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Authors
Zifan, Ali
Ledgerwood-Lee, Melissa
Mittal, Ravinder K

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A Predictive Model to Identify Patients With Fecal Incontinence Based on High-definition Anorectal Manometry

Ali Zifan, PhD, **Melissa Ledgerwood-Lee, BSc**, and **Ravinder K. Mittal, MD**

Department of Medicine, Division of Gastroenterology, University of California, San Diego, CA, USA

Abstract

Background & Aims—Three-dimensional high-definition anorectal manometry (3D-HDAM) is used to assess anal sphincter function; it determines profiles of regional pressure distribution along the length and the circumference of the anal canal. There is no consensus, however, on the best way to analyze data from 3D-HDAM to distinguish healthy individuals from persons with sphincter dysfunction. We developed a computer analysis system to analyze 3D-HDAM data and to aid in the diagnosis and assessment of patients with fecal incontinence (FI).

Methods—In a prospective study, we performed 3D-HDAM analysis of 24 asymptomatic healthy subjects (controls; all women; mean age, 39±10 years) and 24 patients with symptoms of fecal incontinence symptoms (all women, mean age, 58±13 years). Patients completed a standardized questionnaire (fecal incontinence severity index to score the severity of FI symptoms. We developed and evaluated a robust prediction model to distinguish patient with FI from controls using linear discriminant, quadratic discriminant, and logistic regression analyses. In addition to collecting pressure information from the HDAM data, we assessed regional features based on shape characteristics and the anorectal symmetry index.

Results—Low FI severity index scores correlated with low rest pressure (r=0.34), and peak squeeze pressure of the anal canal(r=0.28). The combination of pressure values, anal sphincter area, and reflective symmetry values was identified in patients with FI vs controls with an area under the curve value of 1.0. In logistic regression analyses using different predictors, the model identified patients with FI with an area under the curve value of 0.96 (interquartile range [IQR], 0.22). In discriminant analysis, results were classified with a minimum error of 0.02, calculated using 10-fold cross validation; different combinations of predictors produced median classification

Correspondence: Ravinder K Mittal, MD, Gastroenterology (111D), VA Health Care System, 3350, La Jolla Village Drive, San Diego, CA 92161, rmittal@ucsd.edu, Phone: 858-552-7556, FAX: 858-552-4327.

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Author Contributions: Ali Zifan carried out data analysis, software development, creating figures, and writing of the manuscript. Ravinder K Mittal was involved in conceiving the study, design of experiment, supervised data acquisition, analysis and interpretation of data, drafting, writing and editing the manuscript. Finally, Melissa Ledgerwood-Lee was responsible for recruiting subjects for the study, data acquisition and intellectual input.

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errors of 0.16 in linear discriminant analysis (IQR, 0.25) and 0.08 in quadratic discriminant analysis (IQR, 0.25).

Conclusion—We developed and validated a novel prediction model to analyze 3D-HDAM data. This system can accurately distinguish patients with FI from controls.

Keywords

LDA; QDA; ASI; FISI; anatomy; anal pressure topography

Background & Aims

While fecal incontinence (FI) symptoms are under-reported, surveys reveal that 7–10% of the population, women and men suffer from it and its prevalence increases with age[1, 2]. The risk factors for the development of FI are many, i.e., gender, obstetrical injuries related to vaginal childbirth, multiparity, change in rectal compliance, rectal inflammation, diarrhea and aging [3, 4]. There is general agreement that the anal sphincter mechanism is the key barrier against leakage of rectal contents or anal/fecal incontinence. Multiple studies show that patients with FI have lower rest and squeeze pressure of the anal canal compared to normal subjects[4]. Pope and Harris first described the use of infusion manometry to measure anal canal pressure accurately[5]. Since then, several infusion manometry methods have been used, i.e., station-pull through, rapid pull-through techniques and sleeve sensor[6] to measure anal canal pressure. Solid-state pressure transducers[7] that do not require water infusion have also been used by a number of investigators to assess anal sphincter pressure. The current gold-standard to measure anal canal pressure though is high-resolution anorectal manometry (HRAM) [8].

Studies show that the anal canal pressure is not symmetric along its length and circumference [9, 10]. The high definition anal manometry (HDAM) probe captures the axial and circumferential asymmetry of anal canal pressures[11–14]. Another advantage of HDAM is the ability to define the length of anal sphincter high pressure zone, which may play a role in the anal continence mechanism.

