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1	TITLE
2	METHODS OF ANORECTAL MANOMETRY VARY WIDELY IN CLINICAL
3	PRACTICE: RESULTS FROM AN INTERNATIONAL SURVEY
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5	RUNNING TITLE
6	ANORECTAL MANOMETRY PRACTICE SURVEY
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10	AUTHORSHIP
11	Carrington EV ¹ , Heinrich H ^{1,2} , Knowles CH ¹ , Rao SS ³ , Fox M ^{2,4} , Scott SM ¹
12	The International Anorectal Physiology Working Party (IAPWG)
13	
14	¹ National Bowel Research Centre & GI Physiology Unit, Queen Mary University of
15	London, London, United Kingdom
16	
17	² Department of Gastroenterology and Hepatology, University Hospital Zürich, Zürich,
18	Switzerland
19	
20	³ Division of Gastroenterology & Hepatology, Department of Internal Medicine, Medical
21	College of Georgia, Augusta University, Augusta, GA, USA
22	
23	⁴ Abdominal Center: Gastroenterology, St. Claraspital, Basel, Switzerland
24	

25 ADDRESS FOR CORRESPONDENCE

- 26 Dr Henriette Heinrich
- 27 Wingate Institute of Neurogastroenterology
- 28 26 Ashfield Street
- 29 Whitechapel
- 30 London, E1 2AJ
- 31 Tel: +44 20 7882 2677
- 32 Email: <u>h.heinrich@qmul.ac.uk</u>
- 33
- 34
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38 ABSTRACT

39 Background

Anorectal manometry (ARM) is the most commonly performed investigation for assessment of anorectal dysfunction. Its use is supported by expert consensus documents and international guidelines. Variation in technology, data acquisition and analysis affect results and clinical interpretation. This study examined variation in ARM between institutions to establish the status of in current practice.

45

46 Methods

A 50-item web-based questionnaire assessing analysis and interpretation of ARM was
distributed by the International Anorectal Physiology Working Group (IAPWG) via
societies representing practitioners that perform ARM. Study methodology and
performance characteristics between institutions were compared.

51

52 Key results

53 One-hundred and seven complete responses were included from 30 countries. 54 Seventy-nine (74%) institutions performed at least 2 studies per week. Forty-nine centres (47%) applied conventional ARM (≤8 pressure sensors) and 57 (53%) high-55 56 resolution ARM (HR-ARM). Specialist centres were most likely to use HR-ARM compared to regional hospitals and office based practice (63% vs. 37%). Most 57 conventional ARM systems used water-perfused technology (34/49); solid-state 58 59 hardware was more frequently used in centres performing HR-ARM (44/57). All centres evaluated rest and squeeze. There was marked variation in the methods used 60 61 to report results of maneuvers. No two centres had identical protocols for patient 62 preparation, setup, study and data interpretation and no centre fully complied with63 published guidelines.

64 **Conclusions and Inferences**

There is significant discrepancy in methods for data acquisition, analysis and interpretation of ARM. This is likely to impact clinical interpretation, transfer of data between institutions and research collaboration. There is a need for expert international co-operation to standardize ARM.

69

71 KEYWORDS

- 72 Anal manometry
- 73 Anorectal manometry
- 74 High-resolution anorectal manometry
- 75 Anorectal physiology
- 76 Anorectal dysfunction
- 77 Faecal / fecal incontinence
- 78 Constipation
- 79

80 KEYPOINTS

81

- There is marked variation in technology employed, data acquisition, analysis
 and reporting of ARM results between institutions.
- More than half of the centres surveyed use high-resolution ARM for the
 performance of anorectal manometry. High-resolution technology was utilized
 most often in specialist centres with high throughput.
- None of the centres surveyed complied fully with the widely cited guidelines for
 'minimum standards' of anorectal manometry.

89

91 ABBREVIATIONS

- 92 AGIP Association of GI Physiologists
- 93 ANGMA Australasian Neurogastroenterology and Motility Association
- 94 ANMA Asian Neurogastroenterology and Motility Association
- 95 ANMS American Neurogastroenterology and Motility Society
- 96 ARM Anorectal manometry
- 97 ENMS European Neurogastroenterology and Motility Society
- 98 HR-ARM High-resolution anorectal manometry
- 99 IAPWG International Anorectal Physiology Working Group
- 100 RAIR Rectoanal inhibitory reflex
- 101 USA United States of America
- 102 UK United Kingdom
- 103
- 104
- 105

106 **INTRODUCTION**

Several investigations are available for the assessment of anorectal structure and function in patients who present with intractable symptoms of anorectal dysfunction, characterised by faecal incontinence and / or disordered evacuation (1-3). Anorectal manometry (ARM) is the best-established technique available to detect abnormalities of sphincter function and / or recto-anal co-ordination, which may important causes of such symptoms (2, 4, 5).

