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Heinrich, Henriette ; Fruehauf, Heiko ; Sauter, Matthias ; Steingötter, Andreas ; Fried, Michael ; Schwizer, Werner ; Fox, Mark

Abstract: BACKGROUND: Guidelines recommend instruction and motivation during anorectal manometry; however, its impact on findings has not been reported. This study assessed the effects of standard versus enhanced instruction and verbal feedback on the results of anorectal manometry. METHODS: High-resolution manometry was performed by a solid-state catheter with 10 circumferential sensors at 6 mm separation across the anal canal and two rectal sensors. Measurements were acquired first with standard instruction and then with enhanced instruction and verbal feedback. On both occasions, squeeze pressure and duration during three voluntary contractions and intra-rectal pressure and recto-anal pressure gradient (RAPG) during three attempts at simulated defecation were assessed. KEY RESULTS: A total of 70 consecutive patients (54 female; age 25-82 years) referred for investigation of fecal incontinence (n = 31), constipation, and related disorders of defecation (n = 39) were studied. Enhanced instruction and verbal feedback increased maximum squeeze pressure (Δ10 ± 28.5 mmHg; P < 0.0038) and duration of contraction (Δ3 ± 4 s; P < 0.0001). During simulated defecation, it increased intra-rectal pressure (Δ12 ± 14 mmHg; P < 0.003) and RAPG (Δ11 ± 20 mmHg; P < 0.0001). Using standard diagnostic criteria, the intervention changed manometric findings from locally validated 'pathologic' to 'normal' values in 14/31 patients with incontinence and 12/39 with disorders of defecation. CONCLUSIONS INFERENCES: Enhanced instruction and verbal feedback significantly improved voluntary anorectal functions and resulted in a clinically relevant change of manometric diagnosis in some patients. Effective explanation of procedures and motivation during manometry is required to ensure consistent results and to provide an accurate representation of patient ability to retain continence and evacuate stool.

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The effect of standard compared to enhanced instruction and verbal feedback on anorectal manometry measurements

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Abstract

Background *Guidelines recommend instruction and motivation during anorectal manometry; however, its impact on findings has not been reported. This study assessed the effects of standard versus enhanced instruction and verbal feedback on the results of anorectal manometry.* ***Methods*** *High-resolution manometry was performed by a solid-state catheter with 10 circumferential sensors at 6 mm separation across the anal canal and two rectal sensors. Measurements were acquired first with standard instruction and then with enhanced instruction and verbal feedback. On both occasions, squeeze pressure and duration during three voluntary contractions and intra-rectal pressure and recto-anal pressure gradient (RAPG) during three attempts at simulated defecation were assessed.* ***Key Results*** *A total of 70 consecutive patients (54 female; age 25–82 years) referred for investigation of fecal incontinence (n = 31), constipation, and related disorders of defecation (n = 39) were studied. Enhanced instruction and verbal feedback increased maximum squeeze pressure (Δ10 ± 28.5 mmHg; P < 0.0038) and duration of contraction (Δ3 ± 4 s; P < 0.0001). During simulated defecation, it increased intra-rectal pressure (Δ12 ± 14 mmHg; P < 0.003) and RAPG (Δ11 ± 20 mmHg; P < 0.0001). Using standard diagnostic criteria, the intervention changed manometric findings from locally validated 'pathologic' to 'normal' values in 14/31 patients with incontinence and 12/39 with disorders of defecation.* ***Conclusions & Inferences*** *Enhanced instruction and verbal feedback significantly improved voluntary anorectal functions and resulted in a clinically relevant change of manometric diagnosis in some patients. Effective explanation of procedures and motivation during manometry is required to ensure consistent results and to provide an accurate representation of patient ability to retain continence and evacuate stool.*

Keywords *high-resolution anorectal manometry, instruction, verbal feedback, voluntary anorectal function.*

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INTRODUCTION

Anorectal manometry has a key role in the assessment of functional disorders of continence and defecation. Quantitative measurements include automatic functions (e.g., resting sphincter pressure, recto-anal inhibitory reflex), and voluntary functions [e.g., squeeze pressure, recto-anal pressure gradient (RAPG) during simulated defecation]. Measurements that require active participation will vary with patient understanding of, and motivation to comply with, instructions. The importance of such factors is evident from the success of behavioral therapy in many patients with