Our goal is to underline the role and impact that the HDAM measurement could have in the diagnosis of fecal incontinence (FI). Along those lines, we developed a systematic approach to analyze and classify HDAM measurements to determine important predictors that could be extracted from the HDAM measurements to distinguish normal subjects from patients. We use “state of the art” data mining and image processing techniques for automatic delineation and measurement of HDAM characteristics in normal and FI patients.

METHODS

Ethical Approval

The UCSD Institutional Review Board approved the investigational protocol (#111030).

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Study subjects

Twenty-four asymptomatic healthy female volunteers (mean age, 39 ±10 years, BMI: 24.6 ± 2.7) and 24 patients with FI symptoms (all females, mean age 58±13 years, BMI ± SD: 30±7.4) were studied. Each subject completed medical history and anal incontinence questionnaire (FISI)[15] to confirm/reject the absence of anal incontinence symptoms (mean FISI 35±11.9). Twenty-two patients gave history of vaginal child birth (median 2, range 1–6), one with no children, and another one with caesarian section. Ten patients described having difficulty during delivery, two gave history of sling operation for urinary incontinence, one patient with history of vaginal prolapse, and one with anal fistula.

High Definition Anorectal Manometry (HDAM)

Anal canal pressures were recorded using the HDAM probe and ManoScan 360 HD™ (Medtronics, Inc., Minneapolis, MN). The probe was placed such that the entire anal high-pressure zone (HPZ) was captured with clearance on the cranial (rectal pressures) and caudal (atmospheric pressure) ends. The circular orientation of probe in relation to the orientation of anal canal was maintained during rest and squeeze. The subjects were positioned in the left lateral position, and were asked to sustain the squeeze for 10 seconds. Three separate measurements per subject were obtained and averaged at rest, and at the peak of sustained maximal anal sphincter/pelvic floor contractions (squeeze) (Figure 1).

DATA ANALYSIS

The HDAM data were imported into Matlab (MathWorks, Inc., Natick, USA) as raw 16×16 matrix and interpolated. The color topographical anorectal images revealed 3 distinct pressure zones: upper zone which represents rectal pressure, the middle zone represents anal canal high pressure zone (HPZ) and the lower zone shows the atmospheric pressures (see Figure 1). In order to obtain a composite HDAM profile of anal canal, across normal subjects and patients, the pressures from the anal HPZ were averaged. Mean pressure calculation at each transducer was performed by optimally aligning the pressure profile in each subject, which was achieved by calculating the correlation coefficient between pressure values of 2 subjects and then sliding the transducer position axially (±3 transducer position) and circumferentially (±1 transducer position). The optimal pressure transducer alignment was taken as the offset that yielded maximal correlation coefficient, which allowed correction for variations in the probe depth insertion and slight, if any, misalignment in the circumferential direction.

In order to build robust features for the classifier we used both descriptive statistic parameters alongside the regional shape metrics. We studied several features extracted from the HDAM data to determine which one can serve as a robust predictor to distinguishing normals from the patients; 1) peak pressure at rest and squeeze (e.g., peak pressure sensor value in a 16×16 HDAM matrix), 2) asymmetry index of the HDAM images, 3) area of the anal sphincter HPZ, and 4) movement of the anal sphincter HPZ with squeeze.

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Anorectal Asymmetry Index (ASI)

We tested the ASI in two forms: binary symmetry index (binary ASI) and grayscale anorectal symmetry index (grayscale ASI). In geometric terms, the binary ASI determines how much a given shape is symmetric (e.g., circle/square have perfect symmetry (i.e., ASI=0) assuming only horizontal and vertical rotations). On the other hand, the gray scale ASI is a measure of the shape differences along with the difference in pressures within the region of anal sphincter HPZ (Figure 2). In order to obtain the binary/grayscale ASI, a binary HDAM image (mask) is first created by thresholding the HDAM image to obtain the shape of the anal HPZ (Figure 3E). In detail, 10 isolines of the HDAM image were extracted using Matlab's in-built contouring algorithm (Figure 3B). At the same time, a 2-level thresholding using Otsu thresholding method[16] was applied, as shown in Figure 3C. The isocontour region, which contained the largest area of the Otsu's labeled region, was chosen as the final boundary of the anal sphincter region, delineating both abdominal and atmospheric pressures from the anal HPZ (Figure 3E). In order to calculate the ASI, horizontal reflective symmetry is first calculated by flipping the HDAM image horizontally and subtracting it from itself (Figure 2). Next, the same is also carried out in the vertical direction. Finally, the ASI is defined as the *mean sum of horizontal and vertical reflective symmetry* of the anorectal manometry topographic image. If a shape is symmetric, the ASI would be 'zero' (e.g., similar to a centered square (or circle) as shown in Figure 2A. In order to obtain the binary ASI, a binary HDAM image (mask), created as discussed previously is used on its own to calculate the ASI index, (Figure 3E) or it can be used as a mask on the original HDAM image to produce the grayscale ASI (Figure 3F) using the above process. The two ASI indices were calculated separately for both normal and patient groups during rest and squeeze, producing a combined total of 96 ASI binary and grayscale values.