113

ARM consists of a series of pressure measurements that assess: (i) involuntary function of the anal canal during rest, (ii) voluntary function during squeeze, (iii) reflex recto-anal co-ordination during rectal stimulation, and (iv) voluntary rectoanal coordination during simulated defecation ('push') (3, 4). ARM may also incorporate an assessment of rectal sensation (4).

119

120 Review articles that describe the ARM technique (3, 4, 6-9) reveal that variations of study protocol impact the results of this investigation (4, 10-13). This limits clinical 121 122 interpretation, transfer of data between institutions and research collaboration. For 123 these reasons, several position statements and working party reports have provided 124 guidance on technique for data acquisition, analysis and reporting (1, 4, 8, 14). 125 Nevertheless, several manometry systems are commercially available and, although 126 evidence is lacking, it is widely presumed that there is important variation in practices 127 between institutions (15-21).

128

The advent of high-resolution ARM (HR-ARM) has brought with it a new dimension ofdata capture and visualization (colour-contour topographical plots), and has the

potential to revolutionize appreciation of anorectal function (22-24). Unfortunately, this
advancement has added a further element of variability in practice; unless efforts are
made early to reach consensus on test performance, this technique may fall victim to
the same pitfalls that have bedeviled other investigations in the field.

135

136 To address these knowledge gaps, and to bring consensus, an expert group (the 137 International Anorectal Physiology Working Group [IAPWG]) was convened to develop 138 and promote internationally accepted standards for the clinical measurement of 139 anorectal physiology, with a particular focus on HR-ARM. As a first step, and to better 140 understand the status of current practice, the group conducted this study to examine 141 ARM practice in different settings and countries. This work tests the hypothesis that 142 there is important variation in ARM practice. The objectives are to inform and facilitate 143 the development of internationally agreed standard operating procedures for data 144 acquisition and analysis.

145

147 METHODS

148 **Questionnaire structure**

A questionnaire examining features of ARM practice was developed using a webbased survey and data collection tool (<u>www.qualitrics.com</u>, Utah, USA). The questionnaire is available in Supplementary material 1. Existing guidelines (2, 4, 8) were used to structure the questionnaire to explore the following areas of interest:

- 153 1) department setup / centre activity;
- 154 2) study indications;
- 155 3) manometry technique and equipment;
- 156 4) study protocol;
- 157 5) data analysis and reporting;
- 158 6) additional investigations.

159 'Department setup / centre activity' explored centre location / specialism and volume 160 of activity performed. 'Study indications' allowed respondents to choose common 161 reasons for test performance (e.g. faecal incontinence, constipation etc.). 'Manometry technique and equipment' examined the use of conventional ARM and / or HR-ARM, 162 163 and detailed the equipment used. 'Study protocol' comprised a series of questions 164 related to common manoeuvres performed to assess rest, squeeze, prolonged 165 squeeze, cough, push (simulated defecation) and the recto-anal inhibitory reflex 166 (RAIR). 'Data analysis and reporting' explored reporting of test results. 'Additional 167 investigations' allowed the respondent to list tests used to complement ARM in the 168 assessment of symptoms of disordered defecation.

169

170 Data were collected in the form of single or compound answer multiple-choice 171 questions for nominal data, slider bar questions for continuous numerical data and open-ended text boxes for descriptive exploration of complex practices. In particular,
questions exploring measurement parameters were constructed using a `select all that
apply` approach.

175

Prior to launch, the questionnaire was piloted by 10 UK institutions to test usability,understanding, clarity and question flow.

178

179 **Questionnaire distribution**

180 Practitioners (clinicians, nurse specialists, and physiologists) who regularly practice 181 ARM were identified and contacted by email via advocates from the following national 182 and international societies with an involvement in colorectal function testing: the 183 Association of GI Physiologists (AGIP) of the British Society of Gastroenterology, the 184 American Neurogastroenterology and Motility Society (ANMS), the Australasian 185 Neurogastroenterology and Motility Association (ANGMA). the Asian 186 Neurogastroenterology and Motility Association (ANMA), and the European Neurogastroenterology and Motility Society (ENMS). In addition, invitations were sent 187 188 to those attending the 2013 Pelvic Floor Society Annual Meeting, and through 189 clinicians involved in the International Anorectal Physiology Working Group (IAPWG) 190 to their own clinical contacts with an interest in the field of ARM.

