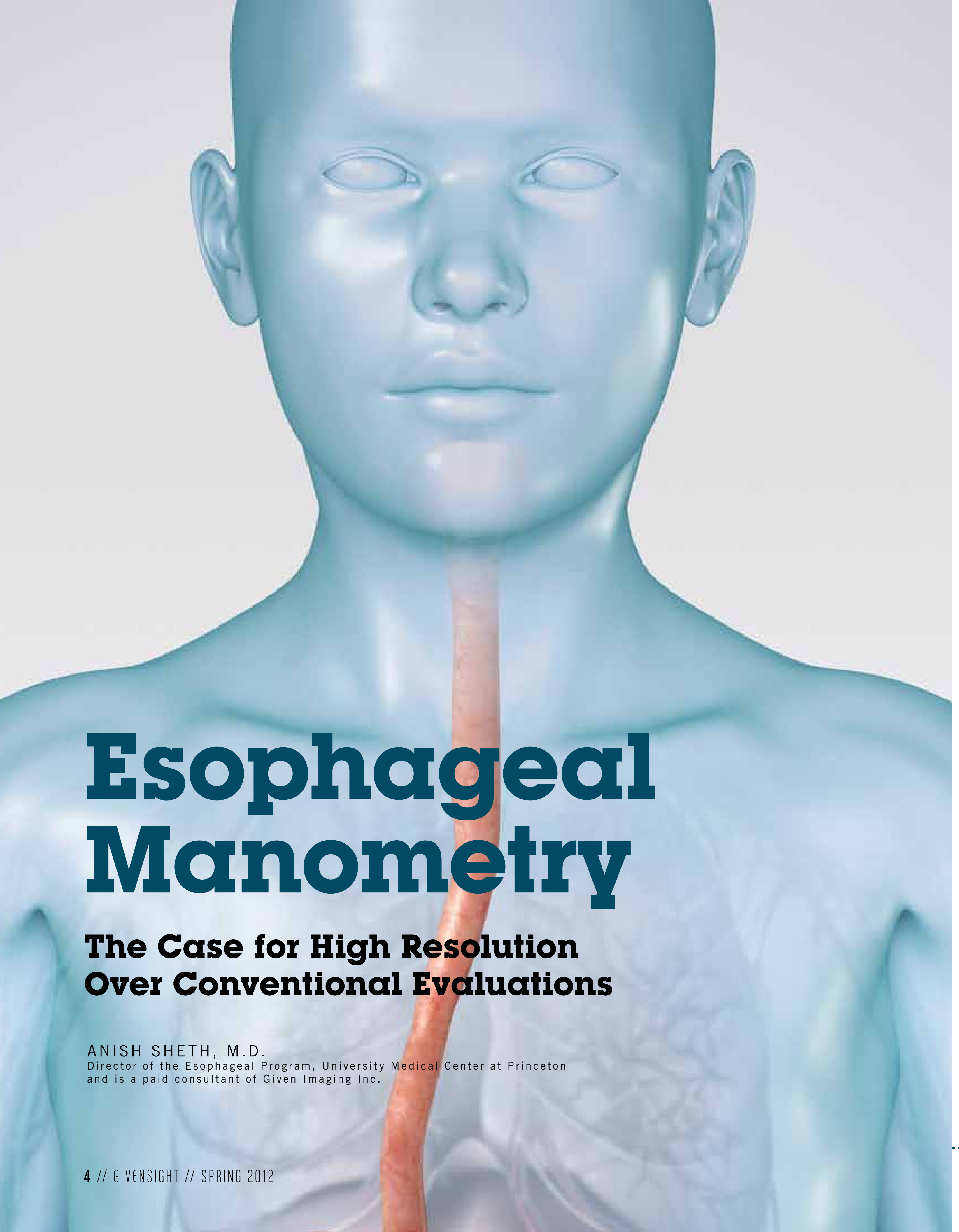
ESOPHAGEAL MANOMETRY – THE CASE FOR HIGH RESOLUTION OVER CONVENTIONAL EVALUATIONS

HIGH RESOLUTION ANORECTAL MANOMETRY – DIAGNOSING DYSSYNERGIC DEFECATION AND FECAL INCONTINENCE

Contents



REFERENCES: 1. Bansal A, Kahrilas PJ. Has high resolution manometry changed the approach to esophageal motility disorders? *Curr Opin Gastroenterol.* 2010;26:344-351. **2.** Jones MP, Post J, Crowell MD. High resolution manometry in the evaluation of anorectal disorders: a simultaneous comparison with water-perfused manometry. *Am J Gastroenterol.* 2007;102(4):850-855. **3.** Conklin J, Pimentel M, Soffer E, eds. *Color Atlas of High Resolution Manometry.* New York, NY: Springer Science + Business Media, LLC; 2009.



Esophageal Manometry

The Case for High Resolution Over Conventional Evaluations

ANISH SHETH, M.D.
Director of the Esophageal Program, University Medical Center at Princeton and is a paid consultant of Given Imaging Inc.

Manometry is the primary tool utilized in the evaluation of functional esophageal disorders. It is the gold standard for diagnosing certain gastrointestinal conditions, such as the motility disorder achalasia. Traditionally, these evaluations had been performed with conventional manometry that uses water-perfused or solid-state catheters, containing 4 to 8 pressure sensors at 5-cm intervals in the esophagus and stomach, and which can include a sleeve sensor at the esophagogastric junction.[1,2]

High resolution manometry (HRM) offers significant advantages in accuracy over conventional manometry. The catheter has more recording sites (36 solid-state sensors),[2,3] permitting the complete definition of intraluminal pressure and the reduction of movement-related artifacts.[4] Closely spaced sensors obviate the need for catheter "pull-through" during lower esophageal sphincter (LES) analysis, thereby enhancing patient comfort and decreasing overall procedure time.[5] Furthermore, HRM data are depicted in spatiotemporal contour plots, making study interpretation easier.[5]

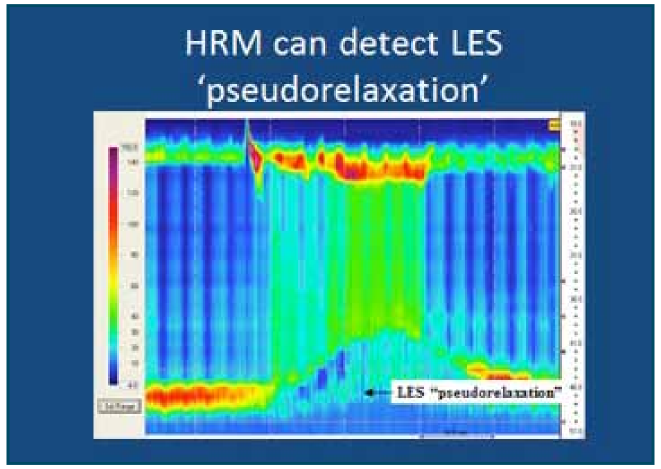
Why is HRM important in your practice?

Achalasia, a common idiopathic motility disorder, is characterized by incomplete LES relaxation and absence of esophageal body peristalsis, which results in difficulty swallowing. HRM can more accurately identify LES impairment and also differentiate simultaneous contractions from isobaric pressurization in the esophageal body. LES "pseudorelaxation" occurs when conventional manometry misidentifies proximal LES migration as LES relaxation, which can lead to a missed diagnosis of achalasia. HRM can easily identify LES movement artifact (see Figure 1) and thereby accurately diagnose impairment in LES relaxation in cases where LES migrates in a cephalad direction (sometimes 8 to 10 cm). The ability of HRM to differentiate among the achalasia subtypes by the pattern of esophageal pressurization may impact choice of therapy.[5]

The problem of pseudorelaxation limits the sensitivity of conventional manometry in diagnosing achalasia. HRM was developed to solve that problem by measuring integrated relaxation pressure (IRP). IRP is measured within the deglutitive window beginning at the time of initiation of the swallow until the arrival of the peristaltic contraction at the LES captures the axial movement of the LES that is attributable to longitudinal muscle contraction.[5]

HRM, with its high number of pressure sensors, facilitates the identification of a confirmed diagnosis of classic achalasia. Irregularities such as abnormal LES relaxation (pseudorelaxation) and sporadic peristaltic waves; mixed peristaltic and simultaneous segments of the esophageal body in a single wave; high amplitude simultaneous waves with or without poor LES relaxation; and severe esophageal body dysfunction but with borderline or normal LES characteristics can be visualized more readily with HRM.[6] Other indications for esophageal manometry include noncardiac chest pain, before and after antireflux surgery, and prior to pH catheter placement.

Figure 1. High resolution image of abnormal LES relaxation called "pseudorelaxation"



Studies confirm the value of HRM

The reproducibility of LES resting and relaxation pressure assessed with HRM is better than with conventional manometry and further supports the clinical use of HRM.[1] In one volunteer study of HRM versus conventional manometry, statistically significant concordance values were found in the HRM group for upper esophageal sphincter pressure ($P = .02$), transition zone length ($P = .01$), LES length ($P = .04$), LES pressure ($P = .05$), LES relaxation pressure ($P = .03$), relative LES relaxation pressure ($P = .05$), gastric pressure ($P = .04$), and contraction amplitude 5 cm above the LES ($P = .03$). With the conventional manometry group, only LES resting pressure was significant ($P = .03$).[1,2]

Another volunteer study compared HRM with conventional manometry in which transient lower esophageal sphincter relaxations (tLESRs) were measured.[4] Here, a similar number of tLESRs were identified during 2 HRM recordings (median per subject 15 and 13; $P = .07$) versus fewer identifications with conventional manometry (median per subject, 11; $P < .01$). The overall concordance rate between the 2 HRM procedures was substantial (kappa = .61), and the interobserver agreement was almost perfect (kappa = .83). However, the interobserver agreement with conventional manometry was only fair (kappa = .38), signaling that HRM results are more reproducible and more accurate than those of conventional manometry.[4]

> "Overall, two thirds of the patients who were referred for manometry had abnormal readings that might not have been otherwise identified."