Statistical Analysis

Non-parametric statistical hypothesis testing was used for statistical comparisons; the significance was defined as $P < 0.05$. Data are reported as median, interquartile range (IQR) and 95% confidence interval (CI) computed via bootstrapping. Logistic regression alongside discriminant analysis[17], both linear discriminant analysis (LDA) and quadratic discriminant analysis (QDA), are applied to predict the probability of a specific outcome (i.e., FI) based upon the explanatory HDAM predictors, to see which method yields the highest predictive power.

RESULTS

High Definition Anal Manometry Pressure

The 3D-HDAM cylindrical data were interpolated to 256×256 and cut along the posterior midline, and unfolded into a 2D rectangular grid. The different colors correspond to different pressures. Figure 4 shows the construction of 3D model of HDAM data in the normal and patient group. A 3D reconstruction of the anal pressure using the mean values at each one of the 256 registered sensors was done by combining all subjects in each group, separately for rest and squeeze, (Figures 4A & 4B for normal and Figure 4C & 4D for patients). These topographs reveal several important features as discussed below.

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Pressure Comparisons

Intra-Group Pressure—The peak pressure of each subject's HDAM image was extracted at rest and squeeze, which produced a single column, 24 rowed vector; comprising of rest and squeeze pressure values for each group. For the normal group, two sided Wilcoxon signed showed a statistically significant difference between median rest pressure of 99 (IQR=84.17) mmHg, 95% CI= [85.68 145.26] and median peak squeeze pressure of 279 (IQR=133) mmHg, 95% CI= [241, 341] (P<0.001). For patient group, the test also rejected the null hypothesis of equal medians at the 5% default significance level (p<0.001), having a rest median of 40 mmHg (IQR=27) with 95% CI= [33 55], and squeeze of 58 (IQR=43) mmHg, with 95% CI= [50, 78].

Inter-Group Pressure—The pressure variation across two groups was assessed using the Wilcoxon rank sum test. Median pressure values between the two groups were statistically different at rest (p<0.001), which was also the case for the squeeze (p<0.001).

Reflective Symmetry Comparisons

Intra-Group Binary Symmetry—The binary symmetry index was calculated for each subject within each group. Median ASI for the normal group at rest was −0.46 (IQR=0.22), CI= [−0.51 −0.36] and for squeeze −0.29 (IQR=0.16), CI= [−0.36 −0.24]. The difference between rest and squeeze was statistically significant for the normal group (p=0.002). However, this was not the case for patient group between rest and squeeze (p=0.64). Median ASI for the patient group at rest was −0.72 (IQR=0.45), CI= [−0.99 −0.58] and for squeeze −0.70 (IQR=0.44) with CI= [−0.89 −0.53]. The normalized difference of the rest and squeeze binary ASI was −0.38, compared to 0.03 for the patient group, indicating that the binary ASI can be a useful feature for distinguishing between normal and patients.

Inter-Group Binary Symmetry—The symmetry index was also compared between the two groups. The difference between normal rest and patient rest was statistically significant for the binary symmetry index, with p<0.001 for rest and also p<0.001 for squeeze.

Intra-Group Grayscale Symmetry—The grayscale symmetry index was calculated for each subject within each group. Median grayscale ASI for the normal group at rest was −43.03 (IQR=23.51), with CI= [−53.93 −35.55] and for squeeze −89.23 (IQR=43.57), CI= [−97.58 −69.16]. The difference between rest and squeeze was found to be statistically significant for the normal group (p<0.001). This was also the case for the patient group between rest and squeeze (p= 0.014). Median ASI values for the patient group at rest was −49.30 (IQR=32.51), CI= [−63.56 −35.30] and for squeeze −67.64 (IQR=49.96) with CI= [−83.71 −51.05]

Inter-Group Grayscale Symmetry—The grayscale symmetry index was also compared between the two groups. The difference between normal rest and patient rest was found not to be statistically significant for the grayscale symmetry index, p= 0.4394 for rest states. However, the differences between normal and patient squeeze grayscale symmetry index was found to be statistically significant (p= 0.048).

