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Normal Values of High Resolution Anorectal Manometry in 132 Romanian Healthy People

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ABSTRACT

Background & Aims: The primary method for assessing anorectal function is high resolution anorectal manometry (HRAM). It is a useful tool in the diagnosis of different anorectal functional disorders such as fecal incontinence or dyssynergia. The aim of the present study was to propose a new set of normal values to be used in practice for East-European individuals, as it was proven that the results are highly influenced by race and sociocultural status.
Methods: We conducted a study based on anorectal manometric values of healthy volunteers analyzed at Clinic Fundeni Institute, Bucharest, Romania, between 2017 and 2022. The anorectal manometry was performed using a solid-state catheter (Diversatek, 23 pressure sensors). All anorectal measurement values were analyzed using the Bioview Software Analysys, respecting the timing and the order from the standardized IAPWG protocol. Manometric measurements were summarized using mean, median, standard deviation, minimum and maximum values. The impact of age and gender on 8 different manometric parameters was further analyzed. Normal ranges for all numeric variables were estimated using the 5th and 95th percentiles of the measurements.
Results: A total of 132 subjects (97 females, 35 males) were enrolled in the study. Median age was similar between groups (54 vs. 55 years). The values for rectal propulsion, anal gradient and anal relaxation proved to be higher in females under 54 years as opposed to older women. The values for resting pressure, maximum squeeze pressure, incremental squeeze pressure were significantly higher in males younger than 54. Regardless of age, values for maximum squeeze pressure, incremental squeeze pressure, duration of squeeze and rectal propulsion were found to be significantly higher in males than in females. Normal values of HRAM in healthy volunteers are presented in a table at the end of the study.
Conclusions: The data presented in the current study are of high value and have a great impact on clinical practice, being the first study offering a spectrum of the normal values for HRAM in an Eastern Europe population.

Key words: high resolution anorectal manometry – fecal incontinence – dyssynergia – normal values.

Abbreviations: HRAM: high resolution anorectal manometry; IAPWG: International Anorectal Physiology Working Group.

INTRODUCTION

The primary method for assessing anorectal function is high resolution anorectal manometry (HRAM). Through colorful topographical plots, this investigation offers an accurate assessment of anal sphincters pressures, rectal sensation and rectoanal coordination during defecation. Thus, it is a useful tool in the diagnosis of different anorectal functional disorders such as fecal incontinence or dyssynergia.

One of the main drawbacks of HRAM has been the lack of solid data regarding standardized values, as well as the lack of a standardized assessment protocol. Attempts to correct both issues have been made in the last years, notably with the publishing of the London Classification in 2020 [1], proposing a standardized protocol and algorithm for the evaluation of the anorectum function. However, studies that define normal HRAM parameter values in different populations, are still lacking. To complicate the matter even further, there are several factors which are known to influence HRAM values, such as: age, gender, and body mass index. One other impediment in the acquisition of data has been the relatively low availability of HRAM, as the catheter itself and required software are rather costly.

After searching the PubMed database, we have been able to identify few studies which quantify HRAM parameters in the general population, notably the study by Carrington et al. [2], Lee et al. [3], Deshmukh et al. [4] and Le Manh Cuong et al, [5]. All these studies have been conducted on healthy, asymptomatic adults. The number of patients included ranges from 30 [5], to 115 [2]. Because the type of catheter greatly influences the values recorded, a comparison of the normal values reported in these studies is not possible as different types of catheters were used (ISOLAB, Diversatek, Unisensor). Thus, we are convinced that there is a need for more studies on the normal values of HRAM analysis, conducted on a larger population.

The aim of the present study was to propose a new set of normal values ready to be used in practice for East-European individuals, as it has been proven that the results are highly influenced by race and sociocultural status.

METHODS

Study Population

A total of 132 subjects with a general good health status and with no symptoms regarding the lower gastrointestinal tract voluntarily agreed to be evaluated for anorectal function during their ambulatory hospitalization in the gastrointestinal unit of the Clinical Fundeni Institute, Bucharest, Romania between 2017 and 2022 (patients with gastroesophageal reflux disease, dyspepsia or viral hepatitis). After signing the informed consent, all subjects were clinically examined, and the individuals found with structural lesions of the anorectal area were excluded. A targeted clinical history (proctological /obstetrical) was obtained in all participants. The study obtained approval of the Medical Ethical Committee. The study population was divided based on gender in group A (females) and group B (males) and further on based on median age (group 1 < 54 years, group 2 > 54 years)

Equipment and Protocol of Study

High resolution manometry was performed with a solid-state catheter (Diversatek, 4 mm diameter) comprised of 23 pressure sensors. The most proximal sensor was located in the latex free balloon attached at the tip of the catheter and used for measuring the rectal compliance.