The ideal patient for esophageal manometry

The achalasia patient may present with any number of mechanical and metabolic abnormalities, from swallowing difficulties, chest pressure, and regurgitation, to weight loss, nighttime cough, and aspiration of food following a full meal.[7] Evaluation of a reported swallowing difficulty usually starts with barium esophagography, upper endoscopy, and esophageal function tests. Endoscopy appears normal in a great many patients – this procedure offers scant diagnostic value – yet it is useful for evaluation of the esophageal mucosa to rule out esophageal carcinoma.

When to refer a patient for esophageal manometry

One study surveyed referring physicians for 286 such procedures and found that manometry was requested in order to assist placement of a pH measuring device (34%), to evaluate symptoms of dysphagia (29%), to evaluate symptoms of chest pain (12%), or to evaluate symptoms of acid reflux (11%).[8] Less common reasons were to rule out a motility disorder and for preoperative testing. Overall, two thirds of the patients who were referred for manometry had abnormal readings that might not have been otherwise identified.[8] Abnormal readings were found in 81% of patients who reported symptoms of gastroesophageal reflux disease, 74% of patients with swallowing difficulties, and 59% of those reporting chest pain.[8] New information was obtained in 87% of patients, a change in diagnosis occurred in 30% of patients, and management decisions changed in 44% of patients, thus underscoring the diagnostic importance of manometry.[8]

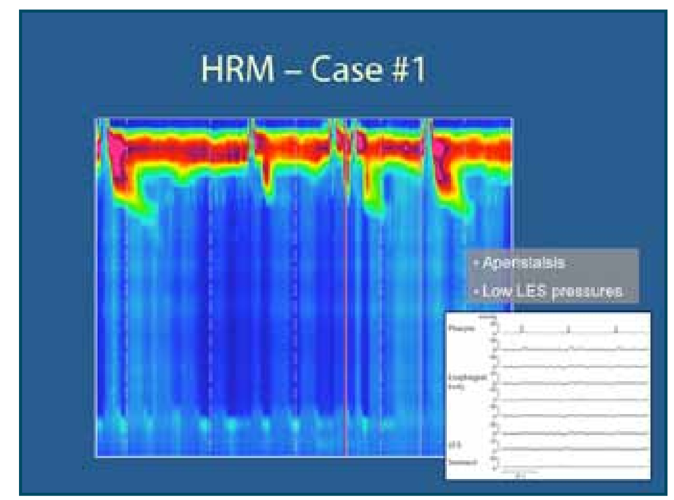
CASE STUDIES

Case 1 – A woman with refractory GERD

A 42-year-old female presented with refractory gastroesophageal reflux disease (GERD). She complained of heartburn and regurgitation that had improved slightly with twice-daily proton-pump inhibitor (PPI) therapy. She requested further workup and recommendations regarding surgical fundoplication. Upper endoscopy showed Los Angeles Classification Grade A esophagitis (1 or more mucosal breaks <5 mm in maximal length) but was otherwise normal.

Refractory GERD is defined as persistent reflux symptoms despite an adequate trial of antireflux therapy. The patient in this case had typical symptoms of GERD and had shown some improvement with PPI therapy. Her endoscopy showed evidence of mild reflux esophagitis. Medical therapy for refractory GERD is limited and many patients may request surgical intervention. Prior to surgical referral, patients should undergo esophageal manometry testing and objective assessment of acid reflux severity with Bravo® capsule or catheter-based pH monitoring. This patient agreed to have HRM.

Figure 2. High resolution image of scleroderma with corresponding line tracing



> "New information was obtained in 87% of patients, a change in diagnosis occurred in 30% of patients, and management decisions changed in 44% of patients, thus underscoring the diagnostic importance of manometry."

This patient's HRM study showed absent peristalsis and diminished LES pressures and is diagnostic of scleroderma of the esophagus. On further questioning, the patient reported Raynaud's phenomenon and a maternal history of autoimmune disease.[2]

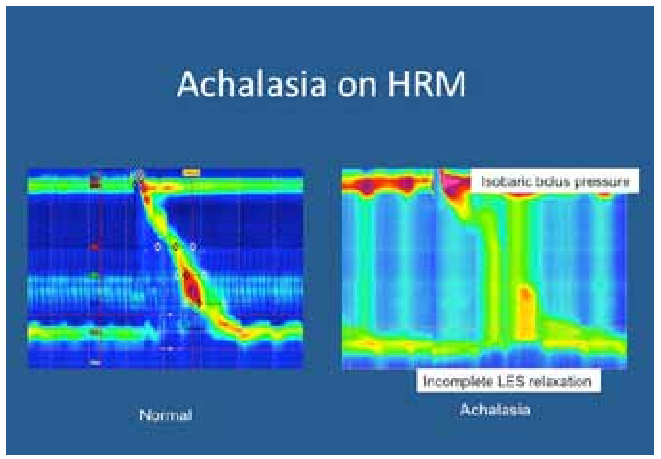
Scleroderma of the esophagus is a contraindication to surgical fundoplication given the universal occurrence of postoperative dysphagia. Gastric prokinetic therapy was added to augment acid-suppression therapy. At follow-up, the patient noted significant improvement with medical therapy and was diagnosed with systemic scleroderma based on serologic testing.

Case 2 – A man with dysphagia

A 57-year-old male presents with a 2.5-year history of dysphagia to solids and liquids with occasional nocturnal regurgitation. Mild heartburn is described, but PPI therapy offered no relief. His endoscopic evaluation was unremarkable.

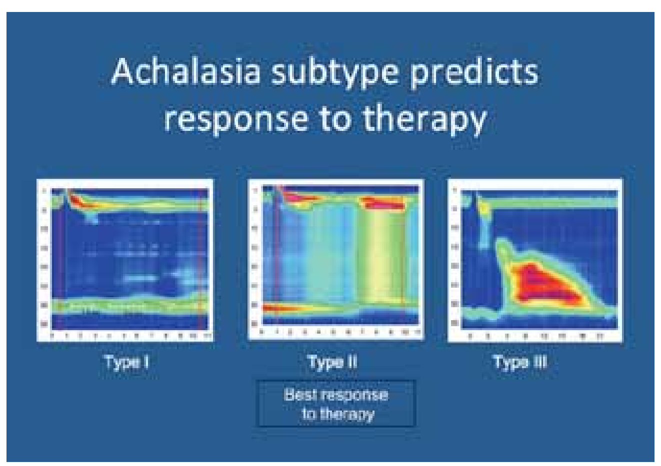
The patient has nonobstructive dysphagia, and further evaluation with HRM is indicated. In this case, the primary clinical concern is achalasia, resulting in difficulty swallowing solids and liquids. Esophageal manometry is the standard for diagnosis.

Figure 3. Achalasia showing incomplete LES relaxation



The patient's HRM shows classic achalasia with isobaric pressurization of the esophagus and impairment in LES relaxation. Furthermore, the achalasia type can be classified based on the pattern of activity in the esophageal body. This patient's subtype, type II, has the best response to therapy.[2]

Figure 4. There are 3 identifiable subtypes of achalasia pictured in high resolution topography: type I, type II, and type III



Treatment options for achalasia include pneumatic dilation and Heller myotomy, a surgical procedure in which the muscles of the cardia are cut, allowing food and liquids to pass to the stomach. Both interventions aim to decrease LES pressure and thereby improve dysphagia.[2,5]

This patient underwent endoscopic balloon dilation with a 30-mm Rigiflex balloon and experienced a dramatic improvement in symptoms. At a 2-week follow-up, he denied dysphagia and was noted to be "100% symptom-free."