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Area Comparisons

Anal HPZ area measurements were carried out on the binary images for each of the 48 subjects, at rest and squeeze (see Figure 3E), by multiplying number of pressure transducers within the segmented region and the surface area of one transducer (8 mm^2).

Intra-Group Area—Signed ranked test showed the difference between rest and squeeze areas was statistically significant for the normal group (p<0.001), which was also the case for the patient group (p<0.001). Median area for the normal group at rest was 12.3 (IQR=0.003) cm^2, CI= [12.295 12.298] and for squeeze 15.21 (IQR=1.24) cm^2, CI= [14.81 15.86]. Median area for the patient group at rest was 12.51 (IQR=0.12) cm^2, CI= [12.47 12.56] and for squeeze 13.71 (IQR=1.56) cm^2, CI= [13.09 14.19].

Inter-Group Area—Wilcoxon rank sum test revealed that the difference between normal rest and patient rest areas was statistically significant (p<0.01). This was also the case for the squeeze areas between the two groups (p<0.01).

Peak Pressure Displacement

The unfolded HDAM image is split in the mid anterior line into two equal halves. Next, the pixel (sensor point) of maximum pressure is found on each half, during rest and squeeze. Finally, the Euclidean distance between the peak pressure points between rest and squeeze is determined. This is carried out for all 48 subjects within the database. Ranked sum test showed that the difference between rest to peak squeeze displacement was statistically significant in the left plane. However, this was not the case for the right half plane (p=0.61). In the left plane of the normal group, median displacement going from rest to squeeze was 4 (IQR=3.25) pixels on a 16 by 16 grid, CI= [2.70 5] for normal and a median of 2.24 (IQR=3.3) pixels, CI= [1 4] for patients. The mean sum of left and right plane displacements were used an additional predictor in the analysis.

Classification Results

The feature vector comprised of each subject's peak pressure, anal HPZ area, ASI (binary) and ASI (grayscale), all at squeeze, and mean peak pressure displacement (mean sum of left and right halves displacements) going from rest to squeeze. Now, different statistical ranking criterions could be used for feature ranking[18]. For, example, using ROC [18](receiver operator characteristics curve and a random classifier slope), the prominent features were, peak pressure, ASI binary, area, ASI gray (all at squeeze), and peak displacement, respectively. The classification results are shown in Table 1. As can be seen in this table, the use of multiple predictors produces the lowest LDA results (row 20 of Table 1). For example, use of peak squeeze pressure produces a 0.0208 redistribution error and cross validation error. The resulting decision boundary is shown in Figure 5 for a pairwise combination of peak squeeze pressure, area, grayscale area and displacement predictors, respectively for a quadratic classifier.

The input of the logistic regression similar to LDA and QDA consisted of five predictors are shown in Table 1. In the latter, receiver operating characteristic (ROC) performance curves were generated by allowing the classification to be from only a single feature (e.g., squeeze

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pressure) to all of the features. The area under the ROC curve quantifies the overall ability of the test to discriminate between normal and patient groups. The prediction model using all of the features (48 by 4 matrix), produced the highest AUC score of 1 as shown in Table 1. This was followed by using only 2 features (48 by 2 matrix) comprised of squeeze pressure values and grayscale ASI values, which also yielded an AUC of 1. Using only a single predictor, peak squeeze pressure produced the highest score of 0.99, while the grayscale ASI produced the lowest AUC of 0.67.

FISI Score Vs HDAM Pressure

Increasing incontinence severity (FISI) correlated with lower HDAM rest and squeeze pressure, however the correlation was weak, producing a Pearson correlation coefficient of r = 0.34 (Figure 9B). This was also the case for the peak squeeze pressures, with a lower Pearson correlation coefficient of r = 0.28 as compared to rest (Figure 9D). The same process was also carried out, between the FISI and pressure values, only this time for the median (i.e., 50th percentile) instead of peak pressure. For the latter, the correlation dropped to r=0.08 for rest and r=0.24 for median squeeze pressure.