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defecation disorders (e.g., recto-anal dyssynergia).[1] Studies have shown that verbal instruction alone without devices, face-to-face, or even by telephone, has effects on voluntary anorectal functions.[2,3] Furthermore, patient willingness to participate predicts the success of behavioral therapy.[4–6] These observations draw attention to the potential importance of effective communication and patient participation also during diagnostic testing. Indeed, lack of effective instruction may, in part, be responsible for the wide variation of normal values reported for anorectal tests and the lack of agreement between manometry and investigations such as defecation proctography.[7–11]

Guidelines emphasize the importance of patient instruction before and after verbal feedback during anorectal studies;[12,13] however, the impact of this practitioner–patient interaction on the results of manometry has not been reported. We performed a before and after study to investigate the effects of standard compared to enhanced instruction and verbal feedback during measurements of voluntary anorectal function.

METHODS

Patients

A total of 118 consecutive patients (91 female, 27 male, age range 24–82 years) were referred between November 2008 and December 2009 for investigation by anorectal manometry for symptoms of fecal incontinence (n = 61) and dyssynergic defecation (n = 47). Of these, 48 patients were excluded from the study because of incomplete investigations (n = 29), investigations being performed by another investigator (n = 11), due to language barrier (n = 4), visible rectal prolapse (n = 2), and visible disruption of the anal sphincter (n = 3).

Thus, 70 patients (54 female, 16 male; age range 24–82 years) were included in the study analysis including 31 patients with fecal incontinence (25 female, 6 male; age range 28–80 years) and 39 with constipation or related disorders of defecation (19 female, 10 male; age range 24–82 years). The latter group included patients referred with suspicion of dyssynergia/outlet obstruction (n = 30), slow transit constipation (n = 4), anal pain, and irritable bowel syndrome (n = 5). Twenty-seven patients had undergone anorectal surgery prior to investigation, most often for anal fissure, hemorrhoids, rectocele, and/or mucosal prolapse. Thirty-eight of 54 women had given birth to one or more children of whom 34 reported traumatic births with perineal tear (of 12 patients that underwent endoanal ultrasound only 4 had overt sphincter lesions). Details of demographic and relevant clinical history in the two patient subgroups are provided in Table 1.

The data presented in this article were obtained prospectively during routine, medically indicated investigations. The retrospective study, analysis, and publication of this data were approved by the local ethics committee.

Anorectal manometry

High-resolution Manometry (Manoscan AR 360; Given Imaging/Sierra Scientific Instruments, Mountain View, CA, USA) was performed by a solid-state catheter with 10 circumferential sensors at 6 mm separation across the anal canal and two sensors in the rectum covered by a 200 mL rectal balloon. ManoView™ analysis software (Given Imaging/Sierra Scientific Instruments) was used for manometric data analysis. All procedures were performed by one investigator.

Table 1 Demographic and relevant clinical history for the two patient subgroups

	Disordered defecation (n = 39)	Incontinence (n = 31)
Age range (years)	24–82	28–80
Gender	29 female, 10 male	25 female, 6 male
Parous	19	19
Traumatic births	18	16
Anorectal surgery	15	12

Manometry protocol

Patients were asked to defecate prior to investigation. Bowel preparation was not used routinely. Patients were studied in the right lateral decubitus position with hips flexed to 90°. Prior to anorectal manometry, a digital rectal exam was performed to rule out structural abnormalities hindering catheter placement and a stool filled ampulla. A water enema was supplied if required. The catheter was then placed such that the rectal balloon was 3 cm proximal to the superior aspect of the anal sphincter. Once positioned, the assembly remained stationary for the duration of the study.

After 3 min wait to allow the patient to become accustomed to the procedure, resting pressure was measured over a 30-s interval. Measurements of voluntary anal sphincter contraction and simulated defecation were performed before and after the intervention by a single investigator. Initial measurements were acquired after standard patient instruction and then repeated after enhanced instruction and with verbal feedback during maneuvers (see below for detail). In both cases, voluntary functions were recorded over a 30-s time frame three times with 1-min time interval between each measurement to avoid the refractory inhibition of sphincter muscle that occurs after active contraction.[14]

Instruction and verbal feedback

General information about the procedure and its medical aims was set out in information sent to the patient prior to arrival in the laboratory. Before the first set of voluntary anal sphincter contractions, all patients received a short 'standard' instruction to perform sphincter contraction for the longest possible time during voluntary anal sphincter contraction and to attempt expulsion of the anorectal catheter and balloon assembly during simulated defecation ('bear down maneuver'). Before the second set of measurements all patients were given 'enhanced' instruction about the importance of squeeze pressure for continence function and were instructed to envision maintaining a contracted fist around the anal canal while maintaining sphincter contraction. In addition, during the contraction, patients were given continuous verbal feedback about contraction quality and were encouraged verbally to maintain sphincter pressure for as long as possible. Similarly before the second set of simulated defecations the importance both of increasing abdominal pressure by contraction of the abdominal wall muscles and also relaxation of the sphincter was emphasized. In addition, during the defecation attempt, patients were given

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verbal feedback about quality of abdominal wall contraction and sphincter relaxation.

