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Reproducibility of High-Definition (3D) Manometry and Its Agreement With High-Resolution (2D) Manometry in Women With Fecal Incontinence

Subhankar Chakraborty¹, Kelly J. Feuerhak¹, Alan R. Zinsmeister², and Adil E. Bharucha¹

¹Clinical and Enteric Neuroscience Translational and Epidemiological Research Program (C.E.N.T.E.R.), Mayo Clinic, Rochester, MN, 55905 USA

²Division of Biomedical Statistics and informatics, Department of Health Sciences Research, Mayo Clinic, Rochester, Minnesota, 55905 USA

Abstract

Background—While widely used in clinical practice, the reproducibility of high-definition anorectal manometry (HD-ARM) is unclear. We evaluated the intra-individual reproducibility of HD-ARM and compared pressures measured with HD-ARM and high-resolution anorectal manometry (HR-ARM).

Methods—Thirty-six women with fecal incontinence had an initial HD-ARM (HD-ARM1); on the same day, after randomization, 21 had a second (HD-ARM2). Sixteen women had a third (HD-ARM3) four weeks later. Twenty-five had also been evaluated by HR-ARM previously. Rectoanal pressures were assessed at rest, during squeeze and simulated evacuation. Concordance among pressures was assessed with Lin's concordance correlation coefficient (CCC).

Key Results—Anal resting and squeeze pressures measured with HD-ARM were reproducible on the same and different days; for average resting pressures of HD-ARM1 versus HD-ARM2, CCC=0.73 (95% confidence interval [CI], 0.53-0.94), and for HD-ARM1 versus HD-ARM3, CCC=0.60 (95% CI, 0.28-0.93). For maximum squeeze pressures of HD-ARM1 versus HD-ARM2, CCC=0.86 (95% CI, 0.75-0.97), and for HD-ARM1 versus HD-ARM3, CCC=0.56, (95% CI, 0.21-0.91). The rectoanal gradient during evacuation was significantly concordant between HD-ARM1 and HD-ARM2 but not HD-ARM1 and HD-ARM3. Resting (CCC=0.38 [95% CI, 0.14-0.62]) and squeeze pressures (CCC=0.73 [95% CI, 0.57-0.89]) measured with HD-ARM1 and HR-ARM were also concordant.

Conclusions & Inferences—Among women with fecal incontinence, measurements with HD-ARM were reproducible on the same (anal resting and squeeze pressures and rectoanal gradient during evacuation) and different days (anal resting and squeeze pressures) and correlated with HR-ARM measurements. These findings support use of HD-ARM and HR-ARM for longitudinal assessments of anal resting and squeeze pressures.

Address for correspondence and reprint requests: Adil E. Bharucha, M.D., Clinical and Enteric Neuroscience Translational and Epidemiological Research Program, Mayo Clinic, 200 First St. SW, Rochester, MN 55905, Telephone: 507-284-2687, Fax: 507-538-5820, bharucha.adil@mayo.edu.

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Keywords

anorectal; fecal incontinence; high definition; high resolution; manometry; reproducibility

Anorectal manometry (ARM) and a rectal balloon expulsion test are used to diagnose defecatory disorders in constipated patients (1-4) and to identify reduced anal pressures in fecal incontinence (FI) (5, 6). Over the past 7 years, high-resolution manometry catheters have been increasingly utilized to conduct anorectal manometry (7). While older, “non-high-resolution” catheters have three or six unidirectional sensors, high-resolution catheters contain several closely spaced circumferential sensor elements along the longitudinal axis. The design of high-resolution catheters varies among manufacturers. There are 2 types of Manoscan catheters: a high-resolution anorectal manometry (HR-ARM) catheter, which has an outer diameter of 4.2-mm and has 12 circumferential sensors; and a high-definition anorectal manometry (HD-ARM) catheter, which has an outer diameter of 10.75 mm and has 256 sensing elements that are arranged in 16 rows, each of which has 16 circumferentially oriented sensor elements. The HR-ARM system provides one value at any level along the longitudinal axis of the anal canal while the HD-ARM catheter system provides pressures recorded by individual sensors around the circumference at any level, thereby enabling an assessment of circumferential symmetry (7).

