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### A Review of the Indications, Methods, and Clinical Utility of Anorectal Manometry and the Rectal Balloon Expulsion Test

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#### Abstract

Anorectal manometry (ARM) comprehensively assesses anorectal sensorimotor functions. This review examines the indications, techniques, interpretation, strengths, and weaknesses of high-resolution ARM (HR-ARM), 3-dimensional high-resolution anorectal manometry (3D-HR-ARM), and portable ARM, and other assessments (ie, rectal sensation and rectal balloon expulsion test) that are performed alongside manometry. It is based on a literature search of articles related to ARM in adults. HR-ARM and 3D-HR-ARM are useful for diagnosing defecatory disorders (DD), to identify anorectal sensorimotor dysfunction and guide management in patients with fecal incontinence (FI), constipation, megacolon, and megarectum; and to screen for anorectal structural (eg, rectal intussusception) abnormalities. The rectal balloon expulsion test is a useful, low-cost, radiation-free, outpatient assessment tool for impaired evacuation that is performed and interpreted in conjunction with ARM. The anorectal function tests should be interpreted with

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reference to age- and sex-matched normal values, clinical features, and results of other tests. A larger database of technique-specific normal values and newer paradigms of analyzing anorectal pressure profiles will increase the precision and diagnostic utility of HR-ARM for identifying abnormal mechanisms of defecation and continence.

#### Keywords

anal sphincter; biofeedback therapy; constipation; high-resolution anorectal manometry

#### Introduction

Anorectal manometry (ARM) is a sophisticated technique that quantifies several aspects of the complex and multifactorial mechanisms that regulate defecation and continence.<sup>1</sup> ARM records contractility and tone of the internal (IAS) and external anal sphincters (EAS); rectal sensitivity and compliance; the reflex relaxation of the IAS in response to rectal distension; the reflex contraction of the EAS in response to cough or Valsalva maneuver; and the dynamic changes of rectal and anal pressures during simulated evacuation. The technological advances of ARM and other techniques that assess colonic and anorectal functions (eg, high-resolution colonic manometry and magnetic resonance imaging [MRI] proctography) have enhanced our understanding of the physiology of defecation and continence and related disorders.

ARM and the rectal balloon expulsion test are recommended initial tests for diagnosing DD in patients who have chronic constipation, anal fissure, or chronic anorectal pain (levator ani syndrome).<sup>2–5</sup> However, because anorectal pressures during evacuation overlap between DD and healthy subjects, further studies are necessary to understand the relative contribution of manometric findings to the pathophysiology of DD.<sup>6</sup> ARM is also useful for identifying anal weakness and rectal sensory disturbances in fecal incontinence (FI),<sup>7,8</sup> and for assessing reflex relaxation of the IAS in response to rectal distension in patients being tested for Hirschsprung disease, as well as those with megarectum or megacolon.<sup>9,10</sup> The use of ARM in clinical practice and scientific research has been fostered not only by increased awareness among physicians and other providers that chronic constipation and FI often have a severe impact on quality of life, but also by the use of pelvic floor biofeedback therapy and other approaches for managing these conditions, as well as the commercial availability of ARM catheters.

Since the introduction of high-resolution ARM (HR-ARM) and 3D-HRM, conventional catheters (ie, water-perfused or solid-state) are used less frequently. Unlike conventional catheters, HR-ARM and 3D-HR-ARM catheters measure *circumferential* pressures *throughout* the longitudinal axis of the anal canal. In addition, 3D-HR-ARM catheters depict and measure the circumferential symmetry of anal pressures at individual locations around the catheter circumference. Several portable systems of ARM, which utilize single-use, air-charged catheters, are now available. Hence, ARM is now more widely utilized in clinical practice and in research.

However, an international survey observed that the methods for anorectal manometry varied considerably among institutions <sup>11</sup>. Among 107 centers in 30 countries, no two centers used identical protocols for preparing patients, conducting studies, and reporting results <sup>11</sup>. Accordingly, the International Anorectal Physiology Working Group (IAPWG), which included 29 members, discussed approaches to standardise the methods and interpretation of manometry . These recommendations were published in 2020. The results of manometry, rectal sensory testing and the balloon expulsion test (or alternative imaging modality) are used to populate a diagnostic classification system (The London Classification) for anorectal disorders <sup>12</sup>. Many centers have adopted these methods. These advances provide the impetus for this review of the indications, methods, analysis, utility, and future directions for ARM.

#### Methods

We searched MEDLINE for articles related to ARM from January 1, 2008, to June 15, 2021. The search excluded review articles, systematic reviews, and letters and comments. Studies involving animals and children were also excluded. The search yielded 1,133 results, and the search strategy was developed by a reference librarian (PJE) and reviewed by another librarian (Supplementary Table 1, MBH). In addition, we included major reviews and selected articles published before 2007 that provide a background for this review. This review includes 89 of the 1133 citations that were deemed relevant and 26 additional citations.

#### Equipment

A variety of systems are used to perform ARM. These systems differ in their pressuresensing technology; the number and spatial distribution of pressure sensors on the catheter; the pressure display; user-friendliness of the modules that guide the operator through the procedure; the analysis of pressures; and the number of uses per catheter (ie, single- vs multiple-use) (Tables 1 and 2, Figure 1).

Measurement of Pressures—Anorectal pressures can be measured with sensors (ie, water-perfused or solid-state) or air-charged catheters.<sup>13–16</sup> Prior to 2007, pressures were exclusively measured with non-HR-ARM catheters, which had several solid-state or waterperfused pressure sensors that were either located at 1 or 2 levels on the catheter or distributed in a circumferentially staggered manner on the long axis of the catheter.<sup>13</sup> The circumferentially staggered sensors on the long axis only measured pressures at 1 aspect around the catheter circumference. Hence, with non-HR-ARM catheters, a stationpull-through maneuver was necessary to measure pressures throughout the anal canal. By contrast, most HR-ARM catheters measure circumferential pressures (Table 1, Figure 1). For example, the ManoScan (Medtronic) HR-ARM catheter has 36 circumferentially oriented, pressure-sensing elements (TactArray; Pressure Profile Systems, Inc) at each level along the longitudinal axis. These 36 sector pressures are averaged to yield a single value. The Unisensor HR-ARM catheter (UniTip; Laborie, Portsmouth, New Hampshire, USA) has circumferential pressure sensors that are embedded within a soft, doughnut-shaped membrane containing silicone gel. This catheter has 11 anal sensors and 1 rectal balloon sensor, most being 8 mm apart. Hence, HR-ARM catheters measure pressures throughout

The pressure-sensing technology, number, and orientation of pressure sensors, and the pressure displays vary among HR-ARM catheters (Table 2, Figure 1). The HR-ARM systems provide either 1<sup>17,18</sup> or several (typically 4) values <sup>19–21</sup> at each of several locations along the longitudinal axis of the anal canal. Hence, the latter catheters (ie, ManoScan 3D-HR-ARM [Medtronic], HRAM-200 [Diversatek], and UniTip HRAM(3D) catheters [MMS/Laborie]) depict pressure topography in 3 dimensions. Other than the Medtronic 3D-HR-ARM catheter (32F) and the Anopress (THD) catheter (48F), most catheters have a diameter of 12F to 16F.

When catheters are damaged, they need to be returned to the manufacturer for repair.