191

No incentive was utilised to increase response rate. The survey was distributed
between September 2013 and July 2015. Responses not completed within 7 days of
commencement were discarded.

- 196This work was undertaken with the endorsement of all societies involved. Data were197collected and held within the requirements of the Data Protection Act. The study did
- 198 not use clinical data and did not require or seek specific ethical approval.
- 199

200 Statistical analysis

Data were analyzed quantitatively using number of observations and proportions. For centre activity comparisons, 'high' volume centres were defined as those performing ≥ 10 studies per week and 'low' volume centres were defined as those performing ≤ 2 studies per week.

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Analyses were performed using a commercially available software package (SPSS
Statistics Version 20: IBM, New York, USA). A P value of <0.05 was considered
statistically significant.

209

211 **RESULTS**

212 **Questionnaire responses**

213 One hundred and nine responses were completed from 125 surveys started (87.2% 214 completion rate). Two duplicate responses from individuals within the same centre 215 were received. In each case, the second response was discarded. This left 107 216 complete surveys available for analysis. Responses were received from 30 countries 217 as detailed in Table 1.

218

219 **Centre activity**

Seventy-nine centres (74%) reported performing more than 2 studies per week with most reporting activity of between 2 – 10 studies per week (52%). Particularly high volume activity (\geq 20 studies per week) was reported by 8 (8%) centres and low volume activity by 13 centres (12%).

224

Forty-nine respondents (46%) described their centre as being within a specialist hospital, 34 (32%) within a general hospital and 24 (22%) within a private hospital or other institution.

228

229 Study indications

Ninety-one respondents (85%) reported that ARM was 'always' performed for assessment of fecal incontinence, with the remaining 16 (15%) reporting that ARM was 'sometimes' performed for this indication. Eighty-six respondents (80%) reported 'always' performing ARM for assessment of constipation, with the remaining 21 (20%) reporting 'sometimes'. ARM was less often performed for anal pain (10% never, 65%) sometimes, 25% always) and for abdominal pain / bloating (59% never, 34%
sometimes, 7% always).

237

238 Manometry technique and equipment

239 Fifty-seven (53%) centres reported using HR-ARM. Forty-nine utilised conventional

ARM (47%). One centre reported using both HR-ARM and conventional ARM.

241

242 Of the 49 centres performing conventional ARM, 34 (69%) reported using water-

243 perfused technology. The remaining 15 (31%) use a solid-state catheter. Water-

244 perfused systems were far less common in those centres performing HR-ARM, with

245 only 13 (23%) using this technology and the remaining 44 (77%) institutions using a
246 solid state catheter.

247

There was marked variation in catheter diameter, sensor number and sensor / port configuration between centres. Catheter diameter varied between 8 – 22F for both water-perfused and solid-state systems. These data are summarized in Tables 2a and 251 2b.

252

253 Study protocol and measurement reporting

254 Manoeuvres performed

The only tests consistently performed by all centres during ARM were the rest and squeeze manoeuvers. For the other manoeuvers, 87 (81%) reported performing prolonged squeeze, 89 (83%) cough, 89 (83%) push (simulated defecation) and 103 (96%) RAIR.

260 **Rest**

The time period most frequently used to record anal resting pressure was 1 minute (76%). The method of reporting most frequently used was 'mean pressure over the whole anal canal length' (55%). These data are further described in Figure 1.

264

As questions were designed as 'select all that apply', it was possible to assess the combination of measurement parameters utilised by each institution. This analysis demonstrated that there were 16 combinations of ways in which rest data were quantitatively reported. The three most common reporting methods were 'mean pressure over the whole anal canal length' alone (29%), 'mean pressure at different levels of the anal canal' alone (15%), and 'mean pressure over the whole anal canal length' together with 'maximum pressure over the whole anal canal' (14%).

272

273 **Squeeze**

During assessment of squeeze, 69 (65%) centres routinely asked subjects to squeeze for a predefined length of time, with 37 (35%) centres allowing subjects to squeeze for 'as long as they were able'. One centre (1%) failed to give valid information on squeeze characteristics.

278

Of those asking subjects to squeeze for a predefined length of time, the most commonly reported squeeze *duration* was 5 seconds (18% of respondents) however there was very little consistency between centres, and 26 (24%) centres reported that requested *short* squeeze duration was >15 seconds. These data are presented in Figure 2a. There was also marked discrepancy between centres in the *number* of squeeze performed, which varied between 1 and 10. These data are presented inFigure 3a.

286

As with parameters of resting anal pressure, there was marked variation in the methods used to report results. The two most common squeeze parameters reported were 'maximum incremental squeeze pressure' (56%) and 'maximum absolute squeeze pressure' (51%). These data are further explored in Figure 1.

