Original Article Three-dimensional high-resolution anorectal manometry parameter for predicting the perineal descent in adult female individuals

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Abstract: The primary objective of this study was to establish the normal range values for diagnosing adult female perineal descent (PD) by using the three-dimensional high-resolution anorectal manometry (3DHRAM). The second aim was to determine the level of agreement in the diagnosis of PD between 3DHRAM and conventional defecography, which was considered as the gold standard. The method used in this research included two parts: I. 249 asymptomatic volunteers, who were previously diagnosed as non-PD by conventional defecography, were divided into two groups: pruripara group (147 subjects) and nullipara group (102 subjects). All the individuals underwent 3DHRAM in the Pelvic Floor Centre, Department of Colorectal Surgery, Tianjin Union Medical Center. On 3DHRAM, perineal descent was defined as the downward movement of the anal high-pressure zone during defecation. The parameters were recorded and the cut-off values were established for each group; II. With the reference ranges and the cut-off values established in part I, 270 adult female patients (116 nulliparous patients, 154 parous patients) with anorectal dyschezia were examined with conventional defecography and 3DHRAM to identify the PD. Kappa coefficient (κ), Chi-Square Tests were used to assess the agreement between 3DHRAM and conventional defecography in the evaluation of PD. As for diagnosis of PD by 3DHRAM, the cut-off value for nulliparous individuals was 6.4 mm (95% CI: 5.2-8.6). The reference range was 0-6.4 mm. The cut-off value for parous was 10.6 mm (95% CI: 8.1-12.4). The reference range was 0-10.6 mm. The agreement between conventional defecography and 3DHRAM with regard to the diagnosis of perineal descent in parous patients group was substantial (kappa 0.847; Chi-Square Tests P = 0.688), while the agreement in nulliparous patients group was moderate (kappa 0.786; Chi-Square Tests P = 0.508). The results of our study demonstrated that 3DHRAM could accurately diagnose the PD without ionizing radiation. The cut-off values for the PD were reliable. Compared with conventional defecography, 3DHRAM had shown resemble diagnostic performance in assessing PD. So with its better tolerance and availability, 3DHRAM could be another reliable diagnosis tool for PD. sample.

Keywords: Perineal descent, three-dimensional high-resolution anorectal manometry, conventional defecography, high-pressure zone

Introduction

As a common phenomenon associated with constipation and incontinence, perineal descent was a general symptom which was detected by Porter [1] for the first time in 1962, it was defined as relaxed pelvic floor in chronic constipation patients by Parks [2] in 1966. Subsequently, other scholars [3] suggested that perineal descent was a general symptom also in fecal incontinence. Nowadays, PD is considered to be the stage of excessive straining for defecation and is accepted to be a secondary phenomenon associated with various diseases causing pelvic outlet obstruction rather than an independent disease inducing chronic constipation and fecal incontinence.

The incidence of PD increased in an ascensus tendency, especially in adult women. Recent date showed that prevalence of PD changed from 12% to 20% [4]. Compared with nullipara, parous patients with constipation were more likely to get a PD. Suitable treatments need promptly detection and accurate diagnosis. Although historical and physical examinations

were essential to assess the PD, conventional defecography remained the gold standard for diagnosing the PD. But the limitation of conventional defecography was that the patients had to be exposed to X-ray and inability to show all anatomic and physiological changes involved in defecation, which might develop some error in diagnosis. So alternatives to conventional defecography, such as endoanal ultrasonography, dynamic magnetic resonance imaging and high-resolution anorectal manometry had been developed for the evaluation of PD in recent years [5]. 3DHRAM was a novel technique which provides a simultaneous assessment of longitudinal and circumferential pressures throughout the length of the anal sphincter and topographical changes in 3 dimensions. Right now, there were only a few published studies utilizing 3DHRM in patients with pelvic floor diseases [6, 7]. Véronique Vitton [8] demonstrated that 3DHRAM could reliably diagnose excessive perineal descent in 2013, but the accurate criterion had not been set up, the cut-off values, reference ranges for diagnosing the PD by using 3DHRAM have not been available until now. The aim of this study was to establish the normal parameter in healthy adult females to diagnose the PD by using 3DHRAM, and to validate the 3DHRAM technique by evaluating its effectiveness and concordance with defecography in the assessment of adult female PD.