Some devices (eg, Manoscan HR-ARM catheter) also can be susceptible to a change in measured pressure, known as *thermal drift*. Thermal drift is a combination of *initial drift*— a difference between the device's calibrated pressure temperature and body temperature— and *baseline drift*, which occurs over time. The thermal compensation software algorithm corrects for thermal effect but not for baseline drift.<sup>22</sup> This residual drift affected the clinical interpretation of the study in approximately 10% of patients.

The air-charged catheters provide either 1 (eg, Anopress) or 4 (eg, mcompass [Medspira]) anal pressure values. While the T-DOC (Laborie) and mcompass catheters measure rectal and anal pressure, the Anopress catheter only measures anal pressure. Hence, the Anopres catheter does not measure the rectoanal gradient during evacuation. In contrast to the HR-ARM systems, the air-charged ARM systems are portable, less expensive, and use only 1 catheter. The mcompass system also has a software module that can be used for biofeedback therapy. However, the spatial resolution of pressures measured and displayed by HR-ARM and 3D-HR-ARM catheters is higher than that seen in air-charged catheters.

**Display and Analysis**—Most HR-ARM systems display pressures as line plots or as color contour plots, which we consider are intuitively easier to interpret than line plots. Although the spatial resolution of HR-ARM catheters is excellent, only a fraction of this information—typically the greatest value at any level in the canal—is used for analysis and made available for diagnostic purposes. For example, at rest, during squeeze, and during rectal distention, the eSleeve option in the ManoScan catheters only considers the greatest pressure at any given instant. These values are then averaged over 20 seconds at rest and during squeeze. During evacuation, the eSleeve identifies the most positive (or least negative) difference (ie, rectoanal gradient) between rectal and anal (rectal-anal) pressure over a 20-second epoch. (It is possible to download the entire dataset for research purposes). Perhaps this explains why anal pressures measured by HR-ARM are generally correlated with, but greater than, those measured by non–HR-ARM.<sup>20,23–26</sup>

#### **Test Procedure**

**Patient Preparation**—Because ARM is a very safe procedure, verbal consent is sufficient. Patients should be informed that they will experience the desire to defecate as the probe is being inserted and during the procedure, and should be asked to inform the operator if they experience discomfort at any time. Significant discomfort may suggest an anal fissure. Constant reassurance is essential. Mental stressors increase anal pressure in healthy persons and DD patients.<sup>27</sup> Acute and chronic stress also alter the cerebral processing of noxious stimuli.<sup>28</sup> However, acute mental stress does not affect rectal sensation or compliance in healthy persons.<sup>29</sup>

Fasting is unnecessary. Since caffeine has been shown to increase anal resting, squeeze pressure, and rectal sensation in healthy persons,<sup>30</sup> it may be prudent to avoid caffeine for 60 minutes before the examination. Although a small study observed circadian variations in rectal sensation and compliance in healthy persons,<sup>31</sup> ARM can be performed at any time of day. Although not considered essential, enemas are routinely administered at some centers, especially if stool is detected on a digital rectal examination. Ideally, the probe should be placed 30 minutes after the enema has been administered. Patients should be kept informed and reasssured throughout the procedure. ARM is generally performed with patients in the left lateral position with knees and hips bent at a 90° angle. The lubricated probe is gently inserted into the rectum. For 3D-HR-ARM catheters that assess circumferential symmetry, the catheter should be accurately oriented to the patient. The probe should remain in situ for the duration of the procedure. Voluntary contraction of the anal sphincter may increase anal pressure upon insertion of the catheter. On average, it takes less than 90 seconds for pressures to equilibrate; 150 seconds is sufficient,<sup>32</sup> and is less than the 3 minutes recommended by the International Anorectal Physiology Working Group (IAPWG).<sup>11</sup>

**Components**—In addition to measuring pressures at rest and during squeeze, simulated evacuation, and cough (or Valsalva maneuver),<sup>13</sup> the rectoanal inhibitory reflex (RAIR), rectal sensation, and the rectal balloon expulsion test (to effectively identify DDs) should be evaluated during the same visit.<sup>5</sup> The details of each procedure (eg, duration, number of squeeze maneuvers, and the method for summarizing squeeze pressures) vary across sites.<sup>11</sup> The IAPWG suggests a minimum standard ARM protocol.<sup>12</sup> This protocol includes precise details (eg, 1 long [30-second] and 3 short [5-second] squeeze maneuvers), which are at least partly determined by the software program. Users have limited ability to adjust these specifications; standardizing protocols will require modifications to the manometry software programs. Hence, it is not feasible for all centers to acquire data with the same protocol. The IAPWG protocol is primarily based on opinion, rather than evidence. Hence evidence-based approaches are necessary to refine the IAPWG protocol for conducting and analyzing ARM. For example, a recent study from the London group in women with FI found that the initial IAPWG protocol <sup>12</sup> is redundant,<sup>33</sup> which suggests that the resting period can be abbreviated from 60 seconds to 30 seconds, and 2 squeeze maneuvers (rather than 3) are sufficient.

#### Anal Resting Pressure

**Procedure.**—Anal resting pressure should be measured. Our understanding of the optimum duration to measure resting pressure is evolving. The IAPWG suggests 60

seconds.<sup>11</sup> In women with FI, 30 seconds is sufficient.<sup>33</sup> In healthy persons, resting pressure measured for 20 seconds is almost perfectly correlated, versus measurements for 60 seconds and 300 seconds <sup>34</sup>. However, a longer duration is necessary to identify ultra-slow waves, which occur at 1 to 2 cycles per minute and have been associated with chronic constipation and hemorrhoids but are of uncertain clinical significance.<sup>35</sup>

**Analysis.**—Data analysis varies among programs. Most software modules average the highest anal pressure at every instant, then average these values over 20 or 30 seconds. Because the HRAM-200 system (Diversatek, Inc) <sup>36</sup> averages anal pressures across radial sensors at every level of the catheter, these values might be lower than those measured with the eSleeve program.<sup>36</sup>

**Interpretation.**—The use of non–HR-ARM has shown several findings worthy of mention. Studies with non–HR-ARM suggest that anal resting tone is generated by the IAS (55%), EAS (35%), and the hemorrhoidal plexus (15%).<sup>37</sup> In a study of 295 constipated women, 36 patients (12%) had low anal resting pressures, and 2 patients (4%) had high anal resting pressures.<sup>38</sup> Non–HR-ARM studies suggest that anal resting pressure is also increased in patients with anal fissure or anal pain.<sup>13</sup> Patients with anal fissure and ultra-slow pressure waves have increased tone and impaired relaxation of the internal sphincter, and enhanced after-contraction following rectal distension,<sup>35,39</sup> which perhaps suggest impaired nitrergic innervation of the IAS.<sup>40</sup>

Since the normal range of anal pressures is relatively wide (eg, from 33–93 mm Hg among women 50 years old, as determined with the ManoScan HRM catheter), many patients with relatively low pressures are in the normal range.<sup>18</sup> Scleroderma, injury to the IAS (eg, during vaginal delivery or after lateral anal sphincterotomy), or hemorrhoidectomy are the commonest explanations for reduced anal resting pressure.<sup>41</sup> Among 119 patients with anorectal disorders, internal and external sphincter injury and a patulous canal, but not puborectalis injury, predicted anal resting pressure <sup>42</sup>. Reduced anal resting pressure had a sensitivity of 51% and a specificity of 70% for identifying injury of the IAS or a patulous canal <sup>42</sup>. A meta-analysis found that the maximum resting pressure had a sensitivity and specificity of 0.60 (95% CI, 0.38–0.79) and 0.93 (95% CI, 0.80–0.97) for diagnosing FI.<sup>43</sup>