The lubricated catheter was positioned with the baseline band in the anal verge and the most distal sensor (used for external reference) placed 1 cm outside the anal verge, assuring visibility of the distal margin of the sphincter.

All of the other sensors were centered in the anal canal and were used for circumferential measurements of pressures at every centimeter of the anal canal length.

The parameters were then analyzed using Bioview analysis software with the InSIGHT G3 HRM system (Diversatek).

Between 2017 and 2020 the protocol of the study was following the steps from The London HRAM Protocol (2014) [2]. Since 2020, all test maneuvers were performed respecting the timing and the order from a standardized protocol (rest, squeeze, cough, push, sensitivity) recommended by International Anorectal Physiology Working Group (IAPWG) [1]. The push maneuver was performed without rectal distension in all cases.

The reported parameters were resting pressure, maximal squeeze pressure, maximum incremental pressure, duration of squeeze, rectal propulsion pressure, rectoanal gradient, anal relaxation percentage, sphincter length and rectal sensation.

The resting pressure was measured after a period of stabilization (3 minutes) and was defined as the maximal pressure of the anal canal at any time point during rest. Maximal squeeze pressure was considered as the highest recorded pressure in the anal canal at any time point during squeeze maneuvers. The maximum incremental pressure was considered as the highest recorded pressure at any time point during squeeze minus the mean maximum resting pressure before the maneuver. The duration of squeeze was defined as the time (sec) during which a pressure ≥ 50% of the maximal squeeze pressure was maintained. The rectal propulsion pressure was defined as the maximal rectal pressure during push maneuver. The rectoanal gradient was considered as the difference between the rectal and anal pressure during push maneuvers [2].

Rectal sensation was evaluated by inflating the rectal balloon with a hand-held syringe in 10 mL increments of air and the threshold volumes for first sensation, desire to defecate, and urgency were recorded.

Bowel prep solutions were not routinely recommended but patients were encouraged to defecate in the morning of the procedure if needed. The procedure was performed with patients in the left lateral position with hips flexed to 90°.

Rectal sensation was evaluated by inflating the rectal balloon with a hand-held syringe in 10 mL increments of air (up to a total of 180 mL), and the threshold volumes for first sensation, desire to defecate, and urgency were recorded.

Statistical Analysis

Manometric measurements were summarized using mean, median, standard deviation, minimum and maximum values.

Normal ranges for all numeric variables were estimated using the 5th and 95th percentiles of the measurements. The impact of age and sex on different parameters was evaluated using initially Mann–Whitney U-tests combined with further analysis using linear regression. Statistical analyses were performed using SPSS Statistics. A p value < 0.05 was considered statistically significant.

RESULTS

A total of 132 patients (group A: 97 females, group B: 35 males) were enrolled in the study. Median age was similar between groups (54 vs. 55 years). 19.58% of females had at least a vaginal delivery. Quantitative values for each maneuver are synthetized in Tables I and II, separated by gender.

Median age for the whole group was 54 years, so we further separated the groups based on this value (group 1 <54

Table I. Quantitative values of HRAM in group A (97 females)

	No	Mean	SD	Minimal	Maximal	Median
Resting pressure, mmHg	97	66	17	26	111	68
Squeeze max, mmHg	97	163	48	89	325	159
Squeeze incremental, mmHg	97	38	28	4	161	32
Duration of squeeze, sec	97	10	8	2	28	6
Rectal propulsion pressure, mmHg	97	57	35	5	140	48
Rectoanal gradient, mmHg	97	-76	38	-243	16	-79
Anal relaxation %	97	95	15	63	100	98
Sphincter length, cm	97	4	1	2	5	4
First sensation, mL	20	35	5	11	45	34
Desire to defecate, mL	20	65	10	45	100	68
Max tolerable volume, mL	20	120	16	85	142	118

Table II. Quantitative values of HRAM in group B (35 males)

	No	Mean	SD	Minimal	Maximal	Median
Resting pressure, mmHg	35	71	18	34	109	71
Squeeze max, mmHg	35	236	80	107	451	233
Squeeze incremental, mmHg	35	55	24	15	123	55
Duration of squeeze, sec	35	18	12	2	28	21
Rectal propulsion pressure, mmHg	35	87	52	13	223	91
Rectoanal gradient, mmHg	35	-75	38	-168	-3	-71
Anal relaxation %	35	98	3	89	100	100
Sphincter length, cm	35	4	1	4	5	5
First sensation, mL	8	28	3	10	35	30
Desire to defecate, mL	8	71	15	65	110	75
Max tolerable volume, mL	8	122	20	100	170	130

years, group 2 >54 years). Age did not influence any of the manometric parameters (Table III).