The configuration of anal probes, particularly the diameter and the manner in which pressures are summarized, affect the measurement of anal pressures. For example, anal pressures at rest and during anal contraction (i.e., squeeze maneuver) recorded with HR-ARM are significantly correlated with but higher than conventional (non-high resolution) manometry (8-10). Another study in healthy people observed that “anorectal pressure and sensory parameters” between HD-ARM measurements two weeks apart were similar (11). However, the intra-individual, day-to-day variability of anorectal pressures measured with HD-ARM in patients and the relationship between pressures measured with HR-ARM and HD-ARM are unknown. These issues are germane to longitudinal studies evaluating the effects of interventions on rectoanal pressures. They are also important because both HD-ARM and HR-ARM catheters are used in clinical practice; HD-ARM catheters are also stiffer and larger than HR-ARM catheters.

Hence, the aims of this study were a) to assess the intra-individual, intraday, and day-to-day reproducibility of anorectal pressures measured with HD-ARM in women with FI and b) to compare anorectal pressures measured with HR-ARM and HD-ARM in these patients.

MATERIALS AND METHODS

Experimental Design

This report represents the findings in a subset of women who were enrolled in a prospective, randomized, double-blind, placebo-controlled clinical trial of clonidine for FI. At the baseline visit, anorectal pressures were measured twice, i.e., before (HD-ARM1) and after (HD-ARM2) randomization to intravenous atropine or placebo on the same day. Pressures were reassessed after randomization to oral clonidine or placebo 4 weeks later. Pressures

recorded with HD-ARM1 and HD-ARM3 in all participants have been reported previously. All participants who had a technically adequate study during HD-ARM1 and were treated with placebo during HD-ARM2 and HD-ARM3 were considered for this report. Except for loperamide, which was used as a rescue agent, no other changes in diet, lifestyle or medications were permitted during the study. Data from HR-ARM, which was performed as part of their clinical assessment in 25 patients, was also considered (12, 13). The study was approved by the Institutional Review Board at Mayo Clinic, registered at clinicaltrials.gov (NCT00884832), and conducted from January 2009 through April 2012. All patients gave written informed consent. All authors had access to the study data and reviewed and approved the final manuscript.

Anorectal Manometry

Anorectal pressures were measured in the left lateral position at rest, during squeeze, and during simulated evacuation using standard procedures (11, 14-16). The HD-ARM probe (Given Imaging, Yoqneam, Israel) is 6.4 cm in length and has an outer diameter of 10.75 mm. It has 256 pressure sensors that are arranged in 16 rows. The HR-ARM catheter (Given Imaging, Los Angeles, CA) has an outer diameter of 4.2-mm outer diameter and 10 circumferential sensors, eight at 6 mm intervals along the anal canal and two in the rectal balloon. At each level, 36 circumferentially oriented, pressure-sensing elements detect pressure using proprietary pressure transduction technology (TactArray). The summary parameters (e.g., average anal resting pressure) were computed with commercially available software that uses similar definitions for HD-ARM and HR-ARM and are described elsewhere (14). The squeeze duration was defined as the duration for which the anal pressure above the resting pressure baseline was greater than 50% of difference between peak anal and resting pressure. Resting pressure was measured once. Squeeze pressures were measured three times; the average was used for analysis. Pressures during evacuation were measured before and subsequently during rectal balloon distention.

Statistical analysis

Continuous variables are expressed as the mean and standard deviation (SD). Lin's concordance correlation coefficient (CCC), Bland Altman plots, and paired parametric or non-parametric tests were used to assess the correlations between HD-ARM readings obtained at different times and between HD-ARM and HR-ARM (17). While the intra-class correlation coefficient (e.g., Pearson or Spearman) only measures the precision of a measurement relative to another, the CCC also measures the accuracy. All tests were two-tailed, and a *P* value <.05 was considered significant.

RESULTS

Thirty-six women (age 56±11 years) underwent HD-ARM1. Of these, 21 had HD-ARM2 (age 57±11 years), 16 had HD-ARM3 (age 58±11 years). Twenty-five had HR-ARM data from clinical assessment (age 55±12 years). The clinical features are summarized in Table 1. The overall fecal incontinence severity score (FISS) indicated mild (0 patients), moderate (7 patients), or severe FI (29 patients). Endoanal MRI demonstrated a normal appearing internal anal sphincter in 18 and a normal external anal sphincter in 16 patients. Six women

had isolated internal sphincter injury, 8 had isolated external sphincter injury and 11 had injury affecting internal and external sphincters.

Intra-individual reproducibility of anal pressures measured with HD-ARM

Anal pressures at rest and during squeeze measured with HD-ARM on the same day (i.e., HD-ARM1 and HD-ARM2) and on different days (i.e., HD-ARM1 and HD-ARM3) were reproducible (Table 2 and Figure). Except for the maximum squeeze pressure, which was greater during HD-ARM2 than HD-ARM1 ($P=0.03$), resting and squeeze pressures measured with HD-ARM were not significantly different.