The software computes the length of the high-pressure zone (HPZ) at rest. For the Manoscan HR-ARM system, the length of the HPZ is the length of the average pressure profile in the resting pressure frame, defined as (rectal pressure + [{anal resting pressure – rectal pressure}  $\times 0.25$ ]).<sup>18</sup> On average, the HPZ is longer in asymptomatic men (3.9 cm) than in asymptomatic women (3.4 cm); this length is not correlated with age.<sup>18</sup> Some patients with DD have a longer HPZ.<sup>38</sup>

#### Anal Squeeze Pressure

**Procedure.**—Anal pressure is measured while patients voluntarily contract the anal sphincter, typically for up to a maximum duration of 20 seconds on 2 occasions separated by a resting period of 30 seconds. The IAPWG protocol recommends one long squeeze (eg, 30 sec) and 3 short squeeze maneuvers (5 s each) to respectively assess external sphincter endurance and maximum voluntary contraction.<sup>12</sup> Normally, only anal not rectal

pressure should increase during squeeze; increased rectal pressure reflects more widespread activation of the abdominal wall rather than isolated activation of the anal sphincter. It is important to continuously monitor and be aware of probe movement, especially after maneuvers such as squeeze, cough, or bearing down, and to adjust the probe when necessary. Squeeze maneuvers that are more frequent and/or against a resistive load are more likely to evoke sphincter fatigue. Further studies are necessary.<sup>44,45</sup>

**Analysis.**—There are 3 parameters: absolute squeeze pressure, the squeeze increment (ie, squeeze – resting pressure), and the squeeze duration. The definitions of these parameters vary among programs. Several programs identify the peak pressure that is sustained for a few seconds at any level in the anal canal.The Manoscan HR-ARM and 3D-HR-ARM software programs erroneously measure the squeeze increment relative to rectal rather than anal resting pressure. <sup>34</sup> Hence, the measured squeeze duration is often inaccurate.

Color plots often reveal 2 distinct HPZs during a squeeze maneuver.<sup>17</sup> The upper and lower zones presumably reflect contraction of the puborectalis and the EAS (Figure 2). On the 3D profile, the resting frame shows a dumb-bell shape, with a high-pressure ring in the middle and a low-pressure area on both sides of the pressure cylinder (Figure 2). On the 2D profile, the high-pressure band is seen in the middle of the image.<sup>46,47</sup> During squeeze, an "hourglass" appearance on 3D mapping or a " $\lambda$ " shape on 2D mapping indicates normal function of the EAS muscle.<sup>46,47</sup> A "trumpet" appearance on 3D mapping is a result of high intrarectal pressure and relaxation of anal residual pressure during bear-down;<sup>46</sup> 2D mapping of attempted defecation shows a red HPZ in the rectum and anal canal, but blue and green low-pressure zones in the end (ie, a low-pressure area in the distal posterior wall of the anorectum).<sup>46,47</sup> In patients with paradoxical puborectalis syndrome, 2D mapping of simulated defecation shows a characteristic HPZ in the distal posterior wall of the anorectum.<sup>47</sup>

**Interpretation.**—The causes of reduced squeeze pressure include noncompliance, failure to understand instructions, and neuromuscular injury to the external sphincter, most commonly due to obstetric injury. A history of sexual abuse has been associated with lower squeeze pressure, even in the absence of anal sphincter injury.<sup>48</sup> Weak squeeze pressures (and resting pressure) are relatively insensitive but more specific for identifying sphincter injury or a patulous anal canal.<sup>42</sup> Hence, anal imaging is probably unnecessary when anal pressures at rest and squeeze are normal.

Unusual for skeletal muscle, the EAS maintains resting tone that is enabled by type 1 (ie, fatigue-resistant, slow-twitch) fibers, which predominate in the human anal sphincter, versus type 2, or fast-twitch muscle fibers in cats and rabbits.<sup>49</sup> A squeeze duration less than 10 seconds measured with non–HR-ARM suggests reduced endurance, which has been associated with impaired continence for liquid, but not formed, stools.<sup>50</sup> Compared to asymptomatic women, the anal squeeze pressure was lower but the EAS was less fatigable in women with FI.<sup>51</sup>

#### Anal Pressure During Cough or Valsalva Maneuver

**Procedure.**—Performed once or twice, these maneuvers are useful for evaluating the integrity of the spinal reflex pathway to the EAS in FI patients with low anal squeeze pressure.<sup>13</sup> The patient is asked to cough or exhale into a balloon attached to a sphygmomanometer to generate a pressure of 20 mm Hg.<sup>52</sup> Normally, the increased abdominal pressure triggers external sphincter contraction. Given the risk of exacerbating a retinopathy, a Valsalva maneuver should not be performed in patients with a history of retinopathy.

**Analysis.**—Similar to the squeeze maneuver, the pressure increment during a Valsalva maneuver is the primary criterion of interest.

**Interpretation.**—The combination of a low squeeze pressure and a normal cough reflex may reflect impaired volitional control of the EAS and/or damage of the central motor pathways above the sacral segments of the spinal cord. A low squeeze pressure and an abnormal cough reflex suggest a defect in the sacral reflex arc. The pressure change during cough was 10 mm Hg higher in HR-ARM than non–HR-ARM but not statistically significant.<sup>25</sup> Also, during coughing, HR-ARM uncovered qualitative and quantitative differences in anorectal pressures between nulliparous and parous healthy volunteers and between healthy volunteers and patients with FI <sup>53</sup>. The clinical significance of these findings is unclear.

#### **Rectoanal Pressures During Simulated Evacuation**

**Procedure.**—During simulated evacuation, patients are asked to bear down as if to defecate. (The term *simulated evacuation* is preferred to *defecation* because the assessment lacks some features of defecation [eg, rectal distention by stool].) At some centers, the maneuver is repeated after distending a 50-mL rectal balloon. However, the incremental utility of evaluating evacuation with a filled balloon versus an empty balloon is unclear. At least 30 seconds should elapse before the next attempted "defecation." Patients should be coached to expel (not withhold) the probe. Such coaching changed the diagnosis from "pathologic" to "normal" values in 14 of 31 patients with incontinence, and in 12 of 39 patients with dyssynergic defecation.<sup>54</sup>

**Analysis.**—This *simulated evacuation* is summarized by several parameters (ie, rectal pressure increment, anal relaxation expressed as absolute pressure and change in percentage, and rectoanal gradient) generally over the 2-second epoch during which the rectoanal pressure gradient is the most positive or least negative.