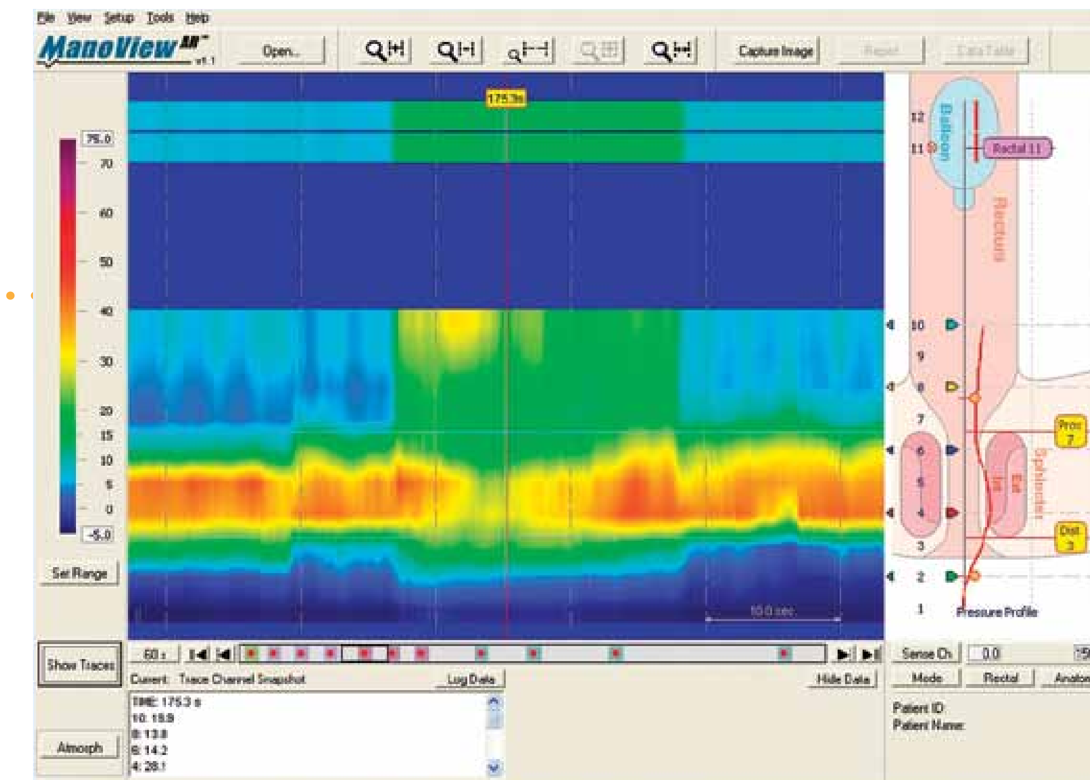
REFERENCES

1. Bogte A, Bredenoord AJ, Oors J, Siersema PD, Smout AJ. Reproducibility of esophageal high resolution manometry. *Neurogastroenterol Motil.* 2011;23:e271-e276.
2. Ayazi S, Crookes PF. High resolution esophageal manometry: using technical advances for clinical advantages. *J Gastrointest Surg.* 2010;14 (Suppl 1):S24-S32.
3. Park MI. Recent concept in interpreting high resolution manometry. *J Neurogastroenterol Motil.* 2010;16:90-93.
4. Roman S, Zerbib F, Belhocine K, des Varannes SB, Mion F. High resolution manometry to detect transient lower oesophageal sphincter relaxations: diagnostic accuracy compared with perfused-sleeve manometry, and the definition of new detection criteria. *Aliment Pharmacol Ther.* 2011;34:384-393.
5. Bansal A, Kahrilas PJ. Has high resolution manometry changed the approach to esophageal motility disorders? *Curr Opin Gastroenterol.* 2010;26:344-351.
6. Galey KM, Wilshire CL, Niebisch S, et al. Atypical variants of classic achalasia are common and currently under-recognized: a study of prevalence and clinical features. *J Am Coll Surg.* 2011;213:155-161; discussion 162-163.
7. Fischella PM, Carter SR, Robles LY. Presentation, diagnosis, and treatment of oesophageal motility disorders. *Dig Liver Dis.* 2012;44:1-7.
8. Lacy BE, Paquette L, Robertson DJ, Kelley ML Jr, Weiss JE. The clinical utility of esophageal manometry. *J Clin Gastroenterol.* 2009;43:809-815.

ManoScan™
High Resolution Manometry
Diagnosing with definition

ManoScan™ AR

ManoScan AR provides comprehensive assessment of the pressure activity of the rectum and anal sphincters with a single placement of a catheter. This advanced diagnostic technology allows physicians to evaluate patients with impaired defecation. The procedure is easy for the clinician to perform and is more patient-friendly than conventional manometry.



- Anorectal HRM can assess and quantify normal reflex pathways as well as the relax, squeeze, and bear down functions of the anal sphincter muscles and rectum
- Anorectal HRM identifies patients who can benefit from biofeedback therapy
- Preferred method for defining the functional weakness of the anal sphincter and for the diagnosis of dyssynergia and abnormal rectal sensation

Q: How much time is involved in performing and analyzing a high resolution esophageal manometry study?

In most centers, the manometry study is performed by trained nursing staff. Each study is scheduled to last 1 hour to allow time for catheter calibration and room turnover. The study itself takes only 10 to 15 minutes, with virtually no need for catheter probe manipulation once proper positioning is achieved, thus minimizing any discomfort experienced by the patient.[1,2] Physician interpretation and report generation takes 5 to 10 minutes per study. In some centers, nurses will "prepare" the study for physician interpretation by placing landmarks in the appropriate locations and performing thermal compensation. This study "preparation" may therefore help further shorten the time it takes for the physician to analyze the manometric findings.

Q: Is high resolution manometry (HRM) better than traditional manometry?

HRM offers significant advantages for patients and providers. HRM produces high-quality studies of a uniform format and lends itself to the development of standardized objective measures of peristaltic and sphincter function of the esophagus.[1] The most important advantage of HRM is its enhanced sensitivity in diagnosing achalasia[1,2] — clinically the most relevant esophageal motility disorder.

Q: How many manometry studies are needed to assess competency in interpreting studies?

The American Gastrointestinal Association (AGA) recommends 50 proctored manometry studies for level 2 certification but does not distinguish between traditional manometry and HRM.[3] Most new trainees will be trained on HRM systems. Physicians already trained in traditional manometry interpretation can attend courses held in conjunction with regional and national meetings in order to acquire the necessary HRM interpretation skills. The table below describes the requirements for training as outlined in the Gastroenterology Core Curriculum sponsored in part by the AGA.[3]

Guidelines for Level 2 Training in Motility:
Threshold Number of Proctored Studies Required Before Assessing Competence

Studies	Required number
Standard esophageal motility	50
Gastric and small-bowel motility studies (either perfused catheter or solid-state transducers, or impedance catheters)	25
Indications, interpretation, and significance of scintigraphic measurement of gastric emptying	25

Q: What is the added value of HRM with impedance?

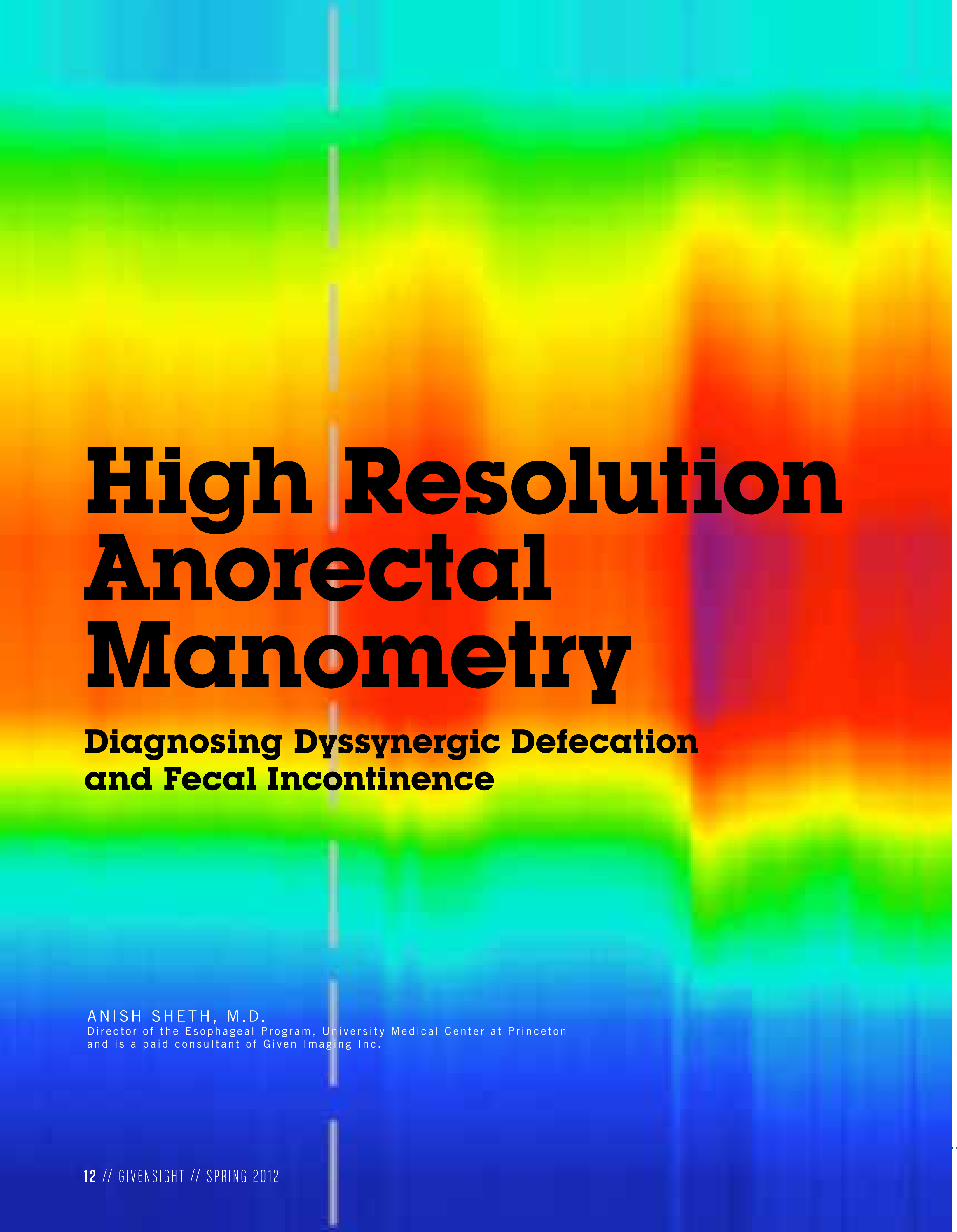
In addition to esophageal pressure activity, HRM systems with impedance technology now have the capability of assessing bolus transit. The clinical relevance of this information is not entirely clear, but impedance can offer additional information in patients with ineffective esophageal motility and distal esophageal spasm. For instance, impedance can distinguish patients with weak peristalsis who have impaired bolus transit from those who do not.[4,5]

Q: Can substances other than water be used during HRM?

Yes. Many centers are now using viscous swallows in patients with dysphagia to reproduce clinical symptoms. Small studies have shown increased diagnostic yield with the addition of these non-liquid swallows.[2,6]

REFERENCES

1. Kahrilas PJ. Esophageal motor disorders in terms of high resolution esophageal pressure topography: what has changed? *Am J Gastroenterol.* 2010;105(5):981-987.
2. Fox MR, Bredenoord AJ. Oesophageal high resolution manometry: moving from research into clinical practice. *Gut.* 2008;57(3):405-423.
3. The American Gastroenterological Association (AGA) Institute, the American College of Gastroenterology (ACG), the American Association for the Study of Liver Diseases (AASLD), and the American Society of Gastrointestinal Endoscopy (ASGE). Training in motility and functional illnesses. In: *The Gastroenterology Core Curriculum.* 3rd ed. New York, NJ: Elsevier; 2007:38-41.
4. Tutuian R, Castell DO. Clarification of the esophageal function defect in patients with manometric ineffective esophageal motility: studies using combined impedance-manometry. *Clin Gastroenterol Hepatol.* 2004;2(3):230-236.
5. Tutuian R, Vela MF, Balaji NS, et al. Esophageal Function Testing with Combined Multichannel Intraluminal Impedance and Manometry: Multicenter Study in Healthy Volunteers. *Clin Gastroenterol Hepatol.* 2003;1(3):174-182.
6. Basseri B, Pimentel M, Shaye OA, Low K, Soffer EE, Conklin JL. Apple sauce improves detection of esophageal motor dysfunction during high resolution manometry evaluation of dysphagia. *Dig Dis Sci.* 2011;56(6):1723-1728.