The concordance between rectoanal pressures during evacuation measured with HD-ARM on the same day and on different days was variable (Table 2). For example, in the absence of rectal distention, anal pressure and the rectoanal gradient were significantly correlated, albeit significantly different ($P=.02$ and $P<.01$, respectively) on the same day but not on different days. After rectal distention, the rectoanal gradient during evacuation measured with HD-ARM was significantly concordant on the same and on different days.

Comparison of rectoanal pressures measured with HR-ARM and HD-ARM

Measurements of the anal squeeze pressure and to a lesser extent the anal resting pressure, with HD-ARM and HR-ARM were significantly concordant. The average ($P<.0001$) and maximum ($P<.05$) anal resting pressures were greater with HR-ARM than HD-ARM1. However, the anal squeeze pressure and duration measured with HD-ARM and HR-ARM were not significantly different. Except for the magnitude of anal relaxation during evacuation with a distended rectal balloon, the concordance between pressures during evacuation measured with HD-ARM and HR-ARM were not statistically significant.

Coefficient of variation for anal pressures

The intra-individual coefficient of variation for anal resting and squeeze pressures measured with HD-ARM was approximately 20%, and lower than the inter-individual coefficient of variation for the corresponding parameters, which was approximately 40% (Table 3). During evacuation, the intra- and inter-individual coefficients of variation for anal pressure were approximately 40%, and considerably higher for the other parameters.

DISCUSSION

Anal resting and squeeze pressures measured with non-high-resolution manometry and HD-ARM are reproducible in healthy subjects (11, 18-23). While HR-ARM and HD-ARM are increasingly used to measure rectoanal pressures in clinical practice, the reproducibility of these measurements in patients is unknown. There are three key observations in this study. First, anal resting and squeeze pressures and the squeeze duration measured with HD-ARM are reproducible on the same and on different days, which supports the use of this technique in longitudinal studies (e.g., in therapeutic trials). However, the rectoanal gradient during evacuation measured with HD-ARM was reproducible on the same day but not on different days. Second, anal resting and squeeze pressures, but not pressures during evacuation, are significantly correlated between HD-ARM and HR-ARM. Third, the anal resting pressure,

intrarectal pressure, and rectoanal gradient during evacuation were greater when measured with HR-ARM than HD-ARM.

Several factors, including probe size, its rigidity, and perhaps distortion of the rectoanal anatomy, may explain why rectal pressures, in particular, during simulated evacuation measured with HD-ARM were not reproducible. Real-time imaging with defecating proctography during anorectal manometry may be helpful to clarify the effects of the probe on the rectoanal anatomy. The HD-ARM probe is rigid and approximately twice the diameter of conventional and HR-ARM probes. Even relatively modest movement of the catheter can be associated with artifact. Although the artifact may be brief, it may affect the measured rectoanal gradient, which is obtained during a 2-second period during which the gradient is the most positive or the least negative. These factors may also explain why the rectoanal gradient is negative in a substantial proportion of healthy people (11). This is a significant limitation because anorectal manometry is widely used to diagnose DD, which are a common cause of chronic constipation (24). Further studies to establish the range of normative values in healthy individuals and to determine the criteria for diagnosing DD with HD-ARM are needed.

Anal pressures measured with HD-ARM and HR-ARM were significantly correlated. While differences were numerically small, the anal resting pressure measured with HR-ARM was significantly greater than HD-ARM. Contrary to previous studies that compared anal pressures with conventional manometry probes of different sizes (25, 26), pressures in this study were lower for the smaller HR-ARM probe. Hence, these differences cannot be readily explained by differences in probe caliber. Conceivably, transformer hardware or software issues may explain these differences. The anal squeeze pressure was not significantly different between HR-ARM and HD-ARM. However, the squeeze duration was longer for HD-ARM (average of 21 seconds) than HR-ARM (average of 13 seconds). Similarly, although no head-to-head comparisons exist, the squeeze duration in healthy women was longer for HD-ARM (28 seconds) than HR-ARM (12-14 seconds) (7). Because the HD-ARM probe is larger and more rigid, it is conceivable that patients may better able to sense this and contract the sphincter muscles around it.