**Interpretation.**—Intuitively, defecation requires coordination between increased rectal pressure and relaxation of the anal sphincters and pelvic floor (Figure 2).<sup>55</sup> Earlier studies have suggested that the rectoanal pressure profile during simulated evacuation was useful for diagnosing DD.<sup>56</sup> However, the rectoanal pressure profiles suggest dyssynergia (eg, anal contraction or a negative rectoanal gradient during evacuation) in approximately 20% and 90% of healthy persons, respectively, with non–HR-ARM and HR-ARM.<sup>56,57</sup> These differences from the idealized normal pattern may be explained by one or more

of the following factors: inability to replicate defecation in a laboratory environment;<sup>58</sup> artifact resulting from impingement of the catheter against the anal mucosa;<sup>59</sup> absence of rectal filling during manometry; and/or performing manometry in the left lateral position. Regardless, these findings undermine the utility of manometry for diagnosing DD.<sup>6</sup> However, it is conceivable that the criteria for dyssynergia in the Grossi paper, which were adapted from non–HR-ARM, were not ideally suited to discriminate between healthy people and DD.<sup>56</sup> Indeed, other HR-ARM criteria (eg, rectoanal gradient during evacuation) can discriminate between patients with normal and abnormal BET.<sup>60</sup> Irrespective of the technique or criteria, the findings must be compared to age- and sex-matched normal values measured with the same technique.<sup>38,60,61</sup> It is not appropriate to compare patient values measured with HR-ARM against normal values that were developed for non–HR-ARM.

#### **RAIR and Rectal Sensation**

**Procedure.**—While rectal balloon distension is a very safe procedure, it should be performed in a graded manner in order to avoid rectal rupture, especially in patients who have previously undergone rectal surgery.<sup>41</sup> The rectal balloon is distended with air in increments of 10 mL until the patient reports a first sensation. Thereafter, the balloon is increased in 20-mL increments to the maximum tolerated volume, subject to a maximum of 400 mL. Each distension is maintained for at least 30 seconds. Patients are asked to report sensations (first sensation, desire to defecate, urgency to defecate, and maximum tolerable sensation). Rectal sensory thresholds are influenced by the stiffness of the rectal balloon. Compared to commercially available latex balloons, the latex-free balloons that are used with HR-ARM are less elastic. Further studies are required to compare rectal sensation evaluated with conventional and HR-ARM.

**Analysis.**—The amplitude and duration of the RAIR depend on the rate and volume of rectal distention.<sup>62,63</sup> Some HR-ARM software programs (eg, Manoscan HR-ARM and 3D-HR-ARM) consider the RAIR to be present when anal relaxation is 25% or greater. Volume thresholds for rectal sensation are assessed. While rectal balloon pressure, termed *compliance* (ie, pressure-volume relationships) can also be measured during balloon distention, the rectal balloon used for HR-ARM is relatively stiff. For example, when the Manoscan HR-ARM catheter balloon is inflated by 50 mL in atmosphere, it has a pressure of 137 mm Hg, which is considerably higher than the rectal pressure at the same volume. Hence, rectal compliance measured with manometry is much less accurate than measurements taken with a barostat.

**Interpretation.**—If no RAIR is evident, the procedure should be repeated after excluding fecal impaction, increasing the rectal distending volume, and asking the patient not to contract the EAS during rectal distension. Besides Hirschsprung disease,<sup>64</sup> RAIR may also be absent in conditions such as dysganglionosis, postcircular myotomy, and lower anterior resection.<sup>9,10</sup> 3D-HR-ARM reveals spatial differences in the magnitude of anal relaxation during RAIR (ie, along the anteroposterior and long axis of the anal canal).<sup>63</sup> No studies have been found that assess RAIR in Hirschsprung disease with HR-ARM..

Studies with non-HR-ARM catheters have observed increased rectal sensation in urge incontinence, proctitis, and irritable bowel syndrome, and reduced rectal sensation in chronic constipation<sup>65,66</sup> and in diabetes with FI.<sup>67</sup> Assessments with HR-ARM catheters disclosed reduced rectal sensation in patients with a DD.<sup>38</sup> Rectal sensory disturbances may be primary or secondary to abnormal rectal capacity or compliance.<sup>65,66</sup> Hence, especially when a manometry reveals a profound sensory disturbance, rectal sensation should be evaluated with a barostat, which is not widely available in clinical practice.<sup>65</sup> Visceral hypersensitivity, including allodynia and hyperalgesia, abnormal colonic transit, and psychological factors are all associated with symptoms of irritable bowel syndrome.<sup>68</sup> Among 164 patients with functional gastrointestinal disorders, including 86 patients with irritable bowel syndrome, rectal barostat distention to 40 mm Hg was 96% sensitive and 72% specific for distinguishing between patients with versus those without irritable bowel syndrome.<sup>69</sup> Conversely, approximately 25% of patients with chronic constipation have reduced rectal sensation (rectal hyposensitivity),<sup>66</sup> often associated with an attenuated or absent urge to defecate, and may be *primary* (due to direct impairment of afferent pathway function). *secondary* (due to altered biomechanical properties), or both.<sup>70</sup> Biofeedback therapy to correct sensory disturbances is beneficial in patients with FI.<sup>71</sup> However, the use of such therapy in patients with DD has not been evaluated.

#### Interpretation of HR-ARM

**Normal Values**—Because the available ARM systems differ in their design and methods used to summarize pressures, catheter-specific normal values are necessary (Tables 3 and 4). For some systems (eg, Diversatek HRAM-200, UniTip 3D, and T-DOC air-charged catheters), no normal values are available (Table 2). Hence, it is not possible to interpret data with reasonable confidence. For the other systems, more normal data are available. At least 40 participants are required to estimate the 2.5 and 97.5 percentiles. Ideally, at least 120 reference values are required to obtain reliable estimates,<sup>72</sup> which is more than the sample size of the largest studies which evaluated 96 asymptomatic women with the Manoscan HRM and UniTip catheters,<sup>17,18</sup> or the 101 asymptomatic women assessed with the Unisensor HRAM catheter.<sup>73</sup>

The association between rectoanal pressures and age, sex, parity, and body mass index varies among studies. To what extent these differences are related to differences in the study populations versus differences in the methods used for summarizing pressures among studies is unclear. For example, measurements with the ManoScan HR-ARM and 3D-HR-ARM catheters and the Diversatek catheter, but not with the UniTip catheter, have revealed that anal resting and squeeze pressures are lower in women than in men, and that the anal resting pressure is lower in older people than in younger people.<sup>17–19,46</sup> Anal resting pressure and to a lesser extent anal squeeze pressure is lower in older persons.<sup>18,19,46</sup> With the UniTip catheter, age was not significantly associated with anal pressures after adjusting for parity.<sup>17</sup> Hence, separate normal values for men, nulliparous women, and parous women are provided. Rectal pressure during a simulated evacuation is greater in older than in younger asymptomatic women and men.<sup>18</sup> For variables that are not associated with age, only sex-specific normal variables are necessary. Normal values should ideally be assessed in healthy persons with normal rectal balloon expulsion time,<sup>18</sup> as up to 15% of

asymptomatic healthy persons have prolonged rectal balloon expulsion time. Several studies in healthy persons are not included in Table 3 because the equipment and/or analysis were performed with techniques that are not widely used.<sup>74–76</sup>

**Refined Analysis**—HR-ARM measures pressures in 2 dimensions (ie, along the length of the anal canal and in time). In addition, 3DD catheters also assess circumferential asymmetry. The commercial software programs condense this rich dataset to summary variables (eg, maximum squeeze pressure), which mostly represent pressures measured at one location in the anal canal over a few seconds. For example, the eSleeve-based analysis (Medtronic) of the rectoanal gradient during the evacuation method uses the highest anal pressure at each instant (at 10 Hz) to summarize anal pressure. Because the highest, and not the lowest, anal pressure is used to calculate the gradient, the gradient is generally not the greatest pressure difference between the rectum and the anal canal. Perhaps this at least partly explains why the gradient is negative in asymptomatic healthy people. Secondly, "the specific sensor that is used to summarize anal pressure often moves over the 20-second evacuation period".<sup>60</sup> Thirdly, the highest anal pressure measurement is prone to artifact, for example, due to catheter impingement.<sup>77</sup>

Investigators have attempted to overcome these limitations by exporting and analyzing the raw data with customized programs. Similar to the lower esophageal sphincter, the anal sphincter integrated pressurized volume reflects the duration, magnitude, and longitudinal dimension of anal pressure during simulated evacuation;<sup>61</sup> in that study, the integrated pressurized volume, but not anal pressure, was correlated, albeit weakly, with balloon expulsion time. The anal squeeze integral was more sensitive than the squeeze pressure for distinguishing between healthy women and women with FI.<sup>78</sup> In addition to pressure integrals, the anal sphincter pressure symmetry index, the area of the anal HPZ, and movement of the HPZ during squeeze can also be extracted from 3D-HR-ARM.<sup>79</sup> The incremental utility of these interesting approaches for distinguishing between health and FI is limited.