High Resolution Anorectal Manometry

Diagnosing Dyssynergic Defecation and Fecal Incontinence

ANISH SHETH, M.D.
Director of the Esophageal Program, University Medical Center at Princeton and is a paid consultant of Given Imaging Inc.

High resolution manometric (HRM) techniques have improved the accuracy of identifying the mechanisms of fecal incontinence and dyssynergic defecation, a cause of chronic constipation. Clinical practice and uncontrolled studies suggest anorectal manometry can be useful in assessing certain conditions such as fecal incontinence, pelvic floor dyssynergia, Hirschsprung's disease, and anatomic defects of the anal sphincters. In the case of fecal incontinence, anorectal manometry is used to define functional weakness of one or both sphincter muscles, with the complementary use of anal endosonography demonstrating whether this weakness is caused by anatomic derangement, and also to perform biofeedback training. For pelvic floor dyssynergia, anorectal manometry is used to support findings of other tests and to perform, monitor the outcome of, and possibly predict responses to biofeedback training. In Hirschsprung's disease in children (congenital aganglionic megacolon), anorectal manometry is used to confirm diagnosis, and it is also used to diagnose anatomic defects of the anal sphincter if an imaging method such as ultrasonography is not available.[1]

THE PLACE FOR MANOMETRY AMONG COMMON ANORECTAL DISORDERS

Constipation and fecal incontinence are 2 anorectal disorders commonly encountered in clinical practice. Women who have undergone prior pelvic surgery or childbirth are at particularly greater risk for developing defecatory difficulties. A detailed physical and neurologic examination and digital rectal examination (DRE) are essential in the diagnostic evaluation of constipation or fecal incontinence.[2] Several diagnostic imaging techniques are available for the assessment of anorectal abnormalities. These include barium enema, evacuation proctography (defecography), anal ultrasonography, magnetic resonance imaging and computed tomographic scanning, and colon transit studies.[1] The methods used to assess neuromuscular function are conventional anorectal manometry and high resolution anorectal manometry, which are also used to test for rectal sensation. Several types of probes and pressure-recording devices are available to measure rectal sensation when several maneuvers are performed, such as squeeze, party balloon inflation, attempted defecation, and intermittent rectal balloon distension.[2] Many patients with constipation and fecal incontinence will improve with medical and pharmacologic therapy, whereas those with refractory symptoms may require additional diagnostic testing, such as anorectal manometry, which quantifies sphincter pressures, rectal sensation and compliance, and rectoanal reflexes.[2] High resolution anorectal manometry provides greater physiologic detail that may improve assessment of anorectal disorders.[3]

Constipation, Dyssynergic Defecation, and Colonic Inertia

Most cases of constipation can be successfully managed with

> "High resolution anorectal manometry provides greater physiologic detail that may improve assessment of anorectal disorders."

dietary modification and laxative administration. Refractory constipation (i.e., primary constipation) is usually caused by altered anorectal neuromuscular function or altered colonic function.[4]

Dyssynergia – the pressure problem that manometry can measure

Dyssynergia is an acquired behavioral disorder of defecation and is characterized by dysfunction of coordination of anorectal muscles and pelvic floor muscles during defecation.[2] In most individuals, dyssynergia is a consequence of faulty toilet habits, painful defecation, obstetric or back injury, and brain-gut dysfunction.[2] Constipated patients who have the urge to defecate but experience incomplete evacuation and the need for frequent straining may be suffering from dyssynergia.[2] The most common abnormality is impaired anal sphincter relaxation. Failure of the anal sphincter muscles to relax with defecation impairs stool bolus exit. Diminished intrarectal pressure generation caused by pelvic floor weakness is another common cause of defecatory dysfunction.

Anorectal manometry provides a comprehensive assessment of pressure activity in the rectum and anal sphincter region, together with an assessment of rectal sensation, rectoanal reflexes, and rectal compliance, and is necessary for a diagnosis of dyssynergic defecation. Manometry can identify dyssynergic patterns of defecation, which may be categorized into 4 types.[5] Type I is characterized by the ability to generate an adequate pushing force (increase in intraabdominal pressure) along with a paradoxical increase in anal sphincter pressure. Type II is characterized by the inability to generate an adequate pushing force (no increase in intrarectal pressure) but can exhibit a paradoxical anal contraction. With type III, the patient can generate an adequate pushing force (increase in intrarectal pressure), but either has absent or incomplete (<20%) sphincter relaxation (i.e., no decrease in anal sphincter pressure); and with type IV, the patient is unable to generate an adequate pushing force and demonstrates absent or incomplete anal sphincter relaxation.[5]

Anorectal manometry is useful for the diagnosis of dyssynergic defecation and altered rectal sensation and can identify patients who may benefit from biofeedback therapy. Anorectal manometry catheters can also be used therapeutically to provide biofeedback, and is the preferred treatment for constipated patients with dyssynergia; however, HRM may provide better characterization of dyssynergia.[2,6]

Colonic inertia – using manometry to assess biofeedback therapy

Chronic constipation is traditionally classified as isolated outlet obstruction, isolated colonic inertia, or both.[7]

Colonic inertia, also known as slow-transit constipation, is characterized by prolonged colon transit resulting in infrequent bowel movements. Patients with isolated colonic inertia can be managed successfully with laxative and/or promotility agents. However, refractory cases may require surgical intervention, most commonly with subtotal colectomy.[7] Radiologic studies such as magnetic resonance defecography can be used to identify which anorectal abnormalities might be suitable for surgical intervention.[8] The prevalence of outlet obstruction depends on the method used for its identification. Anorectal manometry is reported to identify this disorder 20%-75% of the time in constipated patients, and a similar percentage is identified by balloon expulsion testing (23%-67%).[7] Patients simulate defecation during manometry, and thus abnormalities in anal sphincter relaxation can be identified.[2] In addition, anorectal manometry yields valuable information regarding anal sphincter strength, anorectal reflexes, and rectal sensation.[2] Solid-state manometry probes with microtransducers are ideal for biofeedback therapy.[4] Here, the transducers that are located in the rectum and anal canal offer a visual display of pressure activity throughout the anorectum, providing visual feedback to the patient. Sensory training can also be performed using the same probe. Thus, this system can serve as a comprehensive device for neuromuscular training.

"The clarity of HRM may improve assessment of anorectal disorders, particularly obstructive defecation."

Fecal incontinence – manometry's role in strengthening sphincter muscles

Fecal incontinence occurs primarily as a result of anal sphincter muscle weakness. The anal sphincter mechanism is made up of the internal (IAS) and external (EAS) sphincters, concentric rings of muscle that regulate retention and passage of stool from the rectum. Muscle weakness can occur due to obstetric trauma or neurologic injury and can manifest as mild undergarment soiling or frank incontinence of formed stool.

In patients with diarrhea, evaluation to identify underlying causes may be beneficial. Stool-bulking agents and antidiarrheal agents can help manage incontinence by firming up the stool. When these measures fail, anorectal manometry is indicated to assess internal and external sphincter pressures and rectal sensation.[2] Manometry catheters can also be used for biofeedback therapy to strengthen the anal sphincter muscles, improve rectoanal coordination, and enhance rectal sensory thresholds.[9]

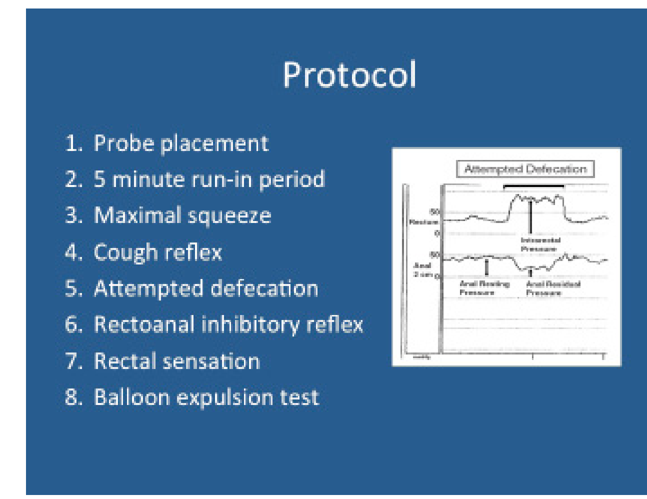
Figure 1. ManoScan High Resolution 12 Channel Adult Anorectal Catheter with 10 sphincter sensors and 2 balloon sensors

Why is high resolution anal manometry better than conventional techniques?

High resolution anorectal manometry catheters consist of 10 circumferential sensors spaced 6 mm apart.[10] They also have proximal sensors that measure intrarectal balloon pressures. One study that compared high resolution anal manometry with water-perfused conventional manometry in patients who experienced fecal incontinence, constipation, and/or fecal soilage found that the resting, squeeze, and relaxation pressures of the 2 methods were significantly correlated.[3] However, anal sphincter pressures recorded by the high resolution technique tended to be higher than those recorded with conventional manometry. HRM provided greater physiologic detail of the intraluminal pressure environment of the anorectum. This study is the first report comparing simultaneously performed high resolution and conventional manometry in patients with anorectal disorders. The clarity of HRM may improve assessment of anorectal disorders, particularly obstructive defecation.