291

There were 18 combinations of ways in which squeeze data were quantitatively reported. The three most common reporting methods were 'maximum incremental squeeze pressure' alone (21%), 'maximum absolute squeeze pressure' alone (13%), and 'maximum incremental squeeze pressure' together with 'maximum absolute squeeze pressure' (12%).

297

298 **Prolonged squeeze**

Similar to the results found with squeeze, there was marked variation in the performance and reporting of *prolonged* squeeze. The *duration* of prolonged squeeze most frequently reported was 20s or 30s (25% for both) however the reported duration ranged up to 60 seconds. These data are shown in Figure 2b. There was similar discrepancy in the *number* of squeezes performed, which varied between 0 and 10. These data are shown in Figure 3b.

305

There was particular variation in results reporting of this manoeuvre. The most common parameters reported for prolonged squeeze were 'duration of squeeze above 50% maximum pressure' (47%). These data are shown in Figure 1. 309

There were 43 combinations of ways in which prolonged squeeze data were quantitatively reported. The two most common reporting methods were 'duration of squeeze above 50% maximum pressure' alone (20%) and 'maximum absolute pressure' alone (10%).

314

315 **Cough**

As previously, there was marked variation in the performance and reporting of the cough manoeuvre. The *number* of cough manoeuvres performed varied between 1 and 10.

319

Notably, 36 centres (40%) reported that they do not use quantitative values to describe results and that instead qualitative assessment of muscle recruitment is utilised. Of those using quantitative measures, the most common metric used was 'maximum anal pressure during cough', which was reported by 28 (31%) of these institutions. These data are shown in Figure 1.

325

There were 12 combinations of ways in which cough data were quantitatively reported. The two most common combinations were the use of 'maximum anal pressure' alone (12%) and 'maximum rectal pressure during cough' together with 'maximum anal pressure during cough' (10%).

330

331 Push (simulated defecation)

As with other manoeuvres, there were notable dissimilarities in test performance andresults reporting of push between centres. Of the 89 institutions that reported

performing push, the majority (91%) performed this test with the subject in the left lateral position. Interestingly, 6 centres (7%) performed the study in both in the left lateral *and* the sitting position, 1 centre (1%) performed studies in the left lateral *and* supine position and 1 centre (1%) performed studies in the left lateral, supine *and* the sitting position (Table 3). As seen previously for other manoeuvres, there was particular variability in the *number* of push manoeuvres performed, which varied between 1 and 10. These data are shown in Figure 3 c.

341

For the performance of this test, 65 (73%) centres reported the use of a rectal balloon associated with the manometry catheter. Nine centres (14% of those using a balloon) routinely fill the balloon to the subjects' first sensory volume, 9 (14%) to the subjects' defaecatory desire volume and 45 (69%) to a pre-defined fixed amount. Two (3%) institutions did not provide information about balloon filling. For those reporting the use of a predefined amount for balloon inflation, the most commonly used amount of air was 50 ml, which was reported by 27 (64%) of these institutions.

349

For reporting of the push manoeuvre, in the context of a 'select all that apply' question format, 21 (24%) centres report push qualitatively from colour contour / line traces and 47 (53%) provide quantitative reports using either in-built analysis software or by deriving values manually from line traces. Twelve (13%) stated that they only report practitioner evaluated visualisation of appropriate muscle recruitment / co-ordination. Twenty-nine centres (33%) did not give information on how push was manometrically reported.

357

359 **RAIR**

Overall 103 centres routinely perform RAIR assessment. Of these, the majority perform one RAIR during each study (39%). Again however, there was great variability, with 2 centres (2%) reporting that they routinely perform 10 RAIRs as part of their standard clinical protocol. These data are shown in Figure 3d.

364

Thirty-six centres (36%) report provoking RAIR by incremental inflation of a rectal balloon by fixed volumes of air, and 17 (17%) with only a *single* fixed volume of air. Forty-eight (47%) did not provide information about the inflation method for the provocation of RAIR.

369

Thirty (29%) centres reported measuring the RAIR quantitatively, 37 (36%) qualitatively (as present / absent), and 34 (33%) both quantitatively and qualitatively. Six (6%) centres did not provide information of the method used for RAIR reporting.

373

374 Additional investigations

375 No centre reported performing ARM in isolation. All centres reported that they perform

at least one other complimentary test of anorectal structure / function (Table 4).