Data analysis and statistics

An electronic sleeve (e-sleeve in ManoView™ analysis software) was applied to obtain stable measurements of sphincter pressure. This records the maximum pressure between two markers placed above and below the high pressure zone at the anal sphincter. All sphincter pressure measurements are relative to intra-rectal pressure. Resting sphincter tone was the mean pressure recorded by the e-sleeve during 30 s. All measurements of voluntary anorectal function were repeated three times (mean value reported) for 'standard' and 'enhanced' instruction and verbal feedback. Primary analysis of voluntary anal sphincter function was maximum squeeze pressure. Secondary analysis included the pressure increase above resting pressure during contraction and the squeeze duration (time patient could maintain sphincter pressure above resting pressure). The primary analysis of the 'bear down maneuver' was the RAPG: an integrated function of rectal pressurization and sphincter relaxation/opening. Secondary analysis assessed the increase in intra-rectal pressure during the maneuver. No separate assessment of anal relaxation was performed because it is not straight-forward to distinguish the effects of these two functions on recto-anal pressure measurement. However, the presence of paradoxical contraction under both study conditions was documented.

In addition to the primary analysis that included all patients, the results from patients with incontinence and patients with constipation and other disorders of defecation were assessed separately. Furthermore, the effect of instruction and feedback on diagnostic classification was assessed using published normal ranges of manometric measurement for solid-state equipment validated locally with high-resolution manometry (Heinrich H, Fruehauf H, Sauter M, Fox M, unpublished data).[13,15]

Data were expressed as mean change in pressure ($\Delta \pm$ SD). The mean values and ranges are provided in Table 2. Mean values for squeeze, intra-rectal pressures, and squeeze duration before and after enhanced instruction were compared using paired *t*-tests. No statistical comparisons were made between the two patient groups. Statistical analysis was performed by Microsoft Excel and Graph Pad Prism. Significance was set at $P < 0.05$. Conservative estimates based on published data in healthy volunteers based on a two-tailed *t*-test show that a total of 70 patients would be necessary to detect a 20 mmHg difference in voluntary squeeze pressures ($P < 0.05$) with a power of 80%.[15]

RESULTS

Anal sphincter pressure

Resting sphincter tone was 79 ± 38 mmHg overall, with lower pressures recorded in patients with incontinence than the group with defecation disorders (65 ± 28 mmHg *vs* 91 ± 42 mmHg). Maximum squeeze pressures were increased by detailed instruction and verbal feedback (Δ10 ± 29 mmHg; $P < 0.0038$). Similar findings were present when squeeze pressure was measured relative to resting pressure (Δ11 ± 29 mmHg; $P < 0.0016$). Results are summarized in Table 2.

For the subgroup of patients with fecal incontinence, no significant effect of instruction and verbal feedback on squeeze pressure could be observed on maximum squeeze pressure (Δ2 ± 27 mmHg; $P = 0.6371$) or squeeze pressure rise relative to resting pressure (Δ4 ± 27 mmHg; $P = 0.34$). In patients with disorders of defecation, instruction and feedback increased squeeze pressure (Δ16 ± 28 mmHg; $P < 0.0009$) and squeeze pressure relative to resting pressure (Δ16 ± 28 mmHg; $P < 0.0009$) (Fig. 1A)

Voluntary sphincter contraction was classified as weak if the pressure rise was <40 mmHg above resting pressure.[13,14] Of 15 patients ($n = 7$ with incontinence) with an abnormal low pressure after standard instruction, six (40%) patients ($n = 3$ with incontinence) produced a 'normal' >40 mmHg squeeze pressure rise above resting pressure after intensive instruction and verbal feedback.