Figure 2. HRM protocol

Manometry protocols vary by center; however, they typically



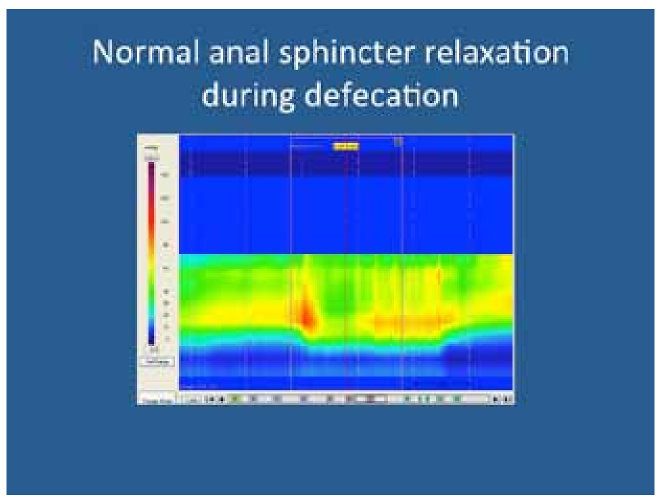
include the activities listed in the chart above. Testing is well-tolerated and typically takes 15 minutes. Following characterization of physiologic abnormalities, biofeedback can be provided to enhance anal sphincter pressures, improve anorectal coordination, and improve rectal sensation.

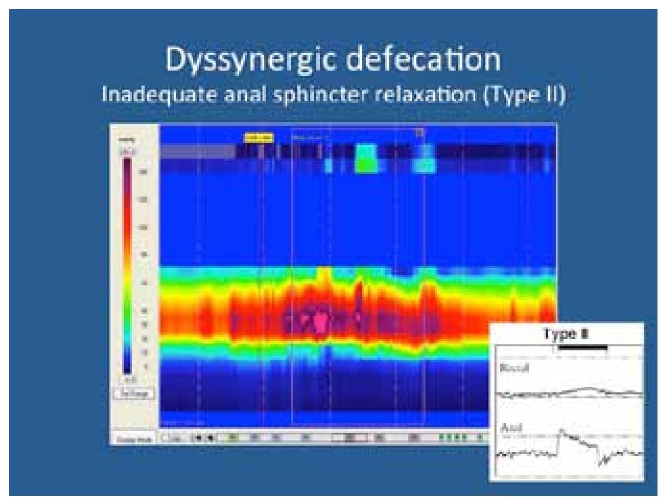
Case 1 – A woman with laxative-refractory constipation

A 45-year-old female presented with refractory constipation. She tried several types of laxatives but complained of persistent difficulty in defecating. She frequently strained and occasionally had to perform manual disimpaction. Her prior history was notable for 3 vaginal childbirths and an abdominal hysterectomy.

Anorectal manometry was performed in this patient with laxative-refractory constipation to assess for dyssynergic defecation. Manometry demonstrated type II dyssynergia characterized by impaired intrarectal pressure generation and paradoxical anal sphincter contraction during attempted defecation.

The patient was enrolled in weekly biofeedback sessions to correct these physiologic abnormalities. At 3-month follow-up, she was no longer receiving any laxative therapy and noted “80%” improvement in bowel function. Her need for manual disimpaction also decreased significantly.



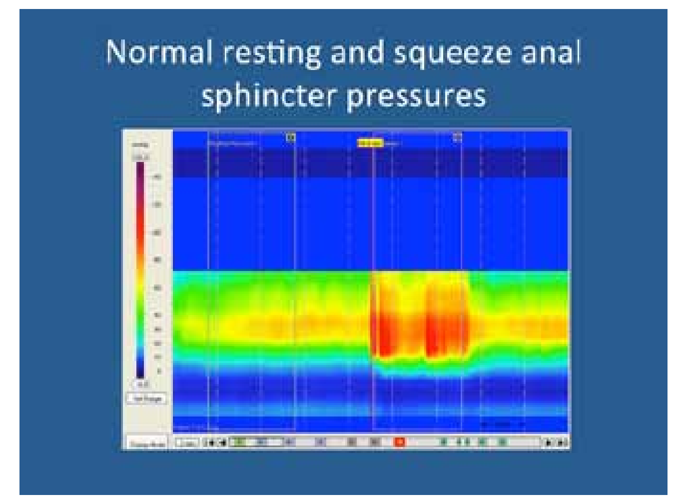


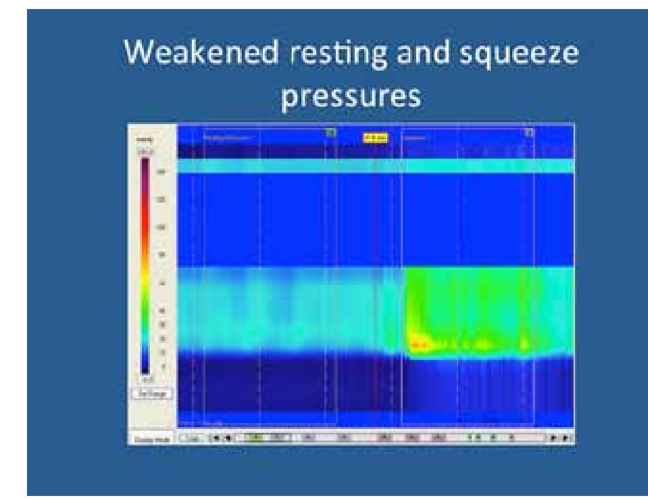
Case 2 – A woman with fecal incontinence

A 67-year-old female presented with fecal incontinence. She noted worsening symptoms over the past few years and restricted her social activities because she feared fecal soiling in public. When questioned further, the patient explained that she had the urge to move her bowels but was frequently unable to get to the bathroom in time. Obstetric history was notable for 3 vaginal childbirths, with 2 of the 3 babies weighing more than 9 pounds.

Anorectal manometry was performed to further characterize sphincter function and revealed normal internal anal sphincter pressures (56 mm Hg) but severely impaired external anal sphincter pressures (62 mm Hg). In addition, rectal sensation was impaired, with balloon inflation first detected at 50 mL (normal ≤20 mL).

Stool-bulking agents such as bran or psyllium and biofeedback were prescribed with good results. At the 4-month follow-up, EAS pressures improved to 80 mm Hg and first rectal sensation to 30 mL. Most importantly, the incontinence frequency decreased from 4 or 5 times a week to once or twice a week and her quality of life was much improved.





REFERENCES

1. Barnett JL, Hasler WL, Camilleri M. American Gastroenterological Association medical position statement on anorectal testing techniques. American Gastroenterological Association. *Gastroenterology.* 1999;116(3):732-760.
2. Rao SS. Advances in diagnostic assessment of fecal incontinence and dyssynergic defecation. *Clin Gastroenterol Hepatol.* 2010;8(11):910-919.
3. Jones MP, Post J, Crowell MD. High resolution manometry in the evaluation of anorectal disorders: a simultaneous comparison with water-perfused manometry. *Am J Gastroenterol.* 2007;102(4):850-855.
4. Rao SS. Biofeedback therapy for constipation in adults. *Best Pract Res Clin Gastroenterol.* 2011;25(1):159-166.
5. Rao SS. Dyssynergic defecation and biofeedback therapy. *Gastroenterol Clin North Am.* 2008;37(3):569-586.
6. Rao SS, Seaton K, Miller M, et al. Randomized controlled trial of biofeedback, sham feedback, and standard therapy for dyssynergic defecation. *Clin Gastroenterol Hepatol.* 2007;5(3):331-338.
7. Ragg J, McDonald R, Hompes R, Jones OM, Cunningham C, Lindsey I. Isolated colonic intertia is not usually the cause of chronic constipation. *Colorectal Dis.* 2011;13:1299-1302.
8. Elshazly WG, El Nekady AE, Hassan H. Role of dynamic magnetic resonance imaging in management of obstructed defecation case series. *Int J Surgery.* 2010;8:274-282.
9. Ozturk R, Niazi S, Stessman M, Rao SS. Long-term outcome and objective changes of anorectal function after biofeedback therapy for faecal incontinence. *Aliment Pharmacol Ther.* 2004;20(6):667-674.
10. Conklin J, Pimentel M, Soffer E, eds. *Color Atlas of High Resolution Manometry.* New York, NY: Springer Science + Business Media, LLC; 2009.

Q: What are the main components of an anorectal manometry study?

Exact manometry protocols will vary by center. Most procedures will include assessment of sphincter strength and relaxation, rectal pressure, and rectal sensation. Additional testing such as cough reflex and balloon expulsion testing are often performed based on study indication.[1]

Q: What is the advantage of high resolution anorectal manometry (HRAM) versus conventional manometry?

Similar to high resolution esophageal manometry, HRAM offers greater anatomic detail, easier study interpretation, and heightened reproducibility. The increased number of circumferential sensors obviates the need for catheter manipulation, thereby shortening study duration and minimizing discomfort experienced by the patient.[2,3]

Q: What role will 3-dimensional HRAM play in patient management?

Newer HRAM catheters equipped with 3-D technology offer even greater anatomic detail.[2] This additional information is most useful when internal and external anal sphincter pressures are assessed and has the potential to aid in the evaluation of patients with fecal incontinence requiring surgical intervention. The 3-D catheter has 256 circumferentially arrayed sensors that can further enhance understanding of anal pressure profiles, normal physiology, puborectalis function, and sphincter defects.[2]

Q: How much training is needed to perform HRAM anorectal studies?

In most centers, anorectal manometry studies are performed by nurses or technicians. Anatomic landmarks are easily recognized, and minimal catheter manipulation is needed. Biofeedback therapy, a critical component of any comprehensive anorectal program, requires more extensive training. For level 2 procedural training,* the American Gastrointestinal Association (AGA) recommends the completion of 30 proctored anorectal manometric studies and 10 proctored anal sphincter biofeedback training sessions.[4]

*According to the The Gastroenterology Core Curriculum, 3rd edition, 6 for level 2 training in motility and functional illnesses, the major goal is to acquire an in-depth knowledge of pathophysiology, clinical presentation, diagnosis, epidemiology, and therapy of gastrointestinal motility and functional disorders. Level 2 procedural training for motility studies involves training in the interpretation of diagnostic tests and is aimed at individuals who seek to be true experts in management of motility and functional disorders.