377

378 Comparison between centres using conventional ARM or HR-ARM

Some differences were seen in demographics and practices when comparing those centres performing conventional ARM versus those performing newer HR-ARM. Within this survey sample, HR-ARM is more frequently utilised by specialist and private hospitals (43/67 [64%] *vs.* 36% performing conventional ARM), whereas conventional ARM is more frequently performed in general hospitals (23/34 [68%] *vs.* 11/34 [32%] performing HR-ARM). Activity between conventional ARM and HR-ARM
performing centres was similar, with 6 (6/49 [12%]) conventional ARM *vs.* 7 (7/57
[12%]) HR-ARM centres reporting low volume activity and 6 (6/49 [12%]) conventional
ARM vs. 9 (9/57 [16%]) HR-ARM centres reporting high volume activity.

388

389 HR-ARM was more commonly reported amongst centres from North and South 390 America (used by 27/36 [75%]). By contrast, it appears that conventional ARM 391 remains popular in the rest of the world with 8 (8/14 [57%]) centres from Asia, the 392 Middle East and Australia and 35 (35/57 [61%]) of European centres continuing to use 393 this technique.

394

395 Despite difficulties in interpreting the widespread variation in methods used to report 396 manometric findings, there was an apparent higher frequency of more integrative or 397 qualitative measures of anorectal function used by centres with HR-ARM. Pertinent 398 examples include:

- rest 'mean pressure over the anal canal' reported by 17 (17/49 [35%])
 conventional ARM centres vs. 42 (42/57 [74%]) HR-ARM centres;
- 401 push 'qualitative reporting of anorectal co-ordination' was utilized by 3 (3/49
 402 [6%]) conventional ARM centres *vs.* 18 (18/57 [32%]) HR-ARM centres;
- 403 cough 'qualitative visualisation of muscle recruitment / co-ordination' was
 404 reported by 6 (6/49 [12%]) conventional ARM centres *vs.* 20 (20/57 [35%]) HR 405 ARM centres.

406

407 **Compliance with guidelines**

408 Results were compared with the protocol outlined in the most widely accepted 409 guideline for ARM (4). This manuscript recommends a minimum 6-sensor catheter 410 with performance of rest, squeeze, cough, push and RAIR maneuvers and suggests 411 reporting of the following basic parameters: `maximum anal resting pressure at 412 intervals within the anal canal ', 'maximum anal squeeze pressure', 'maximum 413 sustained squeeze pressure', 'squeeze duration', 'rectoanal pressure difference 414 during cough', 'residual anal pressure during push' and 'combined qualitative / 415 quantitative reporting of the RAIR'. Only three centers complied with the suggested 416 performance protocol. None of the 107 centers surveyed complied with both the recommended protocol and method for results reporting. In addition, no two centers 417 418 reported identical protocol and analysis techniques.

419

421 **DISCUSSION**

This study confirms the long held impression that striking variation exists in the current practice of ARM. Differences between institutions exist in study indications, equipment used, manometry technique, data acquisition, analysis and reporting. No centre responding to this survey fully complies with previously published and widely cited 'minimum standards' for ARM (4). In particular, there is dissimilarity in the parameters used to report results, a factor that makes accurate comparisons between institutions and further development of the technique challenging.

429

In an environment in which several commercial entities are developing and 430 431 manufacturing diagnostic technologies, a degree of variation is inevitable and may be 432 welcomed for the purposes of innovation. However, when such techniques are applied 433 to clinical practice, nuance in equipment characteristics can have important effects on 434 manometry measurements. This has been studied in both the upper and lower GI 435 tract, and although most studies report good correlation between techniques, absolute values do significantly differ (12, 25-28). This represents a challenge to 436 437 standardisation, as until robust evidence on actual differences in measurement and analysis exists, practitioners will continue to be driven by personal/institutional 438 439 preference when choosing device and equipment specifications.

440

It is clear that the introduction of HR-ARM has brought with it further variability (9). This survey demonstrates that although conventional ARM is most commonly used in combination with water-perfused technology (69% of institutions surveyed), many of those with more novel HR-ARM systems have chosen to use solid-state hardware (77% institutions surveyed). The impact of these differences in hardware/software combinations is yet to be quantified in the anorectum, however studies in the
oesophagus indicate that the choice of technology and can impact diagnostic decisionmaking (29-32).

449

450 In addition, although (limited) normal values for different catheter types and 451 populations exist (15, 33-36), a robust description of pathological measurements seen 452 using HR-ARM is yet to be established. This is likely to explain our finding that, 453 compared to those using conventional ARM, clinicians using modern HR-ARM 454 equipment put more emphasis on qualitative descriptions of global anorectal function than quantitative pressure measurements. Data expression using the colour-contour 455 456 display requires a illustrative approach, and in the oesophagus at least, this has been 457 shown to significantly aid data interpretation and analysis (37).