Materials and methods

Between March 2014 and February 2015, 249 asymptomatic adult female volunteers, in whom non-PD were previously diagnosed by conventional defecography, were enrolled in the study from the Pelvic Floor Center, Department of Colorectal Surgury, Tianjin Union Medical Center. Three experienced senior technicians examined all the individuals. Among these subjects, 102 were nulliparous (mean age 25.3 years, range 18-34) and 147 (mean age 47.5 years, range 24-59) were parous. The inclusion criteria included: female gender; age above 18 to 60 years old; non-perineal descent was diagnosed by conventional defecography before manometric studies; not taking any medication within 3 months before manometric studies: normal defecation within 6 months before manometric studies: stool frequency < 3 times/day and > 3 times/week, stool form type in Bristol 3-5 and type Bristol 4 for more than 3/4 of the time, defecation time < 10 min, no defecation straining, no sense of incomplete evacuation and anorectal obstruction, never defecate with hand assisting, no bowel-related abdominal pain, no fecal incontinence. Exclusion criteria includes: male gender; age over 60 years, age under 18 years; previous surgeries for pelvic floor disorders, gastrointestinal tract (including anorectum) and genitourinary system; histories pelvic trauma and lateral episiotomy or other vaginal surgery or lactating women; previous anorectal radiation.

All the enrolled participants had a clinical interview and physical examination before the study. Then all of them underwent the 3DHRAM, the amplitude of the high-pressure zone's downward movement during squeezing was recorded. Quantitative measurements were made for estimating the reference range and cut-off values.

Conventional defecography

The participants were put in the left lateral position and 200 ml semi-solid barium past prepared in advance was injected into the rectum until the sensation of defecation occurred. Afterward, the participants were asked to sit on a special commode parallel to the X-ray table for lateral visualization of the anal canal and rectum, contract the pelvic floor musculature and empty the rectum as completely as possible. Radiographs were taken at rest, squeezing, and during defecation of the contrast. The coccyx, sacrum, head of the femur, posterior wall of the rectum, and anal canal were identified. As for conventional defecography, perineal descent can be measured as the vertical distance between the pubococcygeal line and the anorectal junction. In normal subjects, the perineum descends 1-3 cm [9] during the evacuation, the distance of more than 3 cm in the position of the anal canal between rest and bearing down was considered PD for nullipara, while the distance of more than 3.5 cm was considered PD for multipara [10].

Manometry

3DHRAM was performed with the participants in the left lateral decubitus position. No enemas were given. No transanal procedures were performed during the two hours prior to the examination to avoid sphincter irritation. The probe was immobilized by a stainless-steel rod. The stainless-steel rod was placed in the ischi-



Figure 1. Downward and upward movements of the high-pressure zone during the defecation. State A, resting phase; State B, defecation phase; State C, the resting phase after the defecation (containing cough reflection). The left black arrow stands for the downward movement of the high-pressure zone when the state changed from rest to defecation; the right black arrow stands for the upward movement of the high-pressure zone after the defecation.

al tuberosity. The probe was placed in the anal verge. The anal canal high-pressure zone was captured with some clearance on the cranial (rectal pressures) and caudal (atmospheric pressure) ends. The circular orientation of the probe was maintained by the practioner during rest and bearing down with the aid of markings on the probe. Separate measurements were obtained at rest and defecation, respectively. The location of the perineal area at rest was measured by using the scale of the probe. The participants are asked to perform the action of defecation as completely as possible, and the new location of the perineal area was measured. The difference in the values between the first and the second measurements was the extent of perineal descent. The amplitude of downward and upward movement of high-pressure zone during the defecation can be seen in Figure 1 while the obvious change in the three dimensional morphology can be seen in Figure **2**. The downward movements of high-pressure zone during the defecation were recorded and the cut-off values were established.

With the diagnostic criterions for PD by using 3DHRAM forecasted above, 270 adult female patients (116 nullipara patients, mean age 24.7 years, ranging in age from 18 to 29; 154 parous patients, mean age 49.2 years, ranging in age from 23 to 58) with anorectal disfunctions underwent the conventional defecography and 3DHRAM examinations to identify the PD. The diagnosis results were recorded and the data was compared. All the participants provided informed written consent. The research was conformed to the ethics committee of the Tianjin Union Medical Center.