Guidelines for Level 2 Training in Motility:
Threshold Number of Proctored Studies Required Before Assessing Competence

Colonic motility studies (either perfused catheter or solid-state transducers)	20
Anorectal motility studies/anal sphincter manometric studies	30
Anal sphincter biofeedback	10
Colonic transit with radiopaque markers or scintigraphy	20

Q: Should my practice offer HRAM?

HRAM has long been thought of as a technology fit for only the most advanced academic centers. The high prevalence of chronic constipation and fecal incontinence, however, argue for widespread adoption of this testing. HRAM interpretation is straightforward and easy to learn. Most importantly, HRAM is able to offer both diagnostic and therapeutic benefits to patients who have failed traditional therapy for constipation and fecal incontinence.[2]

REFERENCES

1. Diamant NE, Kamm MA, Wald A, Whitehead WE. AGA technical review on anorectal testing techniques. *Gastroenterology.* 1999;116(3):735-60.
2. Rao SS. Advances in diagnostic assessment of fecal incontinence and dyssynergic defecation. *Clin Gastroenterol Hepatol.* 2010;8:910-919.
3. Jones MP, Post J, Crowell MD. High resolution manometry in the evaluation of anorectal disorders: a simultaneous comparison with water–perfused manometry. *Am J Gastroenterol.* 2007;102:850-855.
4. The American Gastroenterological Association (AGA) Institute, the American College of Gastroenterology (ACG), the American Association for the Study of Liver Diseases (AASLD), and the American Society of Gastrointestinal Endoscopy (ASGE). Training in motility and functional illnesses. In: *The Gastroenterology Core Curriculum.* 3rd ed. New York, NY: Elsevier; 2007:38-41.

Esophageal Manometry

Abnormal motor functions characteristic of specific clinical disorders often appear as patterns made by the color contour, so diagnosis usually involves pattern recognition.[1]

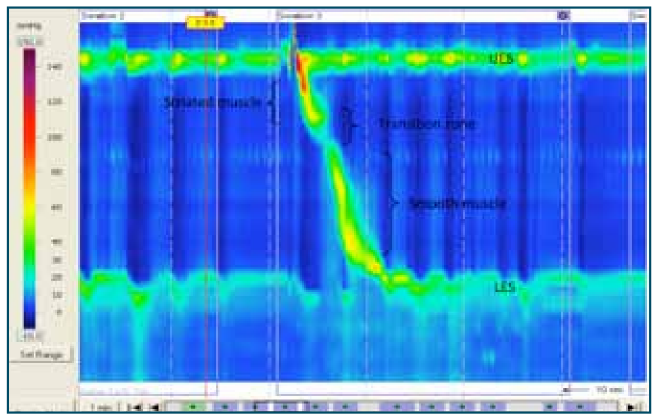


Figure 1. A high resolution color contour plot showing a normal peristaltic sequence produced by water swallows. Pressure is depicted by color and the color at the left shows the relationship between pressure and color. Between the UES and LES is intra-esophageal pressure, and below the LES is intra-gastric pressure. Image provided by Anish A. Sheth, M.D.

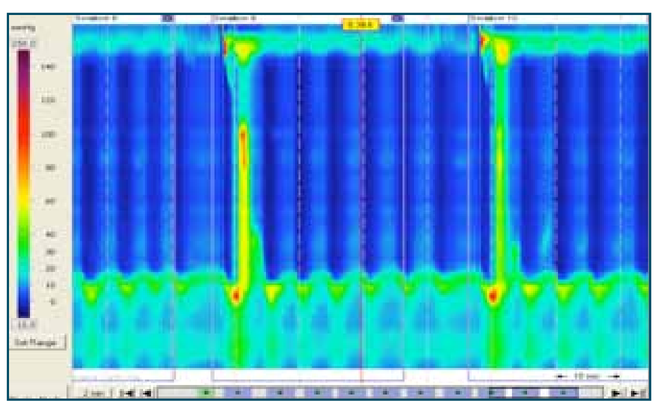


Figure 2. This high resolution color contour plot illustrates a patient with achalasia (type II). The pattern illustrates the pressure waves generated from multiple water swallows. The normal diagonal band of color shown in Figure 1 is replaced by verticle bands of yellows and greens indicating isobaric pressure waves that are weak or ineffectual. The bottom band of green shows impaired or incomplete relaxation of the LES. Both of these pressure dysfunctions are characteristic of achalasia. Image provided by Anish A. Sheth, M.D.

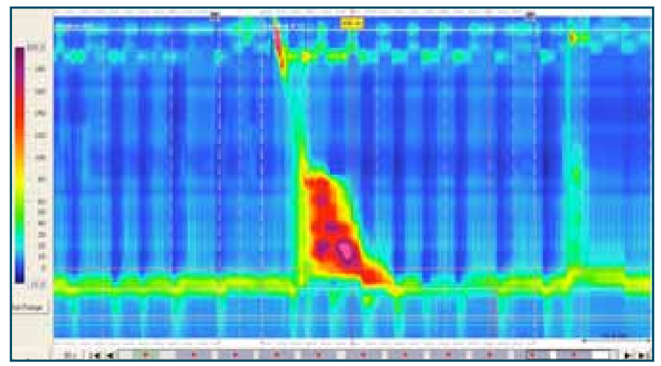


Figure 3. Achalasia (type III). Image provided by Anish A. Sheth, M.D.

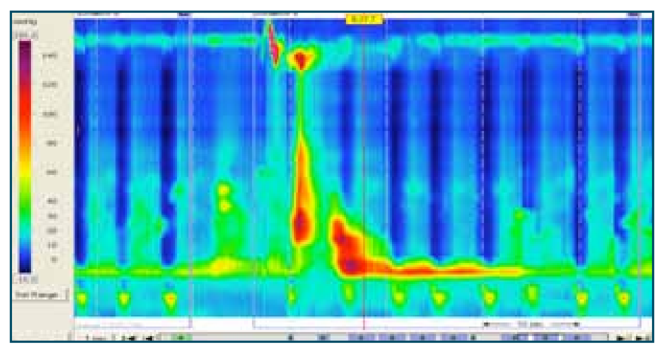


Figure 4. Achalasia variant. Image provided by Anish A. Sheth, M.D.

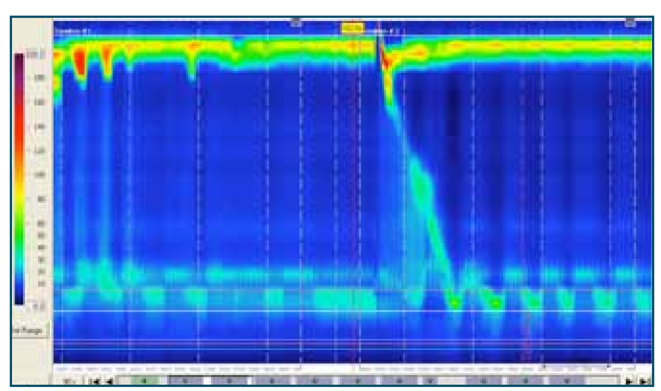


Figure 5. This pattern shows weak peristalsis and hiatal hernia. Image provided by Anish A. Sheth, M.D.

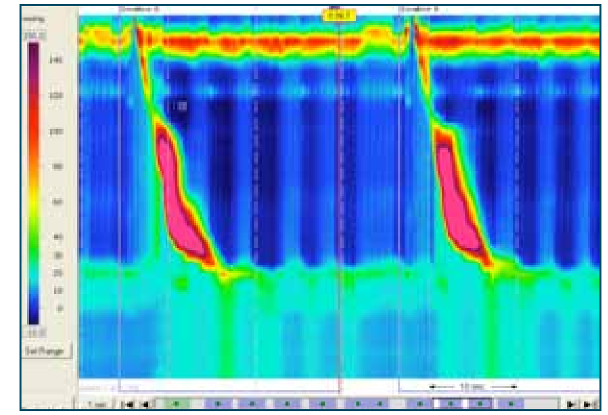


Figure 6. Nutcracker esophagus. Image provided by Anish A. Sheth, M.D.

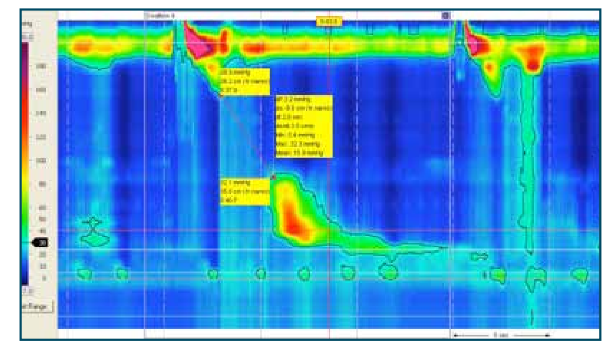


Figure 7. Indicates a large break between the striated muscle and the smooth muscle and weak peristalsis. Image provided by Given Imaging Ltd.

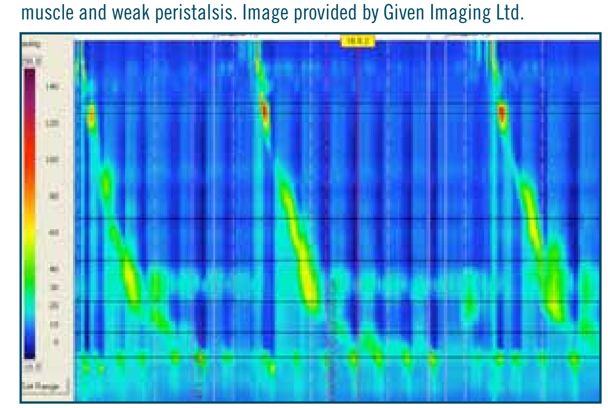


Figure 8. Diminished UES pressures. Image provided by Anish A. Sheth, M.D.