Squeeze duration

Enhanced instruction and verbal feedback produced a significant rise in squeeze pressure duration (Δ3 ± 4 s; $P < 0.0001$). An increase in squeeze duration was

Table 2 Summary data for pressure measurements (mean ± SD and range)

	All			Incontinent			Disordered defecation		
	Standard	Enhanced	*P*	Standard	Enhanced	*P*	Standard	Enhanced	*P*
Squeeze pressure (mmHg)	172 ± 80 (54–444)	182 ± 85 (49–478)	0.0034	152 ± 73 (54–346)	154 ± 65 (50–343)	0.63	190 ± 83 (56–443)	206 ± 92 (51–478)	0.0009
Squeeze/ resting pressure (mmHg)	93 ± 69 (−33 to 308)	104 ± 69 (3–343)	0.0016	85 ± 68 (−33 to 281)	89 ± 90 (−33 to 281)	0.36	99 ± 70 (−23 to 309)	116 ± 72 (3–343)	0.0009
Squeeze duration (s)	13 ± 5 (3–21)	16 ± 5 (3–22)	0.0001	12 ± 6 (3–21)	15 ± 5 (3–22)	0.0001	13 ± 5 (3–20)	16 ± 5 (4–22)	0.0002
Intra-rectal pressure (mmHg)	49 ± 24 (4–114)	61 ± 27 (9–157)	0.003	51 ± 25 (5–114)	64 ± 29 (22–157)	0.0001	47 ± 23 (4–113)	58 ± 25 (9–111)	0.0001
RAPG (mmHg)	−24 ± 34 (−100 to 69)	−13 ± 38 (−90 to 113)	0.0001	−14 ± 23 (−77 to 15)	−4 ± 24 (−68 to 30)	0.0003	−32 ± 39 (−100 to 69)	−19 ± 45 (−90 to 113)	0.0039

RAPG, recto-anal pressure gradient.

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observed both in patients with fecal incontinence (Δ3 ± 4 s *vs* 15 ± 5 s; $P < 0.0002$) and patients with constipation and disorders of defecation (Δ3 ± 4 s; $P < 0.0001$).

Squeeze duration is considered short if not maintained for >10 s.[13,14] Of 20 patients ($n = 10$ with incontinence) with short squeeze duration after standard instructions, 11 (55%) patients achieved normal squeeze pressure times with enhanced instruction and verbal feedback.

Representative high-resolution manometry anorectal pressure topography plots of voluntary anal sphincter contraction ('squeeze') are shown with and without enhanced instruction and verbal feedback in Fig. 2.

Intra-rectal pressure rise

Instruction and verbal feedback achieved a significant rise in intra-rectal pressure during simulated defecation reflecting more effective contraction of abdominal muscles (Δ12 ± 14 mmHg; $P < 0.003$). This increase in intra-rectal pressure was observed in both incontinent (Δ13 ± 15 mmHg; $P < 0.0001$) and patients with constipation and related disorders (Δ10 ± 13 mmHg; $P < 0.0001$). Results are shown in Fig. 3A. Intra-rectal pressure rise was considered to be ineffective if <20 mmHg. Of six patients ($n = 4$ with constipation and evacuation difficulties) with an ineffective intra-rectal pressure rise, four (66%) achieved an effective pressure rise with intensive instruction and feedback. When paradoxical contraction was present in anorectal manometry, it persisted in 12 of 13 cases. Instruction and verbal feedback managed to improve intra-rectal pressure in six cases, but not to the level of significance. Further results are summarized in Table 2.

Recto-anal pressure gradient

Defecation requires not only effective contraction of the abdominal muscles but also relaxation of the anal