Similar to approaches used to classify esophageal motility disorders (eg, subtypes of achalasia),<sup>80</sup> an alternative approach is to characterize anorectal pressure topography during evacuation as follows: minimal change, anal relaxation, paradoxical contraction, and transmission.<sup>60</sup> These patterns were associated with balloon expulsion time. In the seated position, minimal change, anal relaxation, paradoxical contraction, and transmission were associated with a prolonged BET in respectively 45%, 15%, 53%, and 0% of patients. Compared to the rectoanal gradient provided by the commercial software program (ManoView) in the left lateral position, the integrated analysis (ie, pattern and new gradient) in the left lateral position, and separately, the seated ManoView gradient, was more effective for distinguishing between constipated patients with and those without DD.

**Identifying Phenotypes of Functional DDs**—The rectoanal pressure profile during simulated evacuation can be used for subtyping DD. Using solid-state, non–HR-ARM, Rao et al <sup>81</sup> visually recognized that 30% of 100 constipated patients had a normal rectoanal pressure profile during evacuation.. The remainder had paradoxical anal contraction (type I), impaired propulsion (type II), or impaired anal relaxation with (type III) or without (type

IV) adequate propulsion. Since this study was limited to patients, it is unclear how useful these patterns are for distinguishing between healthy persons and patients with DD. Experts agree on the characterization of rectoanal pressure profiles by HR-ARM as type I ( $\kappa$ =0.71), IV dyssynergia ( $\kappa$ =0.61), normal pattern ( $\kappa$ =0.47), type II ( $\kappa$ =0.40), and III dyssynergia ( $\kappa$ =0.35).<sup>56</sup>

In a similar exercise using principal component analysis, 4 key patterns emerged in a cohort of 62 healthy and 295 constipated women: high anal pressure at rest and during evacuation (high anal), low rectal pressure alone (low rectal), low rectal pressure with impaired anal relaxation during evacuation (hybrid), and a short anal HPZ.<sup>38</sup> By design, these patterns are uncorrelated with each other and represent independent physiological dimensions. The high anal and low rectal patterns resemble similar patterns described by Rao.<sup>81</sup> Four phenotypes distinguished healthy persons from patients with abnormal balloon expulsion times, and 2 phenotypes distinguished healthy persons from those with constipation but normal balloon expulsion time.<sup>38</sup> These patterns have a sensitivity and a specificity of 75% for distinguishing between healthy persons and those with DD. However, they are not associated with symptoms, nor do they predict the benefit of pelvic floor biofeedback therapy. Hence, the utility of these patterns in clinical practice is unknown.

**Circumferential Pressure Topography**—The EAS has a triple-looped anatomy. The puborectalis surrounds the posterior and lateral aspects of the anal canal. Hence, the anal pressure profile is asymmetric, especially in the upper canal. The symmetry (or lack thereof) in the anal pressure profile may provide insight into normal or disordered contraction or relaxation of the EAS versus the puborectalis muscle and weakness of these muscles. For example, it can be inferred that the anal squeeze is normally generated by the EAS and puborectalis, respectively, in and above the resting anal HPZ.<sup>63,82,83</sup> However, such inferences are limited by the spacing between adjacent sensors (typically 6 mm) and need to be confirmed by studies with pharmacologic antagonists.

Alterations in pressure symmetry may suggest anal sphincter defects.<sup>82,84,85</sup> Compared to endoanal ultrasound, 3D-HR-ARM had false negative and false positive rates of respectively 14% and 41% for IAS defects and 21% and 30% for EAS defects.<sup>84</sup> The authors concluded that the insufficient level of agreement (between manometry and ultrasound) could not support the reliable use of 3D-HR-ARM for diagnosis. Moreover, these studies did not specify whether the sphincter defects identified with 3D-HR-ARM and imaging (eg, ultrasound) were situated in the same location (ie, around the circumference and length of the anal canal).

**Pressure Measurement in the Posterior Distal Pressure Zone**—Incomplete relaxation or paradoxical contraction of the puborectalis muscle may manifest as a persistent HPZ on the posterior aspect of the upper end of the anal sphincter (Figure 2).<sup>46,47</sup>

**Perineal Descent, Rectal Intussusception, and Rectal Prolapse**—During simulated defecation, a band of high pressure extending from the rectal balloon to the anal canal strongly suggests rectal intussusception or prolapse.<sup>86–88</sup>. This appearance is distinctive. In addition to suggesting rectal intussusception or prolapse, the appearance is

also useful for distinguishing between early and more advanced rectal prolapse, which are generally associated with high and low anal pressures, respectively, presumably because longstanding prolapse stretches and weakens the IAS.<sup>88</sup>

Perineal descent during evacuation can be estimated with 3D-HR-ARM; such measurements are correlated with barium defecography.<sup>84,89</sup> However, these measurements assume that the position of the 3D-HR-ARM catheter relative to the anal canal is the same before and during simulated evacuation. In our experience, this can be challenging. Also, the Bland Altman plots suggest that the difference in perineal descent measured with defecography and 3D-HR-ARM is related to the magnitude of perineal descent.<sup>89</sup>

#### **Opportunities for Future Research**

Prompted by the main limitations of HR-ARM and 3D-HR-ARM, the following opportunities will likely meaningfully expand the use of HR-ARM in clinical practice and research:

- 1. *Expand the database of age- and sex-appropriate normal values with HR-ARM and interpret patient data relative to normal values for the technique.* This is arguably the most important priority.
- 2. *Refine the assessment of anal pressure topography.* This research can be conducted on existing data. Some options are discussed above.
- 3. Use seated ARM. Seated ARM more closely approximates to defecation than left lateral ARM. In 33 studies, of which 2 only included healthy persons, rectal and, to a lesser extent, anal pressures measured with conventional or non–HR-ARM during evacuation were greater, and dyssynergia was less frequently observed in the seated than in the left lateral position.<sup>90–92</sup> One study measured balloon expulsion time in 200 women (136 constipated, 64 healthy). In those who had prolonged expulsion time (n=52), the rectoanal gradient during evacuation was less negative in the seated position than in the left lateral position.<sup>60</sup> Pressure topography was characterized into 4 patterns which, when evaluated in the seated position, were associated with a prolonged BET (minimal change, 45%; anal relaxation, 15%; paradoxical contraction, 53%; and transmission, 0%) (Figure 3). Seated ARM is challenging because the catheter may be displaced during evacuation. A catheter fixation clip may limit this displacement.<sup>60</sup>
- **4.** Use an evidence-based process to standardize the performance of maneuvers during manometry. An iterative approach can be used to refine the current IAPWG protocol and London Classification.
- 5. Use adjunct maneuvers during manometry. Many DD patients strain excessively or perform a Valsalva maneuver during evacuation, resulting in rectoanal discoordination, which hinders rectal evacuation. A simultaneous consideration of rectoanal pressures during evacuation and a Valsalva maneuver reveals rectoanal discoordination and facilitates a diagnosis of DD in selected patients.<sup>52</sup>
- 6. *Investigate newer technologies for measuring anal sphincter functions.* By distending the anal sphincter, anal acoustic reflectometry and the anal barostat

can assess the integrity and distensibility of the anal sphincter barrier.<sup>93–97</sup> A fecobionic silicon bag that resembles the consistency of normal stool has pressure and motion sensors that record pressures, anorectal angles, and expulsion velocity during defecation.<sup>98,99</sup> The incremental utility of these devices for understanding the pathogenesis or guiding the management of FI or DD remains to be established.