The values for rectal propulsion, anal gradient and anal relaxation proved to be higher in female patients under 54 years. As opposed, no differences were observed in females separated by median age for resting pressure, maximal squeeze pressure, incremental pressure, squeeze duration or anal canal length (Table IV).

When analyzing only the male patients, it was found that the values for resting pressure, maximum squeeze pressure, incremental squeeze pressure were significantly higher in patients younger than 54. As opposed to the female group, no differences were observed between males regarding rectal propulsion, anal gradient, anal relaxation or sphincter length (Table V). Regardless of age, values for maximum squeeze pressure, incremental squeeze pressure, duration of squeeze and rectal propulsion were found to be significantly higher in males than in females. No differences by gender were found for resting pressure, anal gradient, anal relaxation and sphincter length (Table VI).

Tests of normality demonstrated that some data (particularly measures of squeeze pressure) were not normally distributed. For this reason, suggested normal ranges have been based on 5th and 95th percentiles rather than 95% confidence intervals (Table VII).

Table III. Effect of age on manometric parameters

	Group 1 (<54 years) (n=98)	Group 2 (> 54 years) (n=139)	p
Resting pressure, mmHg	70 (26-111)	69 (30-109)	0.46
Squeeze max, mmHg	173 (89-451)	163.5 (97-347)	0.71
Squeeze incremental, mmHg	38 (4-158)	37 (11-161)	0.61
Duration of squeeze, sec	12 (2-28)	10 (3-25)	0.7
Rectal propulsion pressure, mmHg	43.5 (5-178)	60 (9-223)	0.15
Rect propulsion, mmHg	-74.5 (-168-16)	-79.5 (-243—12)	0.75
Anal relaxation %	97.5 (61-100)	98.5 (75-100)	0.38
Rect propulsion, mL	4 (2-5)	4 (2-5)	0.92

Table IV. Effect of age on manometric parameters in group A (females)

	Females, <54 years (n=48)	Females, >54 years (n=49)	p
Resting pressure, mmHg	66 (26-111)	71 (30-109)	0.18
Squeeze max, mmHg	160 (89-274)	159 (97-325)	0.67
Squeeze incremental, mmHg	32.5 (4-158)	30 (11-161)	0.5
Duration of squeeze, sec	10 (1-25)	10 (3-21)	0.6
Rectal propulsion pressure, mmHg	59 (9-140)	39.5 (5-132)	0.02
Rectoanal gradient, mmHg	-83 (-243--12)	-73.5 (-128-16)	0.007
Anal relaxation %	98 (75-100)	90 (63-100)	0.03
Sphincter length, cm	4 (3-5)	4 (2-5)	0.26

Table V. Effect of age on manometric parameters in group B (males)

	Males, <54 years (n=16)	Males, >54 years (n=19)	p
Resting pressure, mmHg	78 (49-101)	59 (34-109)	0.04
Squeeze max, mmHg	268 (167-451)	194 (107-347)	0.01
Squeeze incremental, mmHg	61.5 (25-123)	42 (15-93)	0.03
Duration of squeeze, sec	17	19	0.7
Rectal propulsion pressure, mmHg	79.5 (13-178)	99 (21-223)	0.82
Rectoanal gradient, mmHg	-85 (-168—3)	-63 (-138—19)	0.1
Anal relaxation %	100 (61-100)	100 (89-100)	1
Sphincter length, cm	5 (4-5)	5 (4-5)	1

DISCUSSION

Anorectal manometry is one of the most useful tools in evaluating anorectal physiology and in diagnosing functional anorectal diseases [7, 8].

The introduction of HRAM completely changed the approach providing a more qualitative assessment of pressure events during segments of interest. Colored plots offer a more intuitive view of the anorectal pressure changes during resting, squeeze, coughing or push maneuvers [9, 10].

Until the recently published London Protocol by the IAPWG, there was a great variability in the published data regarding the maneuvers used during the study (number and duration), the time intervals needed between maneuvers and, also, in the final report components [1, 11, 12].

The first part of the current study presents a set of data (epidemiological and numeric data for different parameters: mean, median, min, max) based on a large study group of healthy volunteers (one of the largest published), being the first study that follows a standardized protocol of examination and reporting.

This second part of the study presents the effect of age and gender on 8 different manometric parameters.