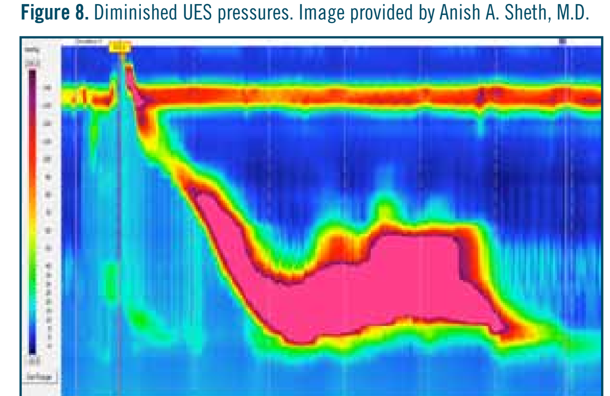


Figure 9. Image of distal esophageal spasm. Image provided by Given Imaging Ltd.

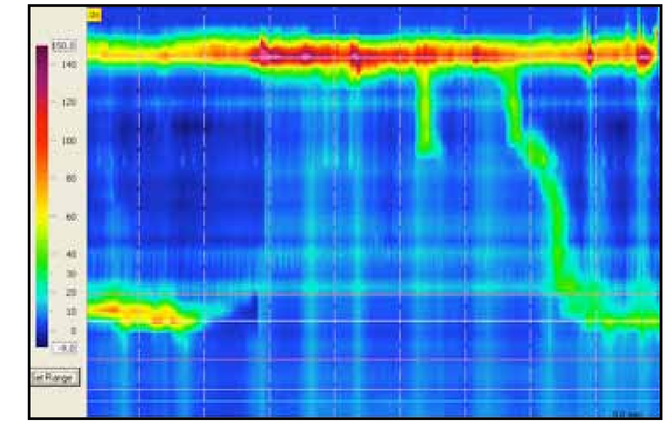


Figure 10. TLESR – Transient Lower Esophageal Relaxation. Image provided by Given Imaging Ltd.

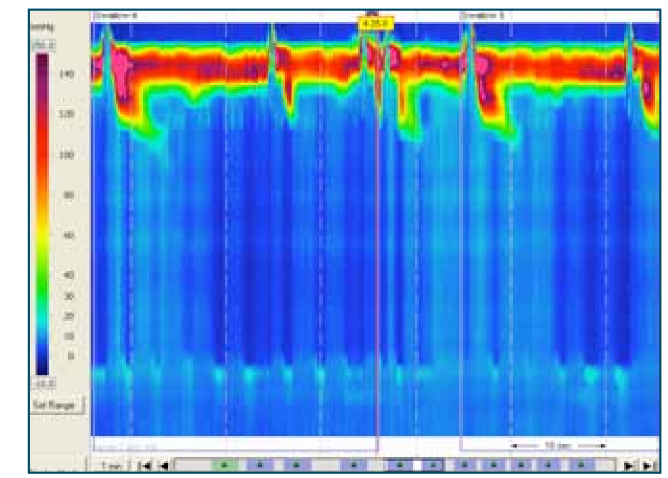


Figure 11. This pattern is from a patient with scleroderma showing aperistalsis of the smooth muscle. Image provided by Anish A. Sheth, M.D.

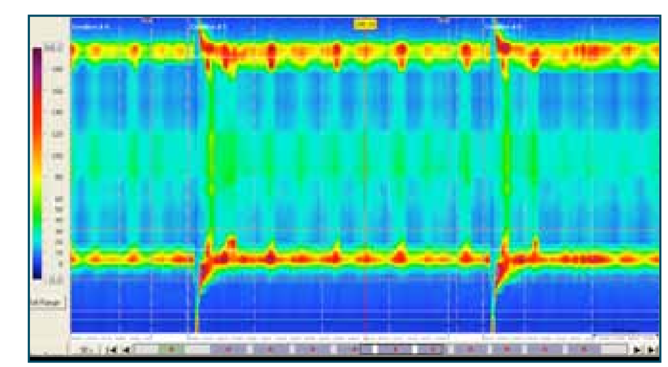


Figure 12. "Mirror image" secondary to catheter coiling. Image provided by Anish A. Sheth, M.D.

REFERENCE: 1. Conklin J, Pimentel M, Soffer E, eds. *Color Atlas of High Resolution Manometry.* New York, NY: Springer Science + Business Media, LLC; 2009.

Anorectal Manometry

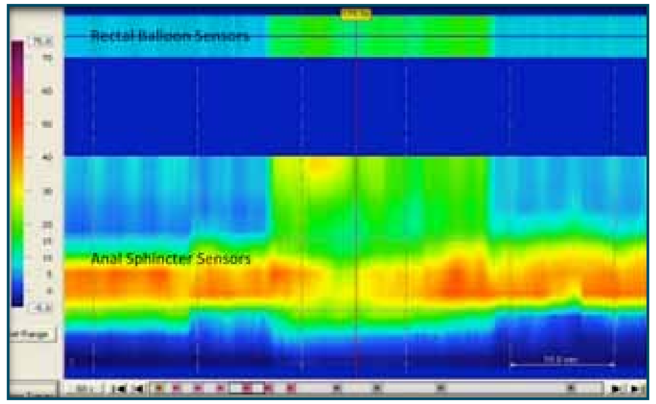


Figure 1. High resolution anorectal manometry contour plot. The green and blue colors indicate relaxation of the sphincters. The orange to red colors indicate contraction of the sphincters. Image provided by Given Imaging Ltd.

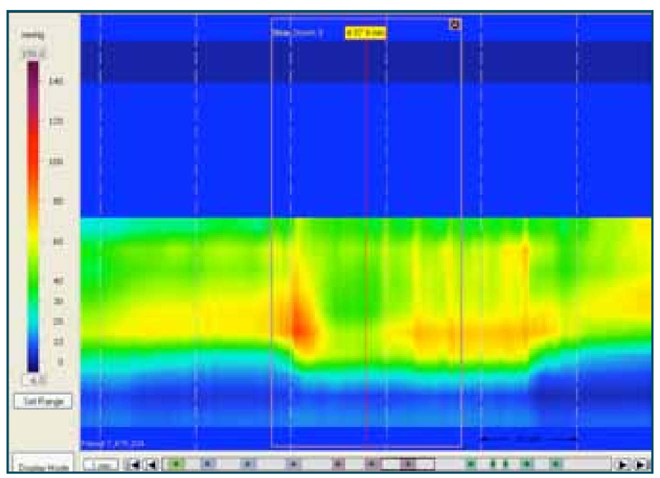


Figure 2. Normal anal sphincter relaxation. Image provided by Anish Sheth, M.D.

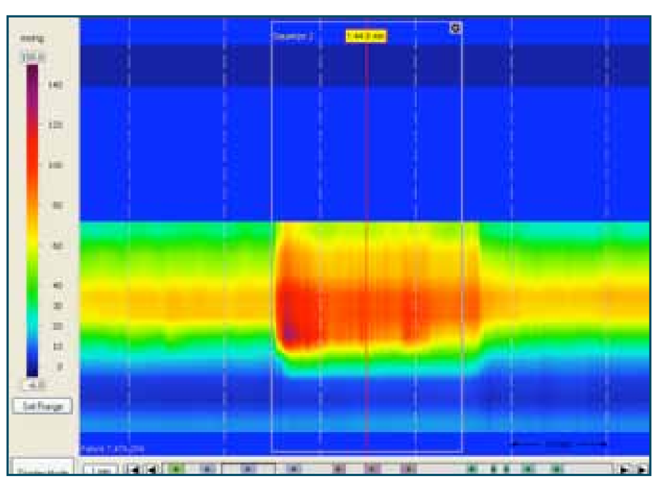


Figure 3. Normal squeeze pressure. Image provided by Anish Sheth, M.D.

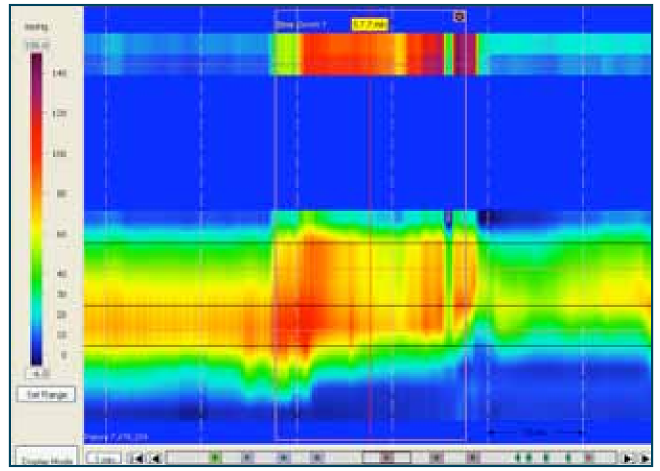


Figure 4. Dyssynergic defecation – paradoxical anal sphincter contraction (type I). Image provided by Anish Sheth, M.D.

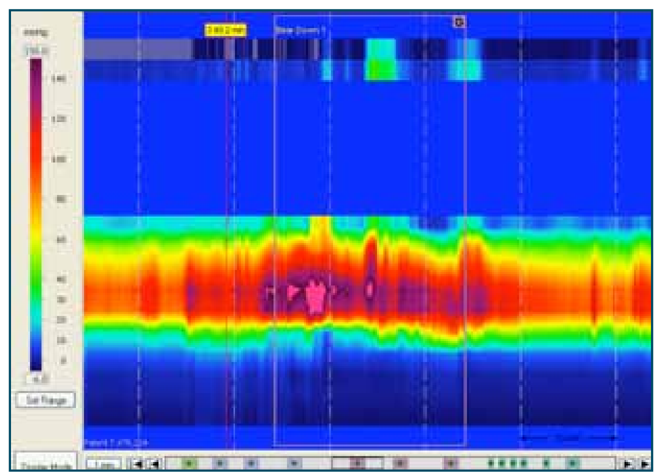


Figure 5. Dyssynergic defecation – inadequate anal sphincter relaxation (type II). Image provided by Anish Sheth, M.D.