#### **Rectal Balloon Expulsion Test**

The rectal balloon expulsion test is a simple, outpatient test to assess rectal evacuation. In patients with a suspected DD, it should be performed in conjunction with ARM or as a stand-alone test that obviates the need for more expensive imaging and manometry. The time required to evacuate a balloon filled with warm tap water (typically 50 mL) in the seated position is assessed. Normal balloon expulsion time depends on the type of rectal balloon,<sup>100</sup> is reproducible among individuals on different testing days,<sup>101</sup> and is inversely related to age.<sup>102</sup>

At most centers, the test is performed with either a latex balloon or latex-free balloon. By convention, the upper limit of normal is 1 minute. More recent studies suggest that a shorter cutoff (eg, 26 seconds) may be acceptable..<sup>18,100,103</sup> In contrast to latex balloons, latex-free latex-freeballoons are set to a standard size. For a Foley catheter inflated to 50 mL, which is above the manufacturer's recommended limit of 30 mL, the upper limit of normal is 2 minutes.<sup>101</sup> Even with the 2-minute cutoff, up to 25% of healthy persons would be misclassified as abnormal because they require more than 2 minutes.<sup>100</sup>

Defecation is usually preceded by the desire to defecate. Some patients with DD have reduced rectal sensation; hence may not perceive the desire to defecate with a balloon inflated to 50 ml.<sup>104</sup> To address this issue, patients can be asked to expel a balloon that is inflated until patients experience the desire to defecate. Among 106 patients with FC and 24 patients with DD, the BET identified those with DD, documented with defecography, with 88% sensitivity and 89% specificity; positive- and negative-predictive values were 64% and 97% for diagnosis of DD, respectively.<sup>105</sup> In this study, the rectal balloon was inflated not to a fixed volume but until patients experienced the desire to defecate, averaging 183 mL, which may compensate for reduced rectal sensation identified in some patients with DD.<sup>66</sup> Further studies are necessary to compare these 2 techniques of assessing rectal evacuation (i.e., fixed versus variable balloon inflation).

In another study of 118 patients with anorectal symptoms, a prolonged BET was very specific (90%) for identifying reduced rectal evacuation measured with MRI.<sup>88</sup> However, similar to an earlier study, <sup>106</sup> the sensitivity of a BET was only 27% compared to MRI. Compared to barium defecography, the BET had a sensitivity of 88%.<sup>105</sup> A BET longer than 1 minute had a sensitivity and specificity of 71% and 100%, respectively, for predicting paradoxical contraction based on ARM.<sup>107</sup> This suggests that a normal BET (using a 60-second cutoff) may not always exclude a DD. The degree of agreement among the major diagnostic assessments of evacuation (rectal balloon expulsion, defecography, manometry) varies considerably among studies,,<sup>88,108</sup> and the gold standard remains unclear. In contrast to defecography, a rectal balloon expulsion test cannot identify structural abnormalities.

Importantly, an abnormal rectal balloon expulsion test predicts the response to biofeedback therapy.<sup>109,110</sup> Therefore, the rectal balloon expulsion test is a useful, low-cost, radiation-free, outpatient assessment tool for impaired evacuation. The optimum methodology, normal values, and clinical utility alongside defecography and manometry need further clarification.

#### Putting It Together

ARM is a useful test for diagnosing DD in constipated patients, identifying anal weakness and rectal sensory abnormalities in FI, and evaluating patients with megacolon or megarectum (Supplementary Table 2). Its usefulness in the assessment and management of anorectal disorders has been endorsed by the American Gastroenterology Association,<sup>3</sup> American College of Gastroenterology,<sup>5</sup> and the American Society of Colon and Rectal Surgeons.<sup>111</sup> The test results should be interpreted in the context of the clinical features, and in conjunction with the results of other tests.<sup>88,108</sup> (Table 5)

The London Classification incorporates the findings of anal manometry, rectal sensation test, and tests to assess rectal evacuation (ie, rectal balloon expulsion test or defecating proctography) into 4 diagnostic algorithms.<sup>12</sup> These algorithms have not been clinically tested and their clinical usefulness has not been validated.

With the advent of HR-ARM, 3D-HR-ARM, and portable manometry, ARM is more widely used in clinical practice. While this is a welcome trend, it is our impression that many practitioners are not adequately trained in conducting and interpreting HR-ARM. HR-ARM and 3D-HR-ARM provide a more refined assessment of anorectal pressure topography, which may uncover anorectal structural abnormalities (eg, rectal intussusception). However, use of HR-ARM and 3D-HR-ARM in diagnosing DD is somewhat limited by the recognition that even asymptomatic healthy persons may exhibit dyssynergia during simulated evacuation, and that patients with chronic constipation may be dissatisfied with their bowel habits despite normal stool frequency and form.<sup>112</sup> A larger database of technique-specific normal values and newer paradigms of analyzing anorectal pressure profiles will increase the precision of HR-ARM for identifying abnormal mechanisms of defecation and continence. Prospective long-term studies that assess the impact of identifying these abnormalities on patient outcomes are necessary to define the relevance of ARM in clinical practice.

#### **Supplementary Material**

Refer to Web version on PubMed Central for supplementary material.

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#### Abbreviations

ARM

anorectal manometry

DD	defecatory disorder
EAS	external anal sphincter
FI	fecal incontinence
3D-HR-ARM	3-dimensional high-resolution anorectal manometry
HPZ	high-pressure zone
HR-ARM	high-resolution anorectal manometry
IAPWG	International Anorectal Physiology Working Group
IAS	internal anal sphincter
MRI	magnetic resonance imaging
RAIR	rectoanal inhibitory reflex

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#### Figure 2.

Representative examples of pressure topography assessed with 3D-HR-ARM. (A) At rest, observe the high pressure zones representing the puborectalis (green) and the internal (IAS) and external anal sphincters (EAS) in red. (B) During squeeze, observe increased pressure generated by the puborectalis and EAS, which are now respectively colored red and magenta. During evacuation, there was normal relaxation (C) or paradoxical contraction (D) of the puborectalis and external anal sphincter.

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#### Figure 3.

Representative images and summary data (median and interquartile values) of rectoanal pressures at rest and during evacuation in the seated position in the 4 patterns. Rectoanal pressures were measured by a 12-sensor catheter depicted in the vertical black bar, upper right corner. Note the transmission of pressure from the rectal balloon throughout the anal canal in the transmission pattern. Footnotes indicate comparison of rectal or anal pressure during evacuation in patients with normal versus prolonged BET in the same pattern. <sup>a</sup> P < .05.