Resting pressure, squeeze pressure, incremental pressure and squeeze duration proved to be significantly higher in males younger than 54, as opposed to older males and showing no differences in the female group separated by age. As opposed, rectal propulsion, anal gradient and anal relaxation values were significantly higher in females younger than 54 as opposed to older females. As for males, no differences were seen regarding these values between age groups.

Table VI. Effect of gender on manometric parameters

	Group A (n=97)	Group B (n=35)	p
Resting pressure, mmHg	68 (26-111)	71 (34-109)	0.69
Squeeze max, mmHg	159 (89-325)	233(107-451)	0.01
Squeeze incremental, mmHg	32 (4-161)	55 (15-123)	0.01
Duration of squeeze, sec	6 (2-38)	21 (2-28)	0.03
Rectal propulsion pressure, mmHg	48 (5-140)	91 (13-223)	0.04
Rectoanal gradient, mmHg	-79 (-243-16)	-71 (-168—3)	0.59
Anal relaxation %	98 (63-100)	100 (89-100)	0.99
Sphincter length, cm	4 (2-5)	5 (4-5)	0.04

Table VII. Normal values of HRAM for use in clinical practice

	Female, < 54 years		Female, > 54 years		Male, < 54 year		Male, > 54 year	
Suggested normal values	Min.	Max.	Min.	Max.	Min.	Max.	Min.	Max.
Resting pressure, mmHg	35	90	31	95	49	97	43	94
Squeeze max, mmHg	102	237	103	280	167	459	133	297
Squeeze incremental, mmHg	11	97	11	93	25	100	18	80
Rectal propulsion pressure, mmHg	10	130	15	133	32	146	24	174
Rectoanal gradient, mmHg	-127	3	-151	-20	-145	-22	-113	-23
Anal relaxation %	66	100	81	100	74	100	92	100
Sphincter length, cm	2.8	5	2	5	2	4	4	5

The impact of age on manometric parameters is controversial and existing studies are showing opposite results. In this study age did not prove to have a significant influence on manometric parameters when used as a single criterion for analysis, without gender correction, similar with other large studies using the same type [3] or different type of catheter [1].

There are some differences when comparing with the Western-European population data [2] or Asian data [3]. These differences were predicted and are most probably secondary to dietary habits, physical activity, overall health status and also by culture that is reflected in the parity and type of birth rate in females [13, 14].

Because of a smaller proportion of patients evaluated for rectal sensation (20 females and 8 males) the main limit of the study is the lack of compared analysis based on age and gender or normal values regarding the first sensation, sensation to defecate and urgency. Another limitation of the study is the lack of data regarding the influence of parity status or body mass index on different manometric parameters.

This study is the first one to report normal values for a representative group of an Eastern European population. The results can be used as a future guide for HRAM results in Romanian subjects.

We can consider these results as cut-off values for diagnosing different anorectal functional diseases such as: anal hypertonia, anal hypotonia, anal hypocontractility or dyssynergia (but this one being more likely a qualitative result). We recommend using these values as presented, divided based on age and gender. In the future we propose completing this study with a more detailed analysis not only on the rectal sensation parameters but also regarding the effect of body mass index and vaginal birth on manometric parameters.

We compared the normal values resulted in the present study with the only other study in the literature using the same type of catheter [3]. We observed similarity of the results even if the ethnicity and type of population is clearly different (East-European vs Asian).

A comparison between normal values obtained in different studies on a different ethnic population is an interesting idea but the retrospective analysis of the existing results would be probably biased by several factors. The first one is the inhomogeneous distribution of study population (number of subjects, gender distribution and parameters used to separate normal values into groups: body mass index, parous status, etc). Other important factors for erroneousl results are the lack of a standardized protocol for the investigation at the moment the studies were conducted and the use of different manometric systems (Unisensor catheter MMS, Isolab Standard Instruments).

In conclusion, the idea of a comparison between different ethnic population could be feasible as a prospective study with a clearly established study group, following the actual proposed standardized protocol [1] and conducted between centers using the same manometric system or dividing the normal values obtained based on each type of system used.

Based on these facts, we believe that creation of a National and /or an European registry of HRAM results could be of great help into developing more studies and providing more interesting results in this interesting neurogastroenterology field.

CONCLUSION

The data presented in the current study are of high value and have a great impact on clinical practice, being the first study offering a spectrum of the normal values for HRAM in an Eastern Europe population.

Conflicts of interest: None to declare.

Authors` contribution: A.D. and G.C. conceived and designed the study. A.D., R.S. and D.O. collected the data. A.D. analyzed the data and interpreted the results. A.D. and D.O. drafted the manuscript. A.D. revised the work. A.D. and G.C. approved the final version of the manuscript.

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