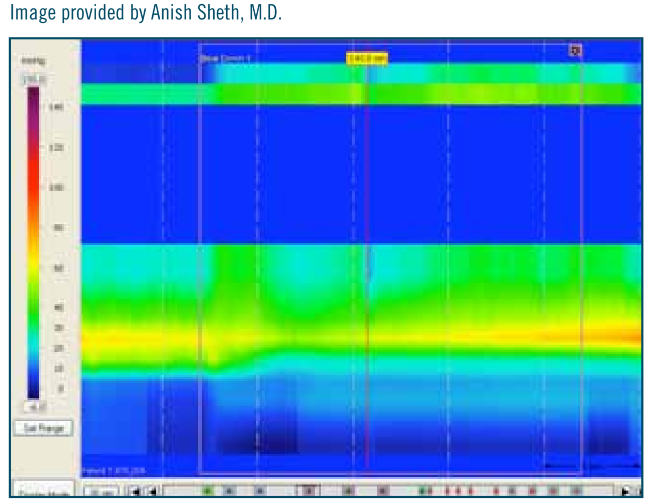


Figure 6. Dyssynergic defecation – inadequate anal sphincter relaxation (type III). Image provided by Anish Sheth, M.D.

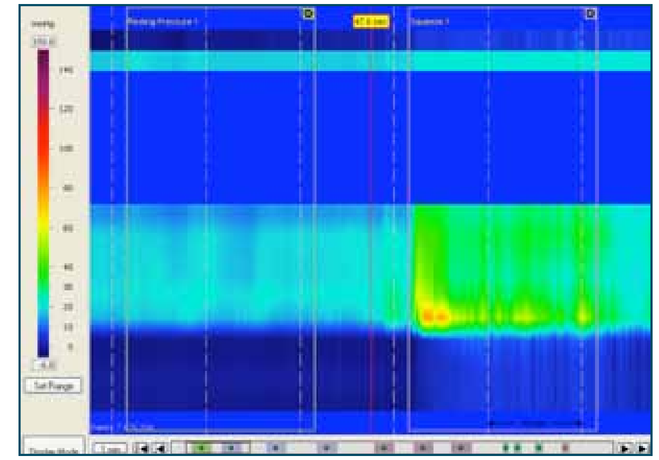


Figure 7. Weakened resting and squeeze pressures. Image provided by Anish Sheth, M.D.

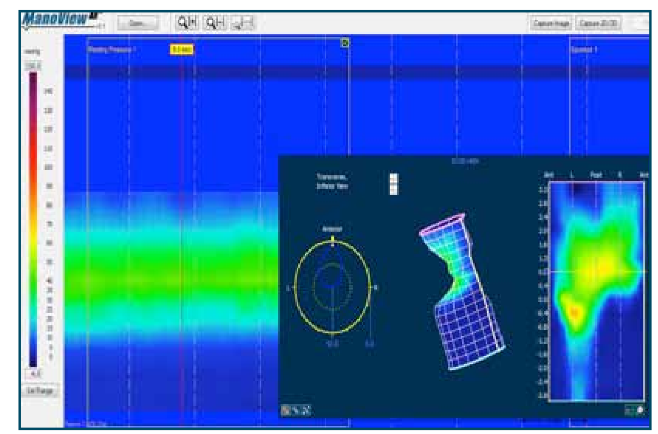


Figure 8. 3-D anorectal manometry image showing a sphincter defect. Image provided by Given Imaging Ltd.

Figure 9. 3-D anorectal probe that can measure 256 pressure points. ManoShield™ sheath design incorporates rectal compliance balloon to eliminate balloon tie-downs. Central lumen with luer fittings – supports RAIR, sensation and intrarectal pressure measurements. Image provided by Given Imaging Ltd.

REFERENCE: 1. Advances in diagnostic assessment of fecal incontinence and dyssynergic defecation. *Clin Gastroenterol Hepatol.* 2010;8(11):910-919.

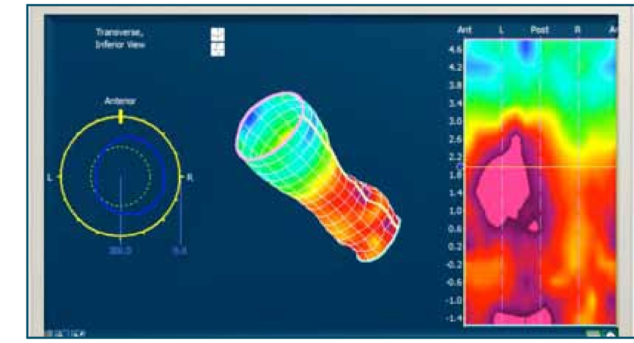


Figure 10. 3-D anorectal manometry configurations. Image provided by Given Imaging Ltd.

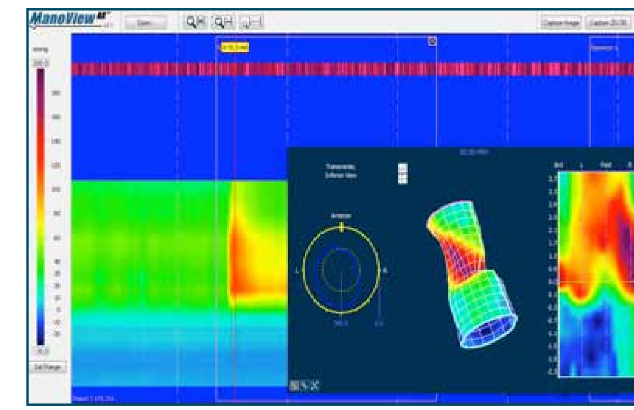


Figure 11. 3-D anorectal manometry image showing anterior low pressure. Image provided by Given Imaging Ltd.

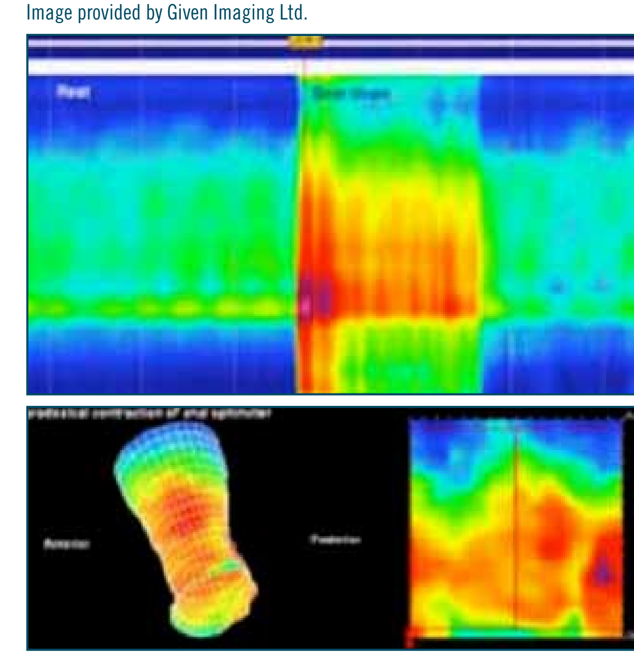


Figure 12. 3-D anorectal manometry showing a patient with dyssynergic defecation. There is an increase in rectal pressure with a paradoxical increase in anal sphincter pressure.[1] Reprinted from *Clin Gastroenterol Hepatol*, Vol 8 / number 11, Rao SSC, Advances in diagnostic assessment of fecal incontinence and dyssynergic defecation, p 16, Copyright 2010, with permission from Elsevier.

ABOUT GIVEN IMAGING LTD.

Since 2001, Given Imaging has advanced gastrointestinal visualization by developing state-of-the-art, patient-friendly tools based on its PillCam® Platform. PillCam capsule endoscopy uses wireless technology and advanced software to provide physicians with clear images of the small intestine via PillCam SB and the esophagus through PillCam ESO. The PillCam COLON, which is an investigational device in the U.S., is designed to visualize the colon. The PillCam capsules are miniature video cameras that patients ingest. Given Imaging's other capsule products include the Agile™ patency capsule, to verify intestinal patency, and Bravo®, the only wireless, catheter-free, 48-hour pH test commercially available for pH testing to assess gastroesophageal reflux disease. In April 2010, Given Imaging acquired Sierra Scientific Instruments, the leading provider of specialty GI diagnostic solutions and pioneer of high resolution manometry for assessing gastrointestinal motility. Sierra Scientific is now a wholly-owned subsidiary of Given Imaging. Given Imaging's headquarters, manufacturing, and R&D facilities are located in Yoqneam, Israel, with operating subsidiaries in the United States, Germany, France, Japan, Australia, and Hong Kong.

For more information, please visit **www.givenimaging.com**.

The risks of catheter insertion into the nasal passage associated with ManoScan ESO high resolution manometry include discomfort, nasal pain, minor bleeding, runny nose, throat discomfort, irregular heartbeat with dizziness, and perforation. In rare instances, the catheter may shift up or down causing false results, or the catheter may be misdirected into the trachea causing coughing or choking.

ManoScan AR procedure complications are rare. The risks include perforation or bleeding of the intestinal wall. Patients with previous rectal surgery, bowel inflammation, or bowel obstruction may have a higher risk for iatrogenic bowel perforation.

For both ManoScan ESO and ManoScan AR procedure medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. The systems are not compatible for use in an MRI magnetic field. Please refer to the User Manual or **www.givenimaging.com** for detailed information.

GIVEN® IMAGING

Expanding the scope of GI

5-001-227