<sup>b</sup> P .01.

<sup>c</sup> P .001.

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#### Table 1.

Comparison of High-Resolution and High-Definition Anorectal Manometry Catheters Versus non–High-Resolution Anorectal Manometry Catheters

	HR-ARM and 3D-HR-ARM	Conventional ARM
Type of sensors	Water-perfused or solid-state	Water-perfused, solid-state, or air-charged
Number of sensors	More sensors, closely spaced	Fewer sensors at wider intervals
Display	Color contour and line plot	Line plot
Techniques	Stationary examination	Pull-through examination
Preparation	Easy	More time-consuming
Anatomical resolution	Good	Poor
Interpretation	Initially by software	Entirely manual
Cost	High	Low
Catheter durability and number of uses	Limited <sup>a</sup>	Less
Life span	Short <sup>a</sup>	Long

Abbreviations: ARM, anorectal manometry; 3D-HR-ARM, 3-dimensional high-resolution anorectal manometry; HR-ARM, high-resolution anorectal manometry.

<sup>a</sup>For HR-ARM catheters that use solid-state sensors.

Modified with permission from Lee TH, Bharucha AE. How to perform and interpret a high-resolution anorectal manometry test. J Neurogastroenterol and Motility 2016;22(1):46–59.

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Table 2.

Catheters	
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Anorectal	
Used	
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	HR-ARM	3D-HR-ARM	UNI-ANO-	HRAM-200	UniTip,	UniTip 3D,	<b>3D-MUI water</b>	T-DOC	mcompass	Anopress
			M0138		K121259-L5- 1444-D	K122359-L5- 1623-D	Perfused <sup>a</sup>	Air- Charged	4	4
Specifications	Medtronic	Medtronic	Catheter (Unisensor) Equipment ( Diversatek)	Diversatek	Catheter (Unisensor) Equipment (MMS/ Laborie)	Catheter (Unisensor) Equipment (MMS/ Laborie)	Catheter (MUI Scientific) Equipment (MMS/ Laborie)	MMS/ Laborie	Medspira	THD Lab
Caliber	4.2mm (12.6F)	10.75mm (32.25F)	12F	16.7F	12F/16F <sup>b</sup>	12F	14F	8F/12F <sup>b</sup>	27F	48F
Pressure-sensing technology	Solid state	Solid state	Solid state	Solid state	Solid state	Solid state	Water perfused	Air- charged	Air-charged	Air- charged
Data acquisition frequency	35 Hz	35 Hz	50 Hz	50 Hz	$10-50~{ m Hz}^{\mathcal{C}}$	$10-50 \text{ Hz}^{\mathcal{C}}$	$10-20~{ m Hz}^{\mathcal{C}}$	$10-20~{ m Hz}^{\mathcal{C}}$	10 Hz	NA
Rectal balloon sensor	2	1	1	1	1	1	1	1	1	0
Rectal sensors	0	0	1	4 (at same level)	1	1	2	0	0	0
Anal sensors	10	240 (15 levels, 16 at each level)	20 (5 levels, 4 at each level)	20 (5 levels, 4 at each level)	6	20 (5 levels, 4 at each level)	20 (5 levels, 4 at each level)	4	4	1
Outside sensors	0	0	1	2	1	1	2	0	0	0
Distance between anal sensors	6 mm	4 mm	10 mm	10 mm	8 mm	8 mm	5 or 10 mm (2 types)	Only 1 level	Only 1 level	Only 1 level
Circumferential pressure sensors at each level in anus, No.	36	16	4	4	1	4	4	4	4	1
Circumferential pressures displayed at each level in anus, No.	1	4	4	4	1	4	4	4	4	1
Normal values-men	47 <sup>18</sup>	$36,^{19} d_{64^{46}} e$	27 <sup>36</sup>	None	19 <sup>17</sup>	None	20 <sup>20</sup> e	None	34	73 <sup>113</sup>
Normal values- women	96 <sup>18</sup>	42, <sup>19</sup> d 46 <sup>46</sup> e	27 <sup>36</sup>	None	96 <sup>17</sup>	None	$40^{20} e$	None	74	80 <sup>113</sup>
In vivo validation vs another device	Vs HR-ARM <sup>21</sup> and water- perfused	Vs HR-ARM <sup>21</sup>	None	None	None	None	Vs solid-state catheter <sup>20</sup> <i>e.f</i>	None	Vs Medtronic HRM <sup>114</sup>	Vs water- perfused HR- ARM <sup>115</sup>

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	HR-ARM	3D-HR-ARM	UNI-ANO- M0138	HRAM-200	UniTip, K121259-L5- 1444-D	UniTip 3D, K122359-L5- 1623-D	3D-MUI water Perfused <sup>a</sup>	T-DOC Air- Charged	mcompass	Anopress
Specifications	Medtronic	Medtronic	Catheter (Unisensor) Equipment (Diversatek)	Diversatek	Catheter (Unisensor) Equipment (MMS/ Laborie)	Catheter (Unisensor) Equipment (MMS/ Laborie)	Catheter (MUI Scientific) Equipment (MIMS/ Laborie)	MMS/ Laborie	Medspira	THD Lab
	manometry 25									
Day-to-day reproducibility	None	Anal pressures at rest and squeeze but not during evacuation are reproducible. <sup>19,21</sup>	None	None	None	None	None	None	None	None
Type of use	Multiple	Multiple	Multiple	Multiple	Multiple	Multiple	Single	Single	Single	Single
Abbaniotiona 3D UD	ADM 2 dimonol	and hide motorial to the second	D monomotern D	ID ADM high 100	a lution on one of the	D A ID	motididai lonootoon	in NIA without	ما متمنامها م	

manometry; KF anorecta 10**U** -AKIVI, IIIGII icuy, HK Abbreviations: 3D-HR-ARM, 3-dimensional high-resolution

 $^{a}$ This is the description for the 3D water-perfused catheter. Other configurations of these water-perfused catheters are available.

 $\boldsymbol{b}_{\text{Separate values for catheter shaft alone (smaller value) and with sensors.$ 

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 $^{C}$ The software program allows the user to select any value within this range prior to the study.

dRectoanal pressures during evacuation were only evaluated in 18 healthy participants.

 $\boldsymbol{e}^{\boldsymbol{\theta}}$  Did not measure rectoanal pressures during evacuation.

 $f_{\rm The}$  2D version of the water-perfused catheter was used in this study.