For conventional manometry, the intra- and inter-individual coefficients of variation for average anal resting pressure were 26% and 39%, respectively. For maximum anal squeeze pressure, corresponding values were 24% and 35%, respectively (18). In this study, values for corresponding parameters were comparable. Because the intra-individual coefficient of variation is lower than the inter-individual coefficient of variation, a smaller sample size would be required to detect the same treatment effect with a crossover than a parallel group design. This inter-individual SD is useful for planning future studies. Based on the SD of approximately 20 units for average resting pressure, sample sizes of 42 and 18 patients per group will provide sufficient power to detect differences of 10% and 15%, respectively, between groups with 80% power and a two-sided test with an α level of 0.05. However, detecting differences of 10% and 15% with a SD of 47 units, which is the observed SD for maximum anal squeeze pressure, will require sample sizes of 223 and 93 patients per group with the same power and α level.

In conclusion, measurements with HD-ARM are reproducible on the same (anal resting and squeeze pressures and rectoanal gradient during evacuation) and different days (anal resting and squeeze pressures) and correlated with HR-ARM measurements in women with FI.

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Subhankar Chakraborty analyzed the data and wrote the manuscript. Kelly Feuerhak acquired the data. Alan Zinsmeister did the statistical analysis. Adil E. Bharucha designed the study, analyzed the data, and wrote the manuscript.

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ABBREVIATIONS

CCC	concordance correlation coefficient
FI	fecal incontinence
HD-ARM	high-definition anorectal manometry
HR-ARM	high-resolution anorectal manometry

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KEY POINTS

- In women with fecal incontinence, the day-to-day reproducibility of anorectal pressures measured with high-definition manometry (HD-ARM) and the relationship to pressures measured with high-resolution manometry (HR-ARM) is unknown. Our objectives were to evaluate this gap.
- Anal resting and squeeze pressures, but not pressures during evacuation, measured with HD-ARM were reproducible on the same and different days and significantly correlated with pressures measured with HR-ARM.
- HD-ARM is suitable for longitudinal assessments of anal resting and squeeze pressures in women with fecal incontinence.

Figure.

Reproducibility for anal resting pressures (A) and maximum squeeze pressure (B) between high-definition manometry studies on the same day (HD-ARM1 and HD-ARM2). Resting (top panel) and squeeze pressures (bottom panel) were correlated between HD-ARM measurements made at different times on the same day (left panel). These differences were not related to mean pressure during HD-ARM1 and HD-ARM2 (Bland–Altman plot, right panel).

Table 1**Clinical Features**

Duration of FI	N (% of total)
Last 6 months	1 (3)
1-2 years	7 (19)
2-5 years	10 (28)
5-10 years	5 (14)
10-20 years	8 (22)
More than 20 years	5 (14)
Frequency of FI	
Daily	6 (17)
Between once/day to once/week	9 (25)
Once a week	7 (19)
Between once/week to once/month	10 (28)
Once/month	3 (8)
Less than once a month	1 (3)

Abbreviations: FI, fecal incontinence

Table 2
Comparison of Rectoanal Pressures Measured With High Definition Manometry on the Same and on Different Days

	Mean pressure $\pm$ SD			CCC (95% CI) ^a		Bland Altman test ^b	
	HD-ARM1 (n=36)	HD-ARM2 (n=21)	HD-ARM3 (n=16)	HD-ARM1 vs HD-ARM2	HD-ARM1 vs HD-ARM3	HD-ARM1 vs HD-ARM2	HD-ARM1 vs HD-ARM3
Rest							
Average pressure	49 $\pm$ 20	52 $\pm$ 22	53 $\pm$ 23	0.73 (0.53,0.94)	0.60 (0.28,0.93)	0.91	0.90
Maximum pressure	59 $\pm$ 21	66 $\pm$ 28	59 $\pm$ 25	0.72 (0.51,0.92)	0.71 (0.45,0.96)	0.36	0.43
Squeeze							
Maximum pressure	112 $\pm$ 47	124 $\pm$ 56 ^c	92 $\pm$ 38	0.86 (0.75,0.97)	0.56 (0.21,0.91)	0.58	0.49
Duration (seconds)	21 $\pm$ 10	22 $\pm$ 11	23 $\pm$ 9	0.65 (0.39,0.91)	0.64 (0.34,0.94)	0.89	0.81
Evacuation without rectal distension							
Anal pressure	47 $\pm$ 16	55 $\pm$ 25 ^c	42 $\pm$ 16	0.50(0.24,0.77)	-0.01 (-0.53, 0.50)	0.058	0.89
Rectal pressure	-0.13 $\pm$ 2	-0.4 $\pm$ 0.9	1 $\pm$ 2	0.32 (-0.01,0.65)	-0.21 (-0.58,0.16)	0.009	0.18
Anal relaxation (%)	18 $\pm$ 39	26 $\pm$ 23	22 $\pm$ 31	0.22 (-0.10,0.54)	0.56 (0.27,0.85)	0.0016	0.018
Rectoanal gradient	-46 $\pm$ 16	-56 $\pm$ 25 ^d	-40 $\pm$ 16	0.53 (0.27,0.79)	0.12 (-0.43,0.67)	0.048	0.72
Evacuation with rectal distension							
Anal pressure	49 $\pm$ 25	50 $\pm$ 21	41 $\pm$ 19	0.33 (-0.04,0.72)	0.52 (0.15,0.89)	0.37	0.19
Rectal pressure	-0.2 $\pm$ 2	-0.4 $\pm$ 1	8 $\pm$ 20 ^a	0.43 (0.09,0.76)	0.02 (-0.06,0.11)	0.05	0.0001
Anal relaxation (%)	3 $\pm$ 20	11 $\pm$ 23	8 $\pm$ 25	0.18(-0.26, 0.61)	0.68(0.41,0.94)	0.84	0.18
Rectoanal gradient	-46 $\pm$ 33	-50 $\pm$ 21	-35 $\pm$ 20	0.37 (0.07,0.68)	0.48 (0.17,0.79)	0.009	0.006