DISCUSSION

There are many advantages of recording anorectal pressure with the HDAM technique, 1) it utilizes solid state pressure sensors that have high fidelity, 2) it allows recording of pressures at high temporal and spatial resolution in both circumferential and axial direction, 3) pressures can be displayed as pseudo color plots, 4) one can calculate parameters such as length and area of the anal HPZ, which has been suggested to be different in patients as compared to normal subjects[19, 20], (shorter in patients) and, 5) it is also possible to study movements of the anal HPZ that may have pathophysiological relevance. The location of peak pressure in the anal HPZ changes between rest and squeeze may vary because different muscles contribute to the rest and squeeze anal pressure. The main goal of the study was to introduce a systematic platform, where FI patients could robustly be separated from normals. We sought simple, local (e.g., peak pressure) and global features (e.g., area) that would make good predictors of class membership for the classes we were trying to distinguish. We tested all of the above variables, for the first time, and used novel statistical methods to determine which parameters are useful by themselves and in combination to differentiate patients from normal subjects. One of the strengths of the proposed method is that, for any task the system ranks the importance of each of the features individually, as well as in combination with others, and eventually prunes the feature space, if a lesser number of predictor yields the same accuracy. The multi-predictor nature of the approach allows robust predictive power, especially due to class similarities, a single predictor fails to optimally separate the two classes. The anal canal pressure provides best discriminatory value, followed by pressure asymmetry, followed by anal canal area (all the former features being at squeeze), and movement of the anal canal. In fact 95% of patients have lower pressure at rest and squeeze compared to normal. The study by Bharucha[4] revealed that 73% of FI patients have lower anal canal pressure compared to controls. Earlier studies that utilized saline load test also show that the anal sphincter barrier is significantly weaker in patients compared to normal[21]. The difference between patients and normal is even bigger in our study compared to others

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because, **1)** our control group consists of nulliparous women; parity (vaginal delivery) is known to be associated with the possibility of injury to anal sphincter[22] and pelvic floor muscles, **2)** our controls are significantly younger than the patients; increasing age is likely to result in lower anal pressure and **3)** we only tested patients referred to a tertiary care center who may not be truly representative of all FI patients. One would require a case control study to determine the relative importance of each of the parameter in contributing towards the FI. The FISI, which is a subjective measure of the severity of fecal incontinence[15] is significantly correlated with anal canal pressure, which again proves the importance of anal sphincter in anal incontinence.

The strength of including variables other than the pressure is that with those in the equation the discrimination between normal and patients is almost 100 percent. The input of the discriminant classifiers logistic regression consisted of five set of features were found to provide high discriminatory power between normal and patients yielding near perfect and perfect classification in discriminant and regression analysis, respectively. Both 10-fold cross-validation error and ROC (AUC) performance curves were generated by allowing the classification to be incremental from only a single feature (e.g., peak squeeze pressure) to the one containing all of features and revealed perfect separation between the two groups.

The HDAM has been in use for more than 5 years and others have used it to study functional anatomy of the anal canal[11], sensory motor control of defecatory reflex[13], normal values in healthy adults[12] and pediatric population[14]. The strength of our study is that in addition to pressure, we tested other variables that can be evaluated from the HDAM data and tested novel algorithm to differentiate patients from normal. With the use of these additional parameters such as the anal HPZ area and symmetry indices we find that the proposed model can be used to distinguish patient from and normal subjects more effectively. Future studies using age and parity matched controls with the methods proposed in this paper, should be able to determine the precise contribution of anal sphincter muscles to the anal incontinence.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Abbreviations

FI	fecal incontinence
FISI	fecal incontinence severity Index
HRAM	high-resolution anorectal manometry
3D-HDAM	three-dimensional high-definition anorectal manometry
HPZ	high pressure zone

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ASI	anorectal asymmetry index
LDA	linear discriminant analysis
QDA	quadratic discriminant analysis
LR	logistic regression
AUC	area under curve
ROC	receiver operating characteristic
IQR	interquartile range
CI	confidence interval