458

Differences in practice were not limited to hardware/software combinations, but appeared to pervade all aspects regarding performance of the technique. The impact of variation in study protocol on ARM results and management of patients with anorectal disorders has not been robustly tested however, it has been shown that changes in patient position, doctor-patient interaction and data analysis all have important effects on anorectal measurements that can impact on clinical diagnosis (13, 38, 39).

466

A number of features found during investigation of study protocol invite discussion. Of
particular interest was the finding that the majority of centres perform push in the left
lateral position. Although sitting is clearly more physiological, only 8% of centres chose
to investigate patients in this manner. It is often argued that testing in the left-lateral

position is one reason for the high rate of dyssynergia in both healthy and patient
populations (40, 41) and investigation in the upright-seated position has been shown
to influence rectal and anal pressure (42, 43). Certainly further exploration of the
impact of patient position is warranted.

475

Another area for consideration is the near universal (96% of institutions surveyed) assessment of the RAIR. Although this is viewed as a useful screening test in paediatric populations (to exclude the presence of Hirschsprung disease) no formal evidence of the application of this test in adult populations exist (44, 45), especially as new diagnosis of this disorder in adults is exceptionally rare and usually made on clinical, radiological and histological grounds.

482

Additionally, despite a lack of evidence for its diagnostic utility (4, 8, 46), cough was performed by 83% of centres. The majority reported qualitative values and when quantitative values were reported there was significant variation in results reporting. The significant variation in results reporting between centres surveyed seem to indicate that the rationale for this test is poorly understood.

488

The finding of discordance in results reporting is particularly interesting. Although current guidelines recommend the utilisation of certain measures for resting and squeeze pressure (4, 8, 46) the diagnostic value of the different measures for discriminating health and disease states is limited (46, 47). This is likely in part to explain the finding that there were 16 combinations of ways in which rest, 18 combinations of ways in which squeeze and 43 combinations of ways in which prolonged squeeze data were quantitatively reported. This inconsistent use of 496 terminology and methods for data acquisition and analysis of ARM findings requires 497 specific discussion because at the very least, such practice can cause confusion when 498 communicating results between practitioners both in the clinical setting and also when 499 published in the literature. This variability can be partly explained by the fact that there 500 are few published studies that investigate the comparative utility of individual 501 manometric measures. There is no evidence to date that demonstrates that one 502 manometric measure conveys superior diagnostic information to another. In addition, 503 although it is well accepted that sphincter pressures are lower in patients with faecal 504 incontinence than in health (48-57) there is only limited evidence that the degree of 505 functional abnormality of the sphincter is related to symptom severity or predictive of 506 treatment success (57-61).

507

508 Guidelines for the diagnosis and management of anorectal disorders recommend 509 more than one test to better characterize pathophysiology and guide treatment. (8, 62, 510 63). The findings of this study show, that the majority of centres surveyed do utilize allied tests such as balloon expulsion, rectal sensation testing and measurement of 511 512 colonic transit for assessment of anorectal dysfunction. However information in the 513 literature on agreement of adjunctive tests and their results with HR-ARM especially 514 in the diagnosis of evacuation disorders is conflicting (64, 65). Up to this time point no 515 studies have investigated the added diagnostic value of different adjunctive testing 516 methods to allow the recommendation of standardized testing sequences of HR-ARM 517 and adjunctive tests for faecal incontinence or evacuation disorders. 518 For this reason published guidelines have been generally based on expert experience 519 and opinion rather than an objective comparison of the utility of different manometric

520 measures or adjunctive tests (3). Indeed, this lack of consensus may be the reason

521 for the relatively slow adoption and rate of publication with HR-ARM compared to 522 oesophageal HRM for which a well-established method and classification system 523 exists (66).

524

525 The authors acknowledge a number of limitations within this study. The first is the 526 method for identification of potential respondents. Efforts were made to identify as 527 many centres as possible through interaction with the societies with an interest in 528 investigation of anorectal function and contacts of the IAPWG. This convenience 529 sample may not necessarily be representative of global practices as a whole, particularly as some centres (especially low volume centres which do not engage 530 531 formally with the societies) may have been underrepresented in the sample. In 532 particular, over 27% of responses were collected from British centres. Therefore, 533 although responses have been collected from 6/7 continents of the world, it would be 534 fair to suggest that results may not be a true reflection of global practices with some 535 bias to practices within the UK and Europe. The second limitation is the likely survey nonresponse bias. As the survey was distributed by third-parties to mailing lists no 536 537 data pertaining to response rate were collected. It is possible that these non-538 respondents differed in meaningful ways from those who completed the survey 539 resulting in voluntary response bias.