Abbreviations: CCC, concordance correlation coefficient; HD-ARM1, visit 1 before randomization, HD-ARM2, visit 1 after randomization; HD-ARM3, Visit four weeks after visit 1
 Results expressed as mean $\pm$ SD;

^aCorrelation coefficient was significant if the 95% CI did not include zero

^bP value for Pearson correlation of differences vs overall mean

^cP<0.05

^dP<0.01 for paired t-test or signed-rank test as appropriate (Comparisons were made as follows: HD-ARM1 vs HD-ARM2, and HD-ARM1 vs. HD-ARM3)

Table 3
Comparison of Rectoanal Pressures Measured by High Definition (HD-ARM1) and High Resolution (HR-ARM) Manometry

	Mean pressure $\pm$ SD		CCC (95% CI) ^a	Bland Altman test ^b	Coefficient of variation for HD-ARM (%)	
	HD-ARM1	HR-ARM			Intra-individual	Inter-individual
N	36	25				
Rest						
Average resting sphincter pressure	49 $\pm$ 19	64 $\pm$ 18 ^c	0.38 (0.14,0.62)	0.16	22	40
Maximum resting sphincter pressure	59 $\pm$ 22	67 $\pm$ 20 ^d	0.39 (0.08, 0.70)	0.81	19	37
Squeeze						
Maximum squeeze pressure	112 $\pm$ 47	129 $\pm$ 60	0.73 (0.57,0.89)	0.01	17	42
Duration of squeeze (seconds)	21 $\pm$ 10	13 $\pm$ 7 ^d	0.56 (0.36,0.75)	0.005	23	46
Evacuation without rectal distension						
Anal pressure	48 $\pm$ 16	57 $\pm$ 21	0.25 (−0.06,0.55)	0.01	30	33
Rectal pressure	−0.1 $\pm$ 2	28 $\pm$ 14 ^c	0.01 (−0.0001, 0.02)	0.001	80	−1171
Percent anal relaxation	18 $\pm$ 39	17 $\pm$ 22	0.29(−0.08,0.64)	0.89	63	218
Rectoanal gradient	−46 $\pm$ 16	−28 $\pm$ 20 ^c	0.03 (−0.19,0.26)	0.051	−29	−34
Evacuation following rectal distension						
Anal pressure	49 $\pm$ 23	50 $\pm$ 22	0.30 (−0.07,0.67)	0.83	31	44
Rectal pressure	−0.2 $\pm$ 2	32 $\pm$ 16 ^c	0.008 (−0.001,0.02)	0.0001	−588	−267
Percent anal relaxation	3 $\pm$ 20	15 $\pm$ 36 ^c	0.38 (0.11,0.64)	0.004	26	90
Rectoanal gradient	−46 $\pm$ 33	−18 $\pm$ 21 ^c	0.04 (−0.14,0.23)	0.63	−25	−44

Abbreviations: CCC, concordance correlation coefficient

^aCorrelation coefficient was significant if the 95% C.I. did not include zero

^bP-value for Pearson correlation of differences vs overall mean

^cP<0.001 for paired t-test or signed-rank test as appropriate

$p < 0.05$ for paired t-test or signed-rank test as appropriate

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