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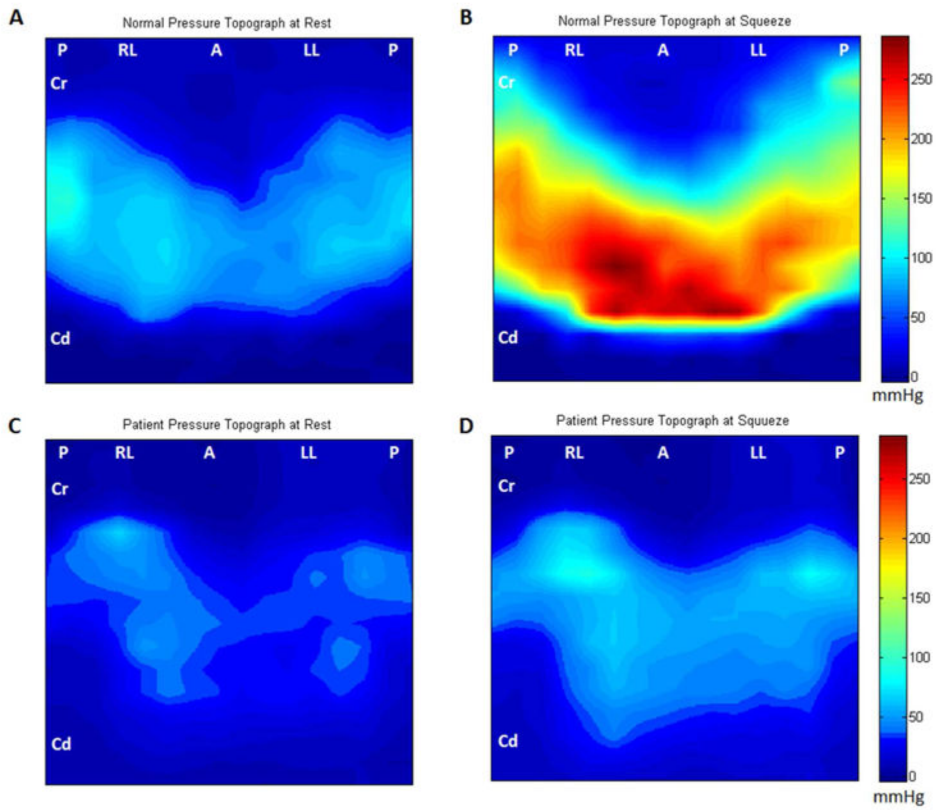

Figure 1.

Anal canal is split at the posterior midline to show surface plot view of the anal canal pressure topograph, (A) normal subject at rest, (B) a normal subject at squeeze, (C) a patient at rest, and (D) a patient at squeeze.

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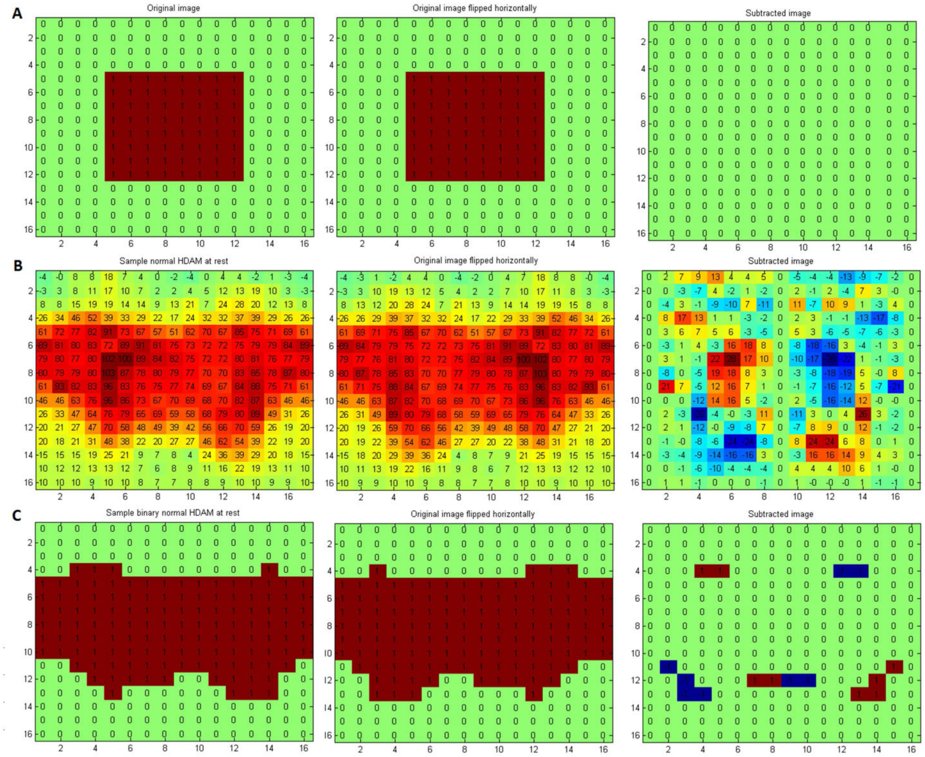

Figure 2.

ASI illustration, (A) the original image is flipped horizontally and the results subtracted from it, producing the top right subtracted image panel. (B) similar to panel A, however this time on a raw unfolded HDAM image during rest, (C) the binary ASI is also extracted in a similar way, however, this time only the binary mask prior to the calculation.

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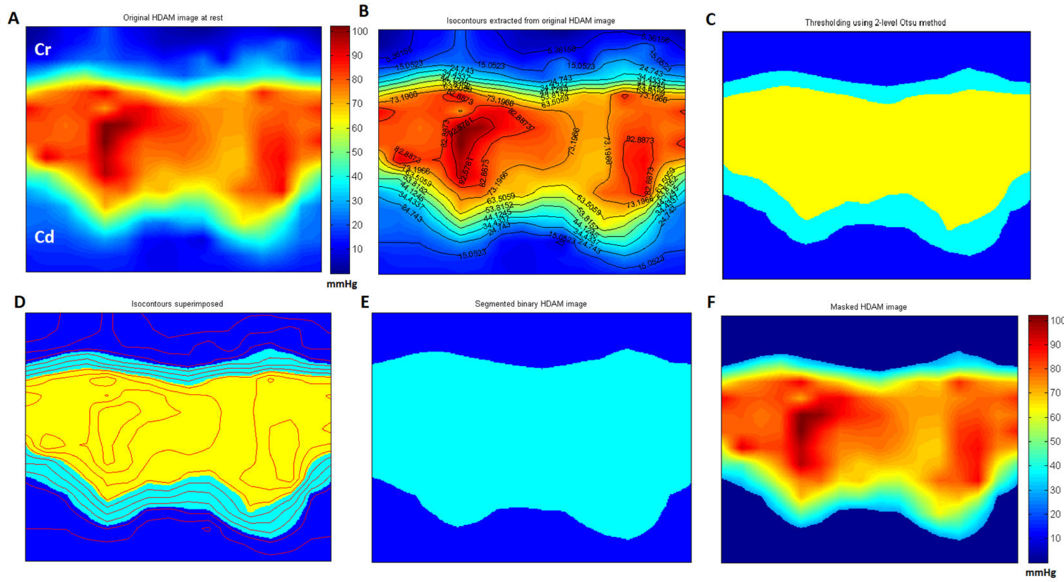

Figure 3.

(A) HDAM image, (B) 10-level isocontour overlaid on the original image, (C) thresholded image of (A) using a 2-level thresholding using Otsu's method, (D) isocontours of (B) superimposed on the result of Otsu's method, (E) final segmented image (mask), (F) masked original image.

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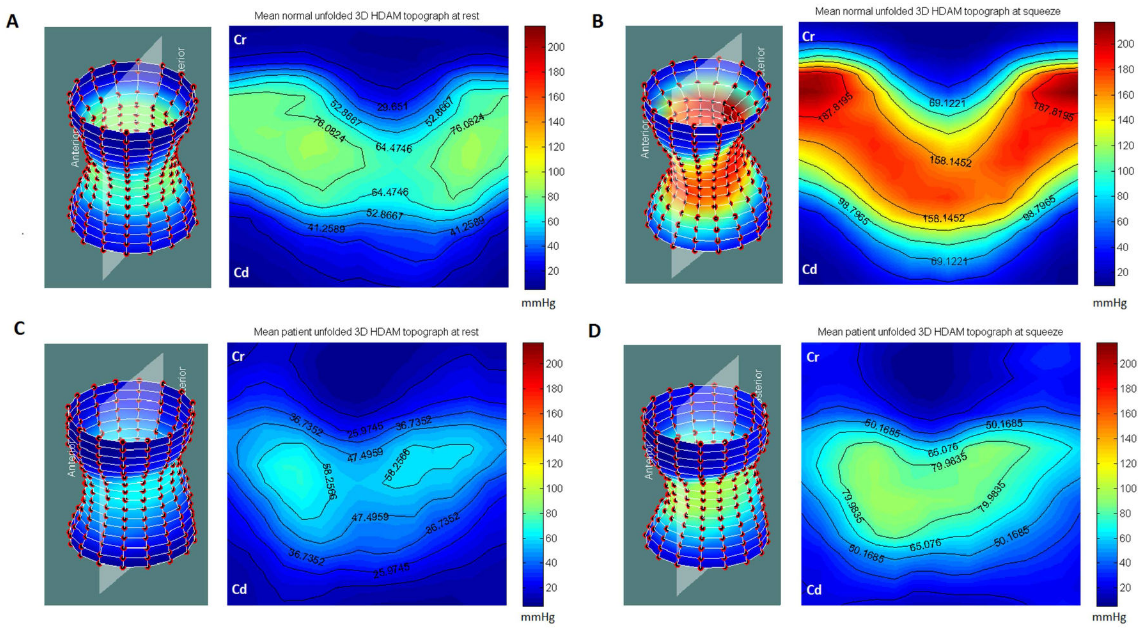

Figure 4.

Composite mean pressures at rest and squeeze for all 24 normals, (A) rest (B) squeeze and for all 24 patients, (C) rest, (D) squeeze. Note, on the left hand side of each panel, a three-dimensional (3D) reconstruction of the anal canal during rest and during squeeze, alongside its unfolded version, for better visualization of the pressure distribution.

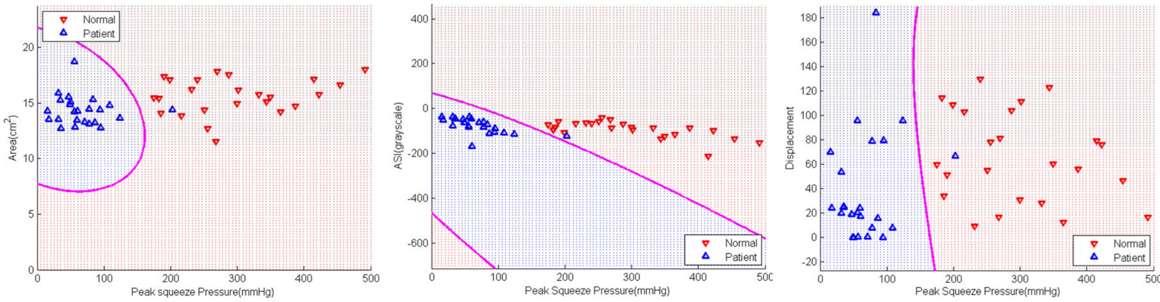

Figure 5.

QDA classification of normal and patient groups using different discriminant feature pairs; peak squeeze pressure, anal sphincter HPZ area, grayscale anorectal symmetry index (ASI), and peak pressure displacement.

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Table 1

Classification results of discriminant analysis and logistic regression carried out on both groups.

	HDAM Features					Redistribution Error		Cross validation Error		AUC
	Pressure	Area	ASI(binary)	ASI(gray)	Displacement	LDA	QDA	LDA	QDA	LR
1	1	0	0	0	0	0.04	0.02	0.04	0.02	0.99
2	0	1	0	0	0	0.29	0.29	0.29	0.29	0.75
3	0	0	1	0	0	0.19	0.19	0.23	0.17	0.92
4	0	0	0	1	0	0.38	0.42	0.38	0.42	0.67
5	0	0	0	0	1	0.40	0.40	0.40	0.40	0.69
6	1	1	0	0	0	0.06	0.02	0.06	0.04	0.99
7	0	1	1	0	0	0.17	0.15	0.15	0.19	0.93
8	0	0	1	1	0	0.08	0.08	0.17	0.10	0.95
9	0	0	0	1	1	0.31	0.29	0.38	0.42	0.75
10	0	1	0	1	0	0.29	0.25	0.29	0.29	0.77
11	0	1	0	0	1	0.23	0.25	0.29	0.33	0.78
12	1	0	0	1	1	0.02	0.02	0.04	0.04	1
13	1	0	0	0	1	0.04	0.02	0.04	0.02	1
14	0	1	1	1	0	0.13	0.10	0.17	0.17	0.96
15	0	1	1	1	1	0.15	0.15	0.17	0.01	0.97
16	1	1	1	0	0	0.02	0.02	0.02	0.04	1
17	1	1	0	1	0	0.02	0.02	0.04	0.04	1
18	1	1	0	1	1	0.02	0	0.02	0.04	1
19	1	1	0	0	1	0.02	0.02	0.02	0.04	1
20	1	1	1	0	1	0.02	0.02	0.04	0.003	1
21	1	1	1	1	1	0.02	0.02	0.02	0.04	1