Statistical analysis

The statistical analysis methods in this study include: <1>. Mean and standard deviation



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Figure 2. Three dimentional morphology during the evacuation. State A, resting phase, the white arrow stands for the initial location of the high-pressure zone; State B, defecation phase, the white arrow stands for distal margin of the high pressure zone went down for some extent during the defection. State C, the resting phase after the defecation, the white arrow regained the initial level after the evacuation.

analysis, which was used to establish the reference ranges and cut-off value; <2>. Chisquared tests and Kappa coefficient statistics, which were used to assess agreement between 3DHRAM and conventional defecography in the evaluation of PD.

The mathematical formulas of mean deviation and standard deviation are described in equation (1) and equation (2). Based on these two statistical methods, the cut-off value for nulliparous individuals was 6.4 mm (95% CI: 5.2-8.6). The reference range was 0-6.4 mm. The cut-off value for parous was 10.6 mm (95% CI: 8.1-12.4). The reference range was 0-10.6 mm.

The mathematical formula of mean deviation is:

Mean deviation =
$$\frac{\sum |x - \mu|}{N}$$
 (1)

The standard deviation value can be calculated by the mathematical formula:

Standard deviation = $\sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i - \mu)^2}$ (2) Where μ is the mean value, which is defined by: $\mu = \frac{1}{N}\sum_{i=1}^{N} x_i$. x_i is each value. Then N is the number of all the values.

Chi-square is a statistical test method which is commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis, which is also referred to as X^2 test. The formula for calculating chi-square is described in equation 3.

$$\chi^{2} = \frac{\sum (o - e)^{2}}{e}$$
(3)

Where "o" indicates the observed data; "e" indicates the expected data. Chi-square is the sum

Table 1. An example showing the calculation
process of Kappa coefficient

Variable		Observer 2			
variable		Yes	No	Total	
Observer 1	Yes	а	b	G1	
	No	С	d	G2	
	Total	F1	F2	Ν	

of the squared difference between observed "o" and the expected "e" data (or the deviation), divided by the expected data in all the possible categories [11].

Kappa coefficient is a statistic which evaluates the inter-rater agreement for qualitative items. It is more robust agreement measurement than simple percent agreement calculation, because kappa coefficient considers the agreement happening by chance.

Kappa coefficient is commonly calculated by equation 4.

$$k = \frac{\text{observed agreement} - \text{expected agreement}}{1 - \text{expected agreement}} = \frac{p_{e} - p_{e}}{1 - p_{e}}$$
(4)

Here one example is used to explain the principle of Kappa coefficient calculation. Suppose two observers are analyzing a group of samples in **Table 1**. "a" and "d" represent the numbers of samples the two observes agree, while "b" and "c" represent the number of samples the two observes disagree [12].

Then, observed agreement and expected agreement can be calculated by equation 5 and equation 6.

$$P_{o} = \frac{(a+d)}{N}$$
(5)

$$P_{e} = \frac{\left(\frac{F1 * G1}{N}\right) + \left(\frac{F2 * G2}{N}\right)}{N}$$
(6)

It is defined that: 0, no agreement between the 2 techniques; 0.00 to 0.19, poor agreement; 0.20 to 0.39, fair agreement; 0.40 to 0.59, moderate agreement; 0.60 to 0.79, substantial agreement; and 0.80 to 1.00, perfect agreement. For all tests, a *P* value of < 0.05 was considered statistically significant. In order to improve efficiency, all data were analyzed by the statistical software package SPSS 13.0 (Chicago, Illinois, USA), which embeds all of above statistical analysis methods.