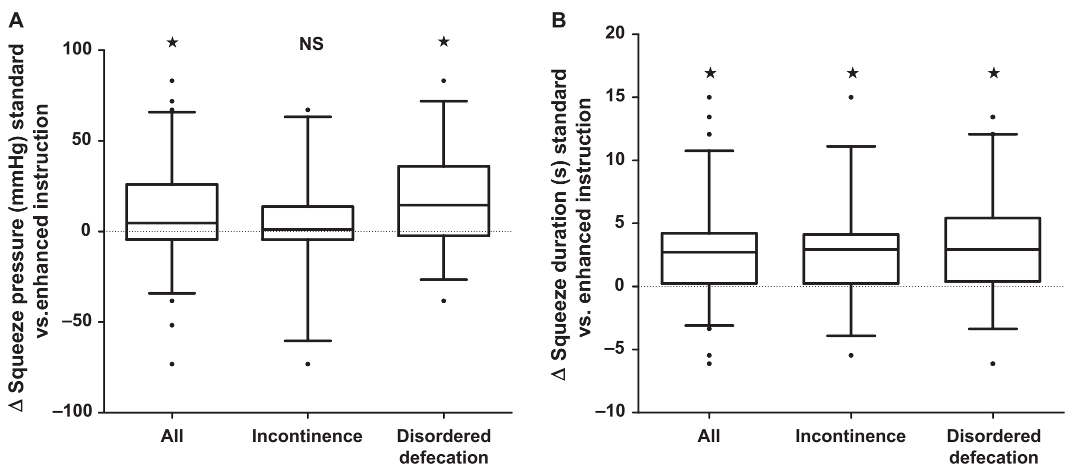

Figure 1 (A) The change of squeeze pressures (Δ mmHg) with standard versus enhanced instruction and verbal feedback overall and for the two patient subgroups. Incontinent patients were not able to raise squeeze pressure significantly (ns). *$P < 0.01$. (B) The change of squeeze pressure duration (Δs) with standard versus enhanced instruction and verbal feedback overall and for the two patient subgroups. *$P < 0.01$. Individual results for each of the three voluntary squeeze attempts are shown in Fig. S1.

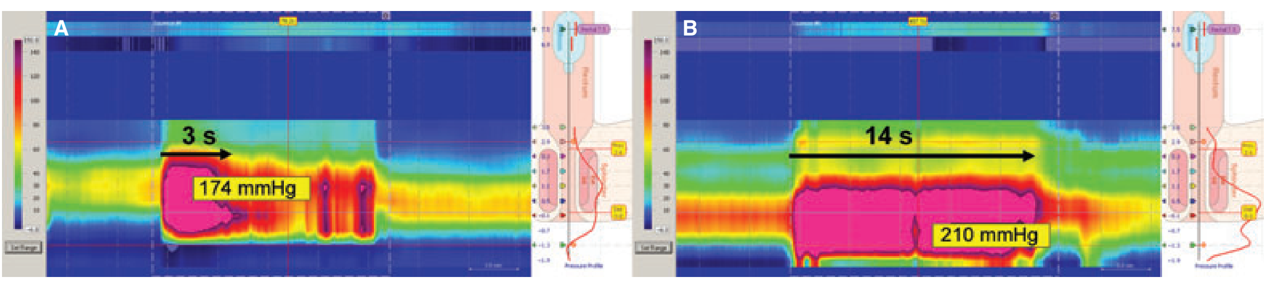

Figure 2 Representative high-resolution anorectal manometry pressure topography plots of squeeze duration with standard (A, left panel) versus enhanced (B, right panel) instruction and verbal feedback, demonstrating increased contractile pressure and prolongation of squeeze duration (black arrows).

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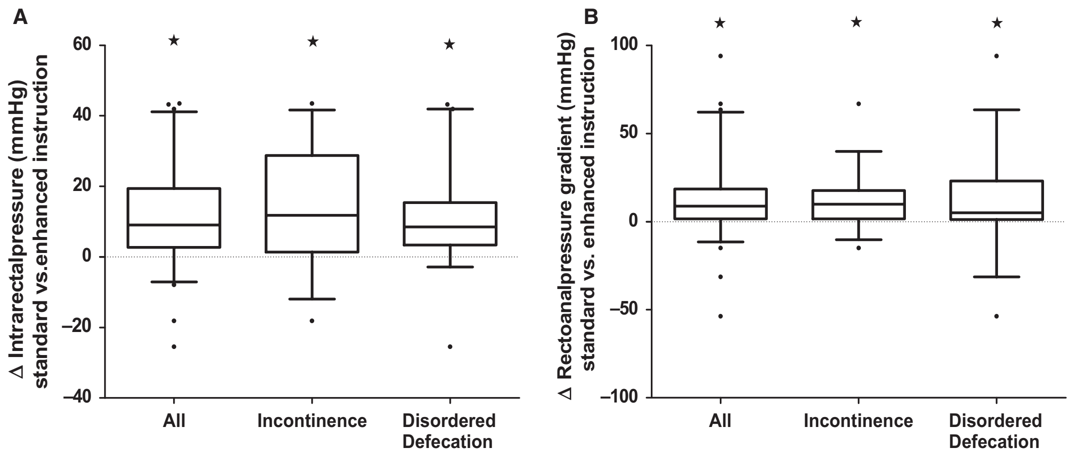

Figure 3 (A) The change of intra-rectal pressure (Δ mmHg) with standard versus enhanced instruction and verbal feedback shows a marked increase overall and in both subgroups. $^*P < 0.01$. (B) The change in recto-anal pressure gradient (Δ mmHg) with standard versus enhanced instruction and verbal feedback for all patients and the two subgroups is shown in the right panel. $^*P < 0.01$. Individual results for each of the three attempts at simulated defecation are shown in Fig. S1.

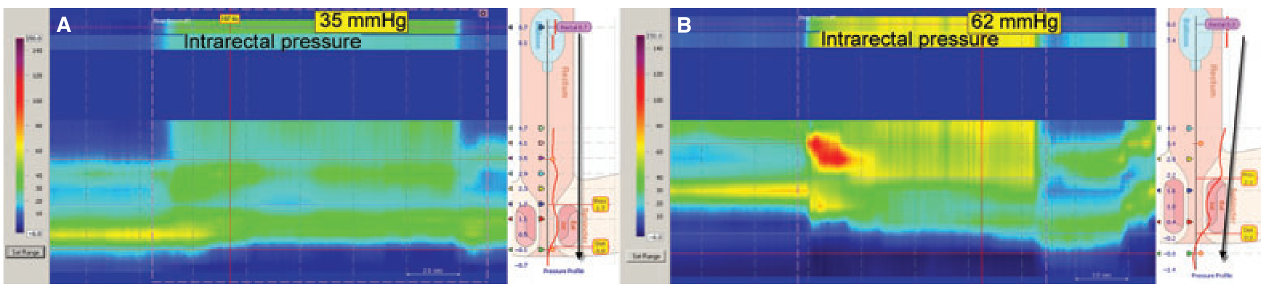

Figure 4 Representative high-resolution anorectal manometry pressure topography plots during the bearing down maneuver with standard (A, left panel) versus enhanced (B, right panel) instruction and verbal feedback, demonstrating increased intra-rectal pressure and recto-anal pressure gradient. In addition to the pressure topography plots, the instantaneous pressure gradient during the simulated defecation maneuver is shown on the right-hand panel (highlighted by black arrows).

sphincter producing a positive RAPG. Overall RAPG was raised with enhanced verbal feedback and instruction (Δ11 ± 20 mmHg; $P < 0.0001$). In patients with fecal incontinence RAPG increased (Δ10 ± 14 mmHg; $P < 0.0003$). Patients with constipation and related disorders generally showed lower RAPG, but the intervention significantly increased RAPG also in this group (Δ12 ± 25 mmHg, $P < 0.0039$). Results are shown in Fig. 3B.

A total of 53 patients had initial negative RAPG ($n = 21$ incontinent, $n = 32$ constipation and evacuation difficulties). With enhanced verbal feedback and instruction, 28 patients showed positive RAPG ($n = 16$ incontinent, $n = 12$ constipation and evacuation difficulties). Full response defined as negative RAPG turning positive on verbal feedback and enhanced instruction was achieved by 10 patients ($n = 6$ incontinent and $n = 4$ constipation and evacuation difficulties). Representative high-resolution manometry tracings of simulated defecation (bearing down) maneuver are shown in Fig. 4.

DISCUSSION

Manometric assessment of voluntary anorectal functions is influenced by multiple factors including equipment and measurement technique, but also patient behavior and motivation.[12] The investigation of continence and defecation is performed in an artificial situation and usually in an abnormal position, most commonly the lateral decubitus. Furthermore, intimate patient behaviors are likely to be disturbed by being closely observed. Guidelines emphasize that patients should be as relaxed as possible and given clear instructions to obtain measurements that reflect their normal behavior [13,16]; however, the content of these instructions is not uniform across groups and the impact of these interventions on pressure measurement

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has not been reported. This study compared the results of anorectal manometry with standard and enhanced instruction and verbal feedback and the impact of this intervention on patient diagnosis.

Enhanced instruction and verbal feedback during the sphincter contractions increased measurements of squeeze pressure and squeeze duration. Weak voluntary anal sphincter function is the most consistent finding in patients with fecal incontinence; however, the effect of intervention was less consistent in this group because some individuals were unable to produce any meaningful increase in sphincter pressure.[17] Nevertheless, using standard cut-off values,[13,14] enhanced instruction and feedback changed the manometric classification from 'pathologic' to 'normal' for squeeze pressure and duration in 3 and 11 patients, respectively. If it is accepted that both are required for effective continence function, then 31 patients with incontinence (100%) had at least one abnormality of voluntary anal sphincter function before and 17 (54%) after the intervention. These findings demonstrate that anorectal manometry conducted without effective instruction and verbal feedback may underestimate the patient's ability to produce effective anal sphincter contraction. Similar effects on anal sphincter pressure and duration have been reported with biofeedback and are considered to be part of its therapeutic effect in patients with fecal incontinence.[1,18–21] This observation demonstrates the immediate impact of instruction on these measurements and suggests that the improvement reported after biofeedback may, in part, be an effect of learning rather than training. However, this does not imply that a brief intervention will produce a similarly rapid improvement in continence function because improving sphincter function is only one component of biofeedback therapy.

Enhanced instruction and verbal feedback produced a rise in intra-rectal pressure and RAPG in all patient groups. During simulated defecation, there is a rise in intra-rectal pressure due to contraction of the abdominal muscles synchronized with relaxation of the external anal sphincter producing the positive RAPG that is required for effective defecation. This voluntary, learned response may be disrupted in patients with constipation and evacuation disorders;[22] however, it is well known that in the laboratory situation, even healthy volunteers sometimes fail to relax the anal sphincter during simulated defecation and that, therefore, there is an important risk of false-positive diagnosis of behavioral disorders of defecation.[14] In our study, there was a high prevalence of negative RAPG after standard instruction that likely reflects widespread patient reluctance to simulate defecation in an unphysiological position under close observation and also technical factors (see below).[17] Enhanced instruction and verbal feedback produced a more effective rise in intra-rectal pressure and/or more complete anal relaxation in the majority of patients. In patients with constipation or disorders of defecation, there was a clinically relevant change from negative (ineffective) RAPG before to positive (effective) RAPG after the intervention in 12/39 patients. These patients would have received a false positive manometric diagnosis of dyssynergic defecation had enhanced instruction and feedback not been applied. These findings are important because biofeedback therapy provides effective management of behavioral disorders of defecation (e.g., recto-anal dyssynergia), but is less effective in other causes of constipation (e.g., slow colonic transit).[20,23,24]

Recto-anal pressure gradient was selected in this study as the best, single measurement of anorectal function during defecation; however, this metric is not familiar to those using conventional manometry and needs to be explained. Physiologic studies of esophageal function have shown that it is not possible to assess lower esophageal sphincter (LES) relaxation pressure independent of the rise of intra-luminal pressure that occurs on swallowing a bolus of fluid.[25] The standard assessment of lower esophageal sphincter (LOS) relaxation is not 'LOS relaxation pressure' or 'percentage relaxation' but the integrated relaxation pressure (IRP).[26] In normal subjects, IRP is only fractionally lower than intra-bolus pressure relative to gastric pressure and may even be higher than resting LOS pressure in patients with low resting LOS pressure due to hydrostatic effects (i.e., the weight of water). Thus, normal IRP is not 0 mmHg (i.e., 100% relaxation/equivalent to gastric pressure), but may be as high as 15 mmHg with water swallows and this represents the intra-bolus pressure gradient required to move water through the esophago-gastric junction.[27] Thus the IRP in esophageal high-resolution anorectal manometry (HRM) is essentially the same metric as the RAPG in anorectal HRM. The key difference to measurements of IRP during water swallows on esophageal HRM, and the reason RAPG is often negative, is that the rectum is empty and nothing is being passed through the anal canal during anorectal manometry. Thus, we do not observe equilibration of pressure across the sphincter because the anal sphincter, although relaxed, is not opened by the passage of fluid/feces. In this situation, the force of defecation drives the catheter against the wall of the anal canal; this contact pressure is recorded and is often high enough to produce a negative RAPG. All reports of recto-anal function by HRM have reported this

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effect.[28,29] The only maneuver that truly demonstrates anal relaxation is the recto-anal inhibitory reflex in response to rectal distention because, in this situation, intra-rectal pressure is not elevated by abdominal compression. Thus, direct measurements of anal relaxation during defecation cannot be assessed by manometry, but only by electromyography or equivalent. Furthermore, our own observations with concurrent conventional and HRM have shown that when complete 'anal relaxation' is observed this is often an artifact caused by catheter movement relative to the anal canal (easily missed on the conventional traces even by experienced investigators). In contrast, the expulsion of the catheter and its return into resting position is observed clearly on HRM.

In summary, we report clinically relevant effects of enhanced compared to standard patient instruction and verbal feedback on manometric measurements of voluntary anorectal functions associated with both continence and defecation. The consistent effect of enhanced instruction on pressure measurements resulted in highly significant findings despite a relatively small average effect size (smaller than that used in the assumptions required for power calculation). The clinical relevance of these findings is underlined by the finding that an important proportion of patients had effects that could affect manometric classification and, therefore, patient management. These results demonstrate the importance of practitioner–patient interaction during investigation to improve patient cooperation and motivation in the highly artificial setting of the hospital laboratory. Previous studies have shown that measurements of anorectal function are reproducible when repeated on the same equipment either by the same technician or by different members of the same research group;[8,30–33] however, there is a wide range of published normal values between research groups. This study indicates that different levels of instruction may, at least in part, explain these inconsistent results. Our experience suggests that investing time to explain procedures and what is expected of the patient increases the likelihood that manometry provides a reliable assessment of continence and defecation. Future studies must assess, firstly, whether findings with enhanced instruction provide a more accurate diagnosis compared to other tests (e.g., EUS, defecation proctography) and, secondly, whether measurement of anal sphincter contraction or RAPG with enhanced instruction can guide treatment decisions and improve clinical outcomes. An alternative interpretation of the results is that enhanced instruction and verbal feedback does not result in measurements that are more representative of normal toileting behavior, but should be considered a treatment intervention similar to that provided by behavioral therapists. This cannot be ruled out and it may be that immediate improvement through enhanced instruction and verbal feedback during manometry is a marker for treatment response to formal behavioral therapy, but further studies are needed. Simple repetition can also improve performance of physical tasks; however the raw data from the three voluntary squeeze and defecation attempts do not support this contention (Fig. S1).

This study is subject to certain limitations. The before and after design is pragmatic and reflects the likely effects of enhanced instruction in 'real life' practice; however, the clinical physiologists that performed the study were not blinded and it was not possible to truly conceal the purpose of the intervention from the patients. These sources of bias were reduced by a protocol that clearly defined 'standard' and 'enhanced' patient instruction and by application of a semi-automated analysis program for measurement of all parameters. As cross-over studies would be confounded by carry-over effects, a parallel group design with random allocation to interventions applied by therapists trained to deliver either standard or enhanced instruction would be necessary to address these concerns; however, this would require a much larger study and the clinical relevance of findings would be more difficult to interpret. A further limitation is the absence of published normal values for HRM. High-resolution anorectal manometry tends to produce higher absolute pressure measurements than conventional manometry, especially for sphincter relaxation pressure.[27] This is because techniques those provide an average (or maximum) measurement of circumferential pressure are sensitive to asymmetric sphincter anatomy.[34,35] Recent studies reveal a systematic overestimate of sphincter relaxation pressure using circumferential sensors compared to 'three dimensional' (3D) representations of sphincter function obtained by high-definition radial arrays of pressure sensors.[36] This is particularly relevant in the anal canal because many women have significant sphincter asymmetry that may be attributed to normal anatomic variation and/or the incision of transverse perineal muscles during episiotomy.[37] The high number of women in our study that reported traumatic births and anorectal surgery may have contributed to the high prevalence of abnormal RAPG in patients with incontinence as well as disordered defecation. Notwithstanding these considerations, these technical issues do not impact on the ability of the study to address its primary aim which was to document the

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response to instruction and not to establish diagnostic accuracy. Indeed, as there was a wide distribution of findings in the study population, application of different diagnostic cut-off values would not have greatly affected the numbers of patients that changed diagnostic classification due to enhanced instruction.

CONCLUSIONS

This study shows that enhanced, compared to standard, patient instruction and verbal feedback during manometry has substantial effects on manometric measurements of voluntary anorectal functions related to continence and defecation. Standard operating procedures not only of technique but also of communication and interaction with patients before and during anorectal manometry are required to ensure consistent results within and between groups performing these tests and should be set out in future guidelines.

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CONFLICT OF INTERESTS

No competing interest declared.

AUTHOR CONTRIBUTION

HH was involved in planning and conduction of study, anorectal manometry measurements, data collection, interpretation and analysis, and drafting of manuscript;HF and MS were involved in planning of study and data interpretation; AS contributed to Data interpretation and analysis; MF was involved in advisory function and data interpretation; WS was involved in planning of study, data interpretation, and drafting of manuscript; MaF contributed toward planning of study, data collection, interpretation and analysis, and drafting of manuscript.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Figure S1. Voluntary anorectal functions were obtained three times before and after enhanced instruction. The effects of repetition and instruction are shown on (a) squeeze pressure (b) squeeze duration (c) intra-rectal pressure (d) recto-anal pressure gradient. A stepwise (not a progressive) improvement in function is observed in each parameter following the intervention. Thus, it is the enhanced instruction and verbal feedback that produces the observed effect and not the repetition of these maneuvers.

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