540

Third are the limitations implicit in design of this pragmatic questionnaire. Due to the complexity of results recording, options for reporting of certain manometric measures and measures of centre activity had to be given as close ended, leading questions. This may have led to response bias due to the lack of study blinding and desire of the respondent to give a 'correct' response. Questions did not force a response, which led to some missing data, particularly for cough and RAIR characteristics. Additionally, there was no data accuracy / question check in place. It is possible that inattention from respondents may have led to inaccurate responses. This may be an explanation for the finding that endurance squeeze duration in some centres was less than 10 seconds.

551

This study provides the first formal evidence of major discordance in international practices of anal manometry. It has demonstrated that methods of both data collection and results reporting are extremely variable and it appears that many centres are not following currently acknowledged best practice. This disparity is likely to be limiting the utility of this technique, preventing data comparison between institutions and may be impacting on clinical decision-making.

558

This study provides a basis for consensus generation in regards to manometric data acquisition and analysis of anorectal measurements akin to the Chicago process for assessment of oesophageal function (67). Such agreement on standard operating is urgently required to reduce undesirable variations in practice and ultimately, the formation of good clinical guidelines for anorectal manometry is likely to have a significant impact on both the clinical and research applications of this technique.

565

566

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- 569
- 570 The International Anorectal Physiology Working Group members are as follows:
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572 Lead contributors

- 573 Emma Carrington, Queen Mary University of London, UK
- 574 Henriette Heinrich, Queen Mary University of London, UK and University Hospital
- 575 Zürich, Switzerland
- 576 Charles Knowles, Queen Mary University of London, UK
- 577 Satish Rao, Georgia Regents University, Augusta, USA
- 578 Mark Fox, St. Claraspital, Basel, Switzerland
- 579 Mark Scott, Queen Mary University of London, UK
- 580
- 581 Other Working Group members
- 582 Donato Altomare, Università di Bari Aldo Moro, Bari, Italy
- 583 Adil Bharoucha, Mayo Clinic, USA
- 584 Rebecca Burgell, Monash University, Melbourne, Australia
- 585 Guiseppe Chiarioni, Unviersity of Verona, Italy
- 586 Phil Dinning, Flinders University, Adelaide, Australia
- 587 Richelle Felt-Bersma, VU Medisch Centrum, Amsterdam, The Netherlands
- 588 Ridzuan Farouk, National University Hospital, Singapore
- 589 Kee Wook Jung, University of Ulsan College of Medicine, Ulsan, Korea
- 590 Anthony Lembo, Beth Israel Deaconess Medical Centre, Boston, USA
- Alison Malcolm, University of Sydney, Australia
- 592 François Mion, University of Lyon, France
- 593 Seung-Jae Myung, University of Ulsan College of Medicine, Ulsan, Korea

- 594 Christian Pehl, Kreiskrankenhaus Vilsbiburg, Germany
- 595 Jose Remes Troche, University of Veracruz, Mexico
- 596 Robert Reveille, Lakewood, Colorado, USA
- 597 Sabine Roman, University of Lyon, France
- 598 Carolynne Vaizey, St Mark's Hospital, Middlesex, UK
- 599 William Whitehead, University of North Carolina, USA
- 600 Rueben K Wong, National University of Singapore, Singapore
- 601

602 **Contributions**

- 603 EV Carrington study/ questionnaire design, data acquisition, data analysis, writing
- 604 manuscript
- 605 H Heinrich data analysis, writing manuscript
- 606 CH Knowles data interpretation, critical evaluation of manuscript
- 607 SS Rao data interpretation, critical evaluation of manuscript
- 608 M Fox data interpretation, critical evaluation of manuscript
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- 642 Working group discosures:
- 643 Donato Altomare none to declare

- 644 Adil Bharoucha none to declare
- 645 Rebecca Burgell none to declare
- 646 Guiseppe Chiarioni consulting Board: Takeda Italia and Allergan Italia, Speaker
- 647 Board: Alpha-Wasserman Italia, Member Anorectal Committee of the Rome
- 648 Foundation
- 649 Phil Dinning none to declare
- 650 Ridzuan Farouk- none to declare
- 651 Richelle Felt-Bersma, none to declare
- 652 Kee Wook Jung none to declare
- 653 Anthony Lembo none to declare
- 654 Alison Malcolm none to declare
- 655 Francois Mion consulting for Medtronic
- 656 Seung-Jae Myung none to declare
- 657 Christian Pehl none to declare
- Jose Remes Troche member of the advisory board for Commonwealth, Allergan and
- 659 Carnot; has received grant support for research from Sanfer and Asofarma; has
- 660 served as speaker for Takeda, Allergan, Medtronic, Carnot and Sanfer.
- 661 Robert Reveille Educational Consultant for Sandhill Scientific, Littleton, CO, USA
- 662 Sabine Roman Consulting for Medtronic and Sandhill Scientific
- 663 Carolynne Vaizey none to declare
- 664 William Whitehead none to declare
- 665 Rueben K Wong honoraria for teaching from Medical Measurement Systems Ltd.
- 666

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- 855

<u>TABLES</u>

Table 1. Frequency of respondents' location by country.

Country	Frequency	%
United Kingdom	29	27.1
United States	15	14
Mexico	11	10.3
Germany	8	7.5
Italy	5	4.7
Switzerland	5	4.7
Australia	4	3.7
Argentina	3	2.8
Chile	2	1.9
Ireland	2	1.9
Korea, Republic of	2	1.9
Malaysia	2	1.9
Spain	2	1.9
Colombia	1	0.9
Costa Rica	1	0.9
Ecuador	1	0.9
Egypt	1	0.9
France	1	0.9
Guatemala	1	0.9
India	1	0.9
Netherlands	1	0.9
Nicaragua	1	0.9
Poland	1	0.9
Russia	1	0.9
Singapore	1	0.9
South Africa	1	0.9
Sweden	1	0.9
Thailand	1	0.9
Turkey	1	0.9
United Arab Emirates	1	0.9
Total	107	100

Table 2. Frequency tables of channel number and distribution for (a) water-perfusedand (b) solid-state catheter systems used by respondents.

(b)

Water perfused manometry: Number of water-perfused channels	Frequency	%
2 - 4	8	17
5 - 8	30	63.8
9 - 11	2	4.3
>12	6	12.8
l'm not sure	1	2.1
Total	47	100

Water perfused manometry: Arrangement of water-perfused channels	Frequency	%
Longitudinally	5	10.6
Spirally	25	53.2
Radially	12	25.5
Longitudinally and radially	4	8.5
I'm not sure	1	2.1
Total	47	100

Solid state manometry: Number of solid-state sensors	Frequency	%
1	1	1.7
2 - 4	11	18.6
5 - 8	7	11.9
9 - 12	18	30.5
13 - 20	2	3.4
21 - 40	4	6.8
>40	11	18.6
I'm not sure	5	8.5
Total	59	100

Solid state manometry: Arrangement of solid-state sensors	Frequency	%
Longitudinally	1	1.7
Spirally	15	25.4
Radially	8	13.6
Longitudinally and radially	29	49.2
I'm not sure	6	10.2
Total	59	100

⁽a)

Table 3. Frequency table of patient positioning during the push manoeuver.

Position during push	Total	Total N=89	
manoeuver	n	%	
Supine	5	5	
Left Lateral	81	76	
Sitting on a commode	11	10	
Other	1	1	

Associated investigations	Never		Sometimes		Always		Total
	n	%	n	%	n	%	n
Anal electromyography	92	85.9	13	12.1	2	1.9	107
Anal endosonography (endoanal ultrasound)	59	55.1	36	33.6	12	11.2	107
Anal sensation (electrical stimulation)	83	77.5	15	14	9	8.4	107
Balloon expulsion	26	24.3	23	21.5	58	54.2	107
Colonic scintigraphy	87	81.3	19	17.8	1	0.9	107
Colonic transit	21	19.7	47	43.9	39	36.4	107
Evacuation proctography	38	66.3	45	42.1	24	22.4	107
Pudendal nerve function (terminal motor latencies)	49	45.8	24	22.4	34	31.8	107
Rectal sensation (balloon distension)	52	48.6	7	6.5	48	44.9	107
Rectal sensation (electrical stimulation)	88	82.2	10	9.3	9	8.4	107
Rectal sensation / compliance (barostat)	88	82.2	9	8.4	10	9.3	107
Saline continence test	69	64.4	19	17.8	19	17.8	107

Table 4. Frequency tables showing use of additional investigations of anorectal function.

FIGURE LEGENDS

- **Figure 1**: Table and diagram showing frequency of measurement parameters utilised for rest, squeeze, prolonged squeeze and cough during ARM protocols.
- **Figure 2**: Comparative histograms of (a) squeeze and (b) prolonged squeeze showing maneuver duration reported during ARM protocols.
- Figure 3: Comparative histograms of (a) squeeze, (b) prolonged squeeze, (c) push and (d) RAIR showing number of maneuvers performed during ARM protocols.