Results

Cut-off values and reference ranges

The distribution of the high-pressure zone's downward movement data was predicted as non-Gaussian distribution by normality test. They had a nearly normal distribution when log10 transformed. The fluctuation amplitude of the high-pressure zone from two groups could be seen in Table 2. The cut-off values by mean and standard deviation on the logarithmic scale were transformed back to the original units to establish the reference range: 0-6.4 mm for nullipara and 0-10.6 mm for pruripara. Pruripara group: the amplitude of high-pressure zone's descent ranged from 7.9 mm to 13.6 mm. cut-off value was 10.6 mm (95% CI: 8.1-12.4). Nullipara group: the amplitude of highpressure zone's descent ranged from 5.3 mm to 9.7 mm, cut-off value was 6.4 mm (95% Cl: 5.2-8.6).

Agreement between two methods

For 3DHRAM, rates of diagnostic concordance with conventional defecography were high for the assessment of perineal descent. The agreement for nulliparous patients regarding diagnosis of PD by using two methods was shown in **Table 3**. Overall, the agreement between two methods in nulliparous patients was classified as substantial (k = 0.786, Chi-Square Tests P = 0.508).

As for the parous patients, the index of agreement between conventional defecography and 3DHRAM with regard to the diagnosis of perineal descent was high, classified as perfect (kappa 0.847; Chi-Square Tests P = 0.688). The result was shown in **Table 4**.

Discussion

Perineal descent was frequent phenomenon. Doctors need more information on the accuracy of available diagnostic techniques to make therapeutic decisions. Choosing the most suitable treatment for perineal descent required a complete clinical investigation and examination techniques capable of identifying anatomical and functional abnormalities. Conventional defecography was an established method which had been used as the gold standard technique in assessing PD [13, 14]. This con-

Voriable	Nullipara (n = 102)		Pruripara (n = 147)		Duoluo	
valiable	Mean ± s.e.m	95% CI	Mean ± s.e.m	95% CI	P value	
Maximum resting pressure (mmHg)	67.4±4.1	63.8-75.7	65.8±2.8	62.6-73.8	0.413	
Mean resting pressure (mmHg)	62.7±2.5	57.4-64.1	60.8±2.9	56.4-63.7	0.748	
Maximum squeeze pressure (mmHg)	187.4±6.5	171.2-205.5	164.8±8.3	152.8-175.3	0.011*	
High-pressure zone length (cm)	3.7±0.1	3.3-3.9	3.5±0.1	3.4-3.7	0.756	
Fluctuation of HPZ during defecation (mm)	6.4±0.9	5.2-8.6	10.6±1.4	8.1-12.4	0.046*	
Anal relaxation rate (%)	21.7±3.2	16.4-27.5	25.1±2.6	18.7-30.2	0.925	

Table 2. The data of two groups from 249 asymptomatic volunteers, who underwent the 3DHRAM

Note: HPZ: high-pressure zone. Date expressed as mean \pm s.e.m or 95% confidence interval (95% Cl). *P < 0.05.

Table 3. Agreement between 3DHRAM and conventional defecography regarding diagnosis ofPD in nulliparous patients

Variable		3DHRAM		
variable		PD	No-PD	Total
Conventional Defecography	PD	84*	6	90
	No-PD	3	23*	26
	Total	87	29	116

"*" concordant findings.

Table 4. Agreement between 3DHRAM and conventional defecography regarding diagnosis ofPD in parous patients

Verieble		3DHRAM		
Variable		PD	No-PD	Total
Conventional Defecography	PD	128*	2	130
	No-PD	4	20*	24
	Total	132	22	154

"*" concordant findings.

ventional defecography technique evaluated of the PD in relation to the pubococcygeal line. Perineal descent was defined as the descent of the anorectal junction from rest to evacuation and could be measured as vertical distance between the pubococcy-geal line and the anorectal junction, same as the vertical distance between the upper anal canal (anorectal junction) and pubococcygeal line. In normal nulliparous individuals, the perineum descends less than 3 cm, while in normal multiparas. The distance was less than 3.5 cm. A difference of more than 3 cm in the position of the anal canal during the defecation was considered perineal descent for the nulliparous while 3.5 cm for the parous.

However, conventional defecography must be performed in a specific radiologic environment.

Patients had to be exposed to radiation. What was more; the pubic bone could not be visualized in clinic practice mostly, which always generated the discrepance of the diagnosis. Additionally, conventional defecography was poorly tolerated by elderly patients, especially during extended exams. With the development of medical technology, a great amount of equipments were invented to redeem the deficiency of conventional defecography for the past few years. 3DHRAM was a new technique that provided a simultaneous assessment of pressures and topographical changes in 3 dimensions. With this novel implement, the fluctuation of anorectal pressure could be seen in direct style during the defecation and it could verdict the PD through the downwards movement of the high-pressure zone (Figure 2B), which was similar to the modality of perineometer, but more advanced than the latter. Compared with conventional defecography, the estimation of PD by 3DHRAM was based on the descent of the high-pressure zone during squeezing, which corresponded to the descent of the anal canal. 3DHRAM required no bony anatomic relationships and only assessed the downward movement of the high-pressure zone without knowledge of the initial position of the anorectal junction.

Different from traditional manometry based on linear waves, this newly developed manometry method provided more accurate changes during the squeezing in 3 dimensions [15]. The 3D spatiotemporal plots could be showed as colored images representing pressure, distance and time [16]. The probe was equipped with 256 tactile pressure microtransducers, a solid state catheter was across the anorectal canal, which was used to measure the anorectal canal pressures and the movement of anal canal high-pressure zone at rest and defecation (**Figure 1**). All the data from measurements were analysed using MANOVIEWTM software (Sierra Scientific Instruments, Los Angeles, California, USA), which could provide a detailed topographical and three dimentional pressure gradient representation.

The probe was plug into the anal canal. The parameters of the high-pressure zone were obtained. The length of high-pressure zone changed slightly during the evacuation so we just pay attention to the inferior border of the high-pressure zone. At the end of the evacuation, the inferior border of high-pressure zone regained its initial position, demonstrating that the position of the probe had not moved during the evacuation. The amplitude of downward and upward movements of the inferior border could be seen in **Figure 1**.

Pregnancy and Delivery were important risk factors for pelvic descending. Pelvic floor endured more pressure during the telophase of the pregnancy. Pudendal nerve was considered to be injured during the delivery [17, 18], especially in first stage of the labor. So the subjects were divided into two groups and the criterion standards were established for each group, which was similar to the criterion of conventional defecography. Among the 154 mulipara patients with dyschesia, 35 of them underwent at least 1 cesarean section, the reason why we didn't subdivide the parous group according to the style of delivery was that the main influence of this parturition on the pelvic floor muscle was in first stage, and on the whole, influence on the pelvic musculus from the cesarean section was similar to spontaneous delivery, which was agreed by many investigators in recent years [19]. The Kappa value of nulliparous group from 270 female patient with dyschezia was lower than that of parous group, the possible reason could be the different elasticity between the nullipara and the pouripara.

The data from the measurement of the highpressure zone's downward movement was similar to normal distribution after the log10 transformed. The reference ranges and cut-off values were obtained by mean and standard deviation. The reference ranges were also obtained by percentages method and the 5th percentile of the measurements in the reference group were available, but it was less convincible compared with the mean method. For comparison of the PD's diagnosis between conventional defecography and 3DHRAM, the Chi-squared test was used and the kappa coefficients were calculated to verify the agreement between two methods.

Although the position in which we placed our participants for the 3DHRAM was considered standard practice for anorectal manometry, the body position could have influenced the results of this study [20-22]. The movement of highpressure zone during squeezing was measured with the participant in the left lateral decubitus position, while the conventional defeacography test was performed with the participants in a physiologically seated position which was currently the only "physiological" defecation position. Anyway, we suggest that the effect of body position should be further explored in future studies. However, there were some limitations in this study. The parity was not calculated in the normal subjects. It was reported that the frequency of delivery was related with the impairment of pudendal nerve [23-26]. Next, the body mass index (BMI) was not taken into account in the study. A recent study has reported the association between BMI and anorectal pressure measured by 3DHRAM [27, 28]. Another limitation was the relatively small number of asymptomatic volunteers. What was more, this study did not include fecal incontinence patients to compare with the constipated patients, which was a speculative study in future.

Conclusion

In conclusion, 3-DHRAM was shown to be a reliable technique for the assessment of perineal descent with the reference ranges established in this research. With its minimally invasive, comfortable position and well tolerated, 3D-HRAM may be another suitable method used to assess the PD patients in future.

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Disclosure of conflict of interest

None.

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