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Author		Oblizaje	k et al <sup>18</sup>		Li e	t al <sup>46</sup>	Lee et	al <sup>36</sup>	Carringto	n et al <sup>17</sup>	Coss-Ada	me et al <sup>19</sup>
Year		2019		2019	3(	13	201	4	201	4	20	15
Participants, No	<50 y	ears (n=58)	50 y	ears (n=38)	4	16	60		96		4	
Country	Uni	ted States	Unit	led States	5	iina	South 1	Korea	United Ki	ingdom	Mexico ar Sta	d United tes
Method	H	R-ARM	H	R-ARM	3D-HI	RARM	HR-A	RM	3D-HR-	ARM	3D-HR	-ARM
Manufacturer	M	edtronic	M	edtronic	Medi	tronic	Divers	atek	MMS/L:	aborie	Medt	ronic
Variables	Mean±SD	10th, 90th percentile	Mean±SD	10th, 90th percentile	Mean±SD	95% CI	Median	IQR	Mean±SD	Min, Max	Mean	95% CI
Maximum resting pressure	85±22	55, 111	66±25	33, 93	68.5±2.4	63.6-73.4					76	71-81
Mean resting pressure					$60.2\pm 2.2$	55.8-64.6	32	24, 42	65±19	25, 111		
Maximum squeeze pressure	207±56	140, 284	193±67	122, 281	$167.4\pm 8.4$	150.5-184.3	75	61, 89	225±89	76, 503	205	186–224
HPZ length	3.3±0.8	2.2, 4.3	3.6±0.7	2.4, 4.6	$3.5\pm0.1$	3.3–3.7			3.5±0.8	1.6, 6.0	4	3.8-4.2
Duration of sustained squeeze	14±7	4, 22	$13\pm 8$	3, 23	$14.7\pm0.8$	13.2–16.3			$11 \pm 9$	2, 30	28	27–30
Anal squeeze increment	122±49	140, 284	126±65	49, 218			20	12, 28	113±62	20, 281	61	53–69
Residual anal pressure	63±19	36, 88	64±23	35, 97	65.2±6.7	51.8-78.7	19	10, 35	43±21	12, 110	36	28-43
Anal relaxation rate, %	27±19	0, 53	9±48	-30, 49	27.2±2.9	21.2-33.0	30	0, 75	24±22	0, 83		
Rectal pressure	25±20	1, 56	37±21	11, 69	45.8±7.2	31.2-60.4	37	27, 51	64±31	18, 200	39	34-45
Rectoanal pressure differential	-38±25	-70, -6	-27±27	-64, 12	$-12.8\pm 8.5$	-29.8-4.1	16	6, 20				
First sensation	39±15	20, 60	35±12	20, 50	$40{\pm}1.8$	36.3-43.6	10	10, 20			24	21–26
Desire to defecate							60	50, 70			88	79–96
Urge to defecate	65±22	40, 100	59±22	40, 90	92.6±4.4	82.2–98.6	115	98, 153			139	130-147
Discomfort	$104 \pm 34$	60, 150	98±28	60, 130	145±5.2	134.6–155.4					193	182–204
Balloon expulsion time	13±12	2, 26	10±12	3, 22			15	10, 30				

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Abbreviations: HPZ, high-pressure zone; 3D-HR-ARM, 3-dimensional high-resolution anorectal manometry; HR-ARM, high-resolution anorectal manometry; IQR, interquartile range; Max, maximum; Min, minimum.

# Table 4.

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Author	Oblizajek e	t al <sup>18</sup>	Li et al <sup>46</sup>		Lee et al <sup>3</sup>		Carrington	et al <sup>17</sup>	Coss-Adam	e et al <sup>19</sup>
Year		2019	2(	013	20	14	20	14	2	015
Participants, No		47		64	6	4	1	6		36
Country	ſ	Inited States	C	uina	South	Korea	United <b>K</b>	Kingdom	Mexico and	United States
Method		HR-ARM	3D-HI	R-ARM	HR-	ARM	HR-/	ARM	3D-H	R-ARM
Manufacturer		Medtronic	Med	tronic	Diver	satek	I/SMIM	aborie	Med	ltronic
Variables	Mean±SD	10th, 90th percentile	Mean±SD	95% CI	Median	IQR	Mean±SD	Min, Max	Mean	95% CI
Maximum resting pressure	83±25	54, 111	69.5±2.2	65.2-73.8					90	83–96
Mean resting pressure			$61.3\pm 2.1$	56.5-65.5	46	39, 56	73±23	38, 136		
Maximum squeeze pressure	257±78	164, 366	$194.8\pm 6.9$	180.9–208.6	178	140, 212	290±155	94, 732	266	245-287
HPZ length	$3.9 \pm 0.8$	2.9, 4.8	$3.6 \pm 0.1$	3.4–3.8			3.9±0.8	2.4, 5.3	4.3	4.1-4.5
Duration of sustained squeeze	$14{\pm}7$	3, 21	$12.3 \pm 0.7$	10.8-13.8			16±11	3, 30	30	28–30
Anal squeeze increment	$174\pm 81$	90, 328			55	41, 77	144±116	40, 474	66	58-73
Residual anal pressure	$105\pm 44$	55, 152	81.2±4.3	72.6–89.7	26	13, 55	57±23	20, 104	40	28–52
Anal relaxation rate, %	5±29	-32, 44	22.5±2.9	16.6–28.3	16	0, 82	16±33	0, 60		
Rectal pressure	47±36	21, 87	72.3±9.4	53.5-91.2	69	44, 98	71±33	20, 140	43	35–51
Rectoanal pressure differential	-58±53	-128, -1	-13.4±7.5	-28.5-1.7	30	6, 66				
First sensation	44±26	20, 72	$44.2\pm 1.8$	40.6-47.8	10	10, 20			22	20–25
Desire to defecate					80	60, 120			94	82-103
Urge to defecate	74±34	40, 120	$102.5\pm 4.1$	94.2–110.8	130	110, 8			163	140–167
Discomfort	123±53	60, 212	$154.5\pm 3.7$	147.1–162					206	192–222
Balloon expulsion time	$12\pm 12$	3, 30			15	5, 50				
Abbreviations: HPZ, high-pressure	e zone; 3D-HF	e-ARM, 3-dimensional hig	th-resolution a	norectal manom	etry; HR-Al	RM, high-res	solution anored	ctal manometr	y; IQR, interqu	lartile range.

Challenges to High-Resolution Anorectal Manometry

Chalkenge	Implications
Differences in catheter design and pressure-sensing technology among manufacturers.	Patient data need to be compared to technique-specific normal values.
Compared to non-HR-ARM catheters, HR-ARM catheters are much more expensive and fragile. They are guaranteed for a limited number of uses (eg, 200 uses or 1 year). They can only be repaired by the company.	In order to avoid interrupting services, laboratories need to purchase and maintain spare catheters. For spare catheters, the warranty may expire before the required number of uses, which entails added expense. Limited commercial availability of less expensive catheters hinders the more widespread use of ARM, especially in lower-income countries.
The ManoScan 3D-HR-ARM probe is rigid, much larger than other probes (10.75 mm), does not conform to the anorectal angle, and has to be held by the operator during the test. This may introduce artifacts, especially if it is not held in the neutral position during maneuvers such as squeeze and bearing down. <sup>19</sup>	
For some methods, normal values are unavailable or have not been assessed in an sufficient number of people.	Absence of normal values substantially reduces the diagnostic utility of manometry.
Manometry is invariably performed in the left lateral position.	Negative rectoanal pressure gradient during evacuation in healthy persons, which limits the use of manometry for diagnosing DD.
The manometry reports, which are used for diagnosis, capture only a small fraction of the information gathered during the test. The diagnostic utility of currently used summary variables (eg, rectoanal gradient) varies among devices and has not been compared to other potential options.	Studies evaluating the utility of various HRM variables and different devices are necessary.
Circumferential pressure topography needs further validation.	Endoanal imaging with ultrasound or MRI remains the gold standard for identifying anal sphincter defects.
Abbreviations: ARM, anorectal manometry; DD, defecatory disorder; 3D-HR-ARM, 3-dimensional high-resolution anore	ctal manometry; HR-ARM, high-resolution anorectal manometry.