Chapter 3

Prediction of findings at defecography in patients with genital prolapse.

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Abstract

Objective: Defecography may be useful in surgical planning of patients with genital prolapse as it enables identification of enterocele and/or rectal intussusception. Although defecography is an invasive and embarrassing procedure for patients, little effort has been made to optimalize selection criteria to demand for defecography or not in the individual patient. We performed this study to investigate whether discrimination of high and low probability of abnormal defecography is possible based on the quantified value of findings from patient history, pelvic examination and a validated questionnaire.

Methods: Of 82 patients with descensus uteri stage II-IV (ICS classification) a history and quantitative measurement of the genital prolapse were obtained. A validated questionnaire was used to assess the presence of defecation and micturition symptoms. Using multivariate logistic regression analyses with Receiver Operating Characteristic (ROC) curves, a diagnostic model to predict the presence of an abnormal defecography was systematically constructed and validated.

Results: The most important predictors for an abnormal defecography were quantification value (QV) of rectocele, history of abdominal or pelvic surgery and constipation. With these variables a prediction rule (3 + 3*history of pelvic surgery + QV of rectocele + 3*constipation) could be constructed that confidently predicts the prevalence of an abnormal defecography (Area Under Curve = 0.73 (95 % CI : 0.61 – 0.83)).

Discussion: This study shows that a diagnostic model based on findings obtained from a non-invasive work-up can accurately predict the presence of an abnormal defecography. Such a model provides the possibility to better consider the decision to demand for defecography in the individual patient.

Introduction

Patients with prolapse of the uterus have a high prevalence of micturition and defecation symptoms.[1] These symptoms may be due to anatomical abnormalities of the anterior and posterior compartment associated with a descending uterus. Failure to identify these abnormalities in the diagnostic process, may lead to incomplete surgical repair. As a consequence, persistent or recurrent micturition and defecation symptoms may occur. Defecography can play an important role in the evaluation of posterior compartment abnormalities, as it enables identification of clinically unsuspected abnormalities and coexisting defecation disorders.[2,3] Defecography provides a dynamic assessment of the defecation process by recording the rectal expulsion of a barium paste that approximates the consistency of feces.[4]

Most studies evaluating the prevalence of defecographic abnormalities are performed in patients with common defecation symptoms, such as constipation or incomplete evacuation of the rectum. Studies evaluating defecographic abnormalities in patients with genital prolapse are scarce. Kelvin and co-workers have shown that the prevalence of defecographic abnormalities is high in patients with genital prolapse, especially in those patients who have defecation symptoms.[2,3] The authors concluded from these findings, that defecography is useful in the pre-operative evaluation of patients with genital prolapse.

Although defecography is an invasive and embarrassing procedure for patients, little effort has been made to optimize selection criteria for defecography in the individual patient. This study was performed to investigate whether the presence of an abnormal defecography in patients with genital prolapse can be predicted based on findings derived from a non-invasive diagnostic work-up.

Methods

Patients

This study is based on data obtained from a multi-center randomized controlled trial comparing vaginal and abdominal prolapse surgery in patients with descensus uteri grade II – IV (according to the classification of the International Continence Society[5] (ICS)). Eighty-two patients were enrolled in this trial between January 1998 and January 2000. The study protocol was approved by the institutional review boards of the three participating hospitals (University Medical Center in Utrecht, Diaconessenhuis in Utrecht

and St. Antonius Hospital in Nieuwegein) and informed consent was obtained from all patients.

Measurements

Each patient underwent before surgery a standardized urogynecologic interview and a complete physical examination, including a classification of the genital prolapse based on the recommendations of the ICS.[5] The ICS classification system involves quantitative measurements allowing a more precise description of the extent of the genital prolapse. These quantitative measurements are normally performed by assessing the distance between six defined points and one fixed reference point (the hymen). As using all six defined points was not very practical, in this study three defined points were used to assess the quantification value (QV) of respectively descensus uteri, cystocele and rectocele. These points were the following: 1) A point that represented the most distal edge of the cervix, 2) A point located in the midline of the anterior vaginal wall 3 cm proximal to the external urethral meatus, 3) A point located in the midline of the posterior vaginal wall 3 cm proximal to the hymen. Quantifications values were assessed by measuring the distance of these points in centimeters above or proximal to the hymen (negative number), or centimeters below or distal to the hymen (positive number), with the plane of the hymen being defined as zero. The ICS classification assigns stages of descensus uteri, rectocele and cystocele according to the measured QV. Stage 0 corresponds to a QV -3 cm, stage I corresponds to a QV > -3 cm but < -1 cm, stage II corresponds to a QV -1 cm but +1 cm, stage III corresponds to a QV > +1 cm but +6 cm and stage IV corresponds to a QV > +6 cm. By ICS definition, the QV of a rectocele and cystocele is between –3 cm and +3 cm. In this study, the QV of descensus uteri was -1 cm or more, as only patients with descensus uteri stage II or more were included.

All patients completed a questionnaire to assess the presence of defecation and micturition symptoms one to three weeks before surgery. The questionnaire consisted of questions selected from the Defecatory Distress Inventory (DDI) and from the Urogenital Distress Inventory. The DDI is a questionnaire developed by our group to assess the presence of defecation symptoms. The DDI consists of 15 items referring to symptoms of obstructive defecation, constipation, fecal incontinence and pain related to defecation. The questions were developed prior to this study and are based on literature and international definitions, interviews with patients who suffered from constipation or fecal incontinence, and on interviews with three experts in the field from the Department

of Surgery and Department of Obstetrics and Gynecology from the University Medical Center Utrecht, The Netherlands. Eventually, a structured interview using the 15 selected items was held with 20 female patients. Questions concerning micturition symptoms were selected from the Urogenital Distress Inventory (UDI).[6] In Appendix A the questions that were selected from the DDI and UDI to assess the presence of defecation and micturition symptoms are presented.

Technique of defecography

All defecographies were performed 1 to 3 months before surgery at the Radiology Department of the University Medical Center Utrecht, the Netherlands. The technique that was used was based on the method described by Mahieu et al.[4] In addition, the vagina was opacified by applying a contrast medium consisting of 30 ml amidotrizoic acid 50 % solution gel, using a syringe with a soft pediatric enema tip. To assess the magnification factor, a midline radiopaque metric ruler was fixed between the buttocks. After sufficient filling of rectum and vagina, the patient was asked to sit on a radiolucent commode. This commode was covered by a water-filled motor scooter tube to cut out flare in the lower part of the image. The whole defecography procedure was recorded on video. All recordings were taken from the left lateral position.

Scoring of defecographic items

All defecographic recordings were analyzed by two of the authors. No information about the patient was made available to them during observation of the defecographies. Before the measurements were started, 10 defecographies, that were not included in the analysis, were observed and discussed until consensus about all definitions was achieved. The inter-observer agreement of the defecographic items scored in this study had been recently studied by our group. The weighted Kappa values for quantification value of enterocele and rectal intussusception were respectively 0.97 (95 % CI 0.93 to 1.00) and 0.91 (95 % CI 0.79 to 1.00). In case of disagreement about the scoring of a defecography, both observers discussed their scorings and came to consensus.

In case an enterocele or rectal intussusception was found at defecography this defecography was considered to be abnormal. An *enterocele* was defined as a peritoneal sac (normally filled with loops of small bowel) that has herniated downwards along the ventral rectal wall.[2] To consider an enterocele present the peritoneal sac should extend to below the top of the vagina. *Rectal instussusception*, or internal procidentia, was defined as an intussusception of the rectal wall, which begins as a circular fold 6 to 8 cm up in the rectum and develops into a condition in which the entire rectal wall folds in towards the

rectal lumen[7]. During straining, the “infolding” progressess and deepens to form a ring pocket. When such a ring pocket is seen at defecography, a rectal intussusception is considered to be present.

Statistical analysis

The aim of the analysis was to investigate whether findings at pelvic examination and reported defecation symptoms can predict the presence of defecographic abnormalities. First, the association between each diagnostic variable and abnormal defecography was quantified using univariate logistic regression analyses. Continuous variables were initially included in the model without categorization as a linear relation was plausible, but various cut-off values and transformations (square root, log) were evaluated.[8] Subsequently, predictors that were univariately associated with the outcome (odds ratio with a p-value < 0.15) were included in a multivariate logistic regression model to evaluate their independent value in the prediction of outcome.[8] Model reduction from this overall model was then performed by excluding variables with p-value > 0.10. This yielded a reduced model. A multivariate model can be considered as one “combined diagnostic test” including several diagnostic findings, with the estimated probability of presence of abnormal defecography as its “test results”.

The reliability (goodness of fit) of the final diagnostic model was quantified by the Hosmer & Lemshow test[9] and the diagnostic ability was quantified using the area under the Receiver Operating Characteristic curve (ROC area).[8,10] An area under the ROC-curve of 0.5 implies that the diagnostic test under study has a discriminatory capacity that does not exceed chance, whereas an area under the ROC-curve of 1 implies that the discriminative capacity of the test under study is perfect. Differences in discriminative value between models were estimated by differences in ROC area with 95 % confidence interval (CI), taking into account the correlation between models as they were based on the same cases.[11]

Of the 82 enrolled subjects, 5 had missing values on one or more variables. To decrease bias and increase statistical efficiency[12], these missing values were filled in (imputed) using the expectation maximization method (SPSS, version 10.0). This method uses all available data to impute the missing values, based on the correlation between each variable with missing values and all other variables.

Next, random bootstrapping techniques were used[8,13] to validate the model and to adjust for overly optimistic estimates of the regression coefficients (or odds ratios) of the included predictors.[8] In this way, the prognostic ability of the model in future but similar

patients is estimated. The final model was then transformed into a scoring rule by dividing the regression coefficients of the included predictors by the smallest regression coefficient. To improve practical application of this rule, these coefficients were rounded to the nearest integer. As the ROC area reflects only the overall discriminative value of a model and not directly its clinical value in terms of absolute patient numbers[14], we additionally estimated the number of correctly and falsely diagnosed patients across various categories of the model's estimated probability.

Table 1. Characteristics of all patients (n=82).

Age (years)	56.4	(10.0)
Parity (number of delivered children)	2.6	(1.1)
Body Mass Index (kg/m^2)	25.2	(3.3)
Prior abdominal or pelvic surgery (n) *	17	(20.7 %)
Cholecystectomy	5	
Appendectomy	7	
Caesarean section	5	
Adnex extirpation	1	
Anterior and / or posterior repair	4	
Burch colposuspension	1	
Defecation Distress Inventory (n)		
Constipation	22	(26.8 %)
Feeling of incomplete evacuation	20	(24.4 %)
Incontinence for flatus	46	(56.1 %)
Incontinence for liquid or solid stools	14	(17.1 %)
Painful defecation	15	(18.3 %)
Difficulty emptying rectum	14	(17.1 %)
Urogenital Distress Inventory (n)		
Frequency	53	(64.6 %)
Urgency	55	(67.1 %)
Stress incontinence	45	(54.9 %)
Urge incontinence	40	(48.8 %)
Mixed incontinence	56	(35.4 %)
Difficulty emptying bladder	37	(45.1 %)
Findings at defecography (n)		
Normal defecography	56	(68.3 %)
Abnormal defecography	26	(31.7 %)
Enterocele	23	(28.0 %)
Rectal intussusception	9	(11.0 %)
Enterocele and rectal intussusception	6	(7.3 %)

Values are means (standard deviation) or numbers (percentage).

* Some patients had undergone more than one surgical procedure.

Results

Table 1 shows the baseline characteristics as well as the results of the DDI, UDI and defecography. Twenty-six (31.7 %) patients had an abnormal defecography. Six (7.3%)

patients had an enterocele and rectal intussusception at defecography. Findings at pelvic examination are shown in Table 2. Both stage and quantification value of descensus uteri, cystocele and rectocele are reported.

Table 2. Findings at pelvic examination before surgery

	Grade	Number of patients	Quantification Value	Number of Patients
Descencus of uterus	II	67	-1	13
			0	46
			1	8
	III	15	2	12
			3	3
Cystocele	0	2	-3	2
	I	8	-2	8
	II	38	-1	1
			0	22
			1	15
	III	34	2	25
			3	9
Rectocele	0	17	-3	17
	I	37	-2	37
	II	23	-1	5
			0	15
			1	3
	III	5	2	3
			3	2

Results of the univariate analyses are shown in Table 3. Odds ratios (ORs) for quantification values of descensus uteri, rectocele and cystocele as obtained from pelvic examination, express the increased odds for abnormal defecography per centimeter of prolapse. For example, the odds for abnormal defecography increases with about 40 % for every centimeter of additional descent of a rectocele. ORs for defecation symptoms express the odds that an abnormal defecography is found in a patient with a specific symptom in comparison to a patient without that symptom. In univariate analyses history of pelvic surgery, quantification value of rectocele and constipation were associated with the presence or absence of normal defecography. Other variables were not associated, neither when analyzed as continuous parameters nor after dichotomization at any value.
Multivariate analyses showed that all 3 (univariately) associated variables were predictors of abnormal defecography. None of the interactions between the determinants that were tested showed statistical significance in the multivariate analyses. The odds ratios and

Table 3. Univariable and multivariable analysis of the association of findings rom patient history, pelvic examination and DDI and UDI questionnaire with presence of rectocele or rectal intussusception at defecography.

	Univariable analysis			Multivariable analysis			
	OR	95 % CI	P-value	ß ¶	OR	95 % CI	P-value
Intercept				- 0.89			
Medical history							
Age (per year)	0.97	0.93 – 1.02	0.25				
BMI (per kg/m²)	1.04	0.90 – 1.20	0.62				
Parity (per child)	1.01	0.66 – 1.55	0.95				
History of abdominal or pelvic surgery	3.71	1.20 – 11.49	0.02	1.34	3.83	1.13 – 13.00	0.03
Pelvic examination							
QV of descensus uteri (per cm)	1.31	0.85 – 2.04	0.22				
QV of cystocele (per cm)	0.97	0.72 – 1.30	0.82				
QV of rectocele (per cm)	1.42	1.03 – 1.94	0.03	0.40	1.49	1.06 – 2.09	0.02
Defecation symptoms assessed by DDI							
Constipation	3.00	1.08 – 8.32	0.04	1.13	3.10	1.03 – 9.38	0.05
Feeling of incomplete evacuation	1.63	0.57 – 4.65	0.36				
Incontinence for flatus	0.88	0.34 – 2.23	0.78				
Incontinence for liquid and solid stools	0.84	0.24 – 2.97	0.78				
Painful defecation	1.57	0.49 – 4.99	0.45				
Difficulty emptying rectum	1.80	0.55 – 5.86	0.33				
Micturition symptoms assessed by UDI							
Frequency	0.96	0.37 – 2.60	0.96				
Urgency	0.89	0.33 – 2.43	0.82				
Stress incontinence	1.70	0.66 – 4.36	0.27				
Urge incontinence	0.59	0.23 – 1.51	0.27				
Mixed urinary incontinence	0.60	0.21 – 1.61	0.30				
Difficulty emptying bladder	1.49	0.57 – 3.86	0.42				

DDI = Defecatory Distress Inventory; UDI = Urogenital Distress Inventory; OR = odds ratio; CI = confidence interval;
QV = quantification value; ß = regression coefficient.

regression coefficients of these independent predictors are presented in Table 3. After bootstrapping the regression coefficients of history of abdominal or pelvic surgery, QV of rectocele and constipation wre respectively 1.20, 0.35 and 1.01. The ROC of the model (as calculated with the regression coefficients obtained by bootstrapping) including all 3 variables was 0.73 (95 % CI: 0.60-0.86). Exclusion of a variable from this model significantly decreased the ROC area. Re-entering univariate non-significant variables in the multivariate model did not statistically improve the ROC area. The reliability of the model was fair (p-value of the Hosmer & Lemeshow test > 0.30).

Table 4 shows for the model the distribution of patients with and without abnormal defecography across selected categories of the model's estimated probability. According to the developed prognostic model, 39% of all 82 patients had a probability of less than 20% to have an abnormal defecography. Sensitivity and specificity (reading Table 4 vertically), as well as predictive values (reading horizontally), can be obtained for different probability thresholds. For example reading the model vertically shows that in the probability group > 0.70, 19% of all 26 patients with abnormal defecography would be correctly classified (i.e. true positive rate or sensitivity). Whereas 2% of all 56 patients without abnormal defecography, would not (false positive rate). In the low probability group (p 0.20), 48% of all patients without abnormal defecography would be correctly classified (true negative rate or specificity), whereas 19% of all patients with abnormal defecography would be missed (false negative rate). Reading the model horizontally, in the high (p > 0.70) probability group 5 of the 6 patients had an abnormal defecography (i.e. the positive predictive value would be 83%), whereas in the low probability group 27 of the 32 patients did not have an abnormal defecography (i.e. the negative predictive value would be 84%).

Table 4. Absolute number of patients (%) with and without abnormal defecography according to the probability of abnormal defecography as estimated by the diagnostic model.

Score	Estimated probability	N	Abnormal defecography	Normal defecography
0 - 1	0.20	32 (39)	5 (19)	27 (48)
2 - 4	0.21 – 0.40	29 (36)	7 (27)	22 (39)
5 - 7	0.41 – 0.70	15 (18)	9 (35)	6 (11)
8 - 10	> 0.70	6 (7)	5 (19)	1 (2)
	Total	82	26	56

The model was transformed to a more easily applicable diagnostic rule by dividing the regression coefficient of each variable (Table 3) by 0.35 (the smallest regression coefficient) and rounding it to the nearest integer. By assigning points to each variable

present, a total score was computed for each individual patient using the following formula: 3 + 3*history of abdominal or pelvic surgery + QV of rectocele + 3*constipation. The three points were added to prevent a negative score in patients without a history of abdominal or pelvic surgery, who did not report constipation and had a QV of rectocele < 0 cm. Theoretically a patient can have a score from 0 to 12. For instance, a patient who did not undergo abdominal or pelvic surgery, had a rectocele descending until 1 centimeter above the hymen (QV = -1 cm) and reported constipation at the DDI received a score of 3 + 3*0 + -1 + 3*1 = 8. In our population the total score ranged from 0-10 and the ROC area of the rule was 0.73 (95 % CI : 0.61 – 0.83). The first column of Table 4 shows the score categories of the rule which corresponded to the probability categories of the prognostic model.

Sensitivity and specificity, for thresholds other than given in Table 4, can be obtained from Figure 1 which shows the cumulative distribution of patients with and without abnormal defecography across the entire score range of the rule. If one score-threshold would be used, for example a 2 (considering a score 2 a negative 'test'result indicating absence of abnormal defecography, and > 2 as a positive result indicating abnormal defecography presence), 23% of all patients with abnormal defecography would be missed (a sensitivity of 77%) and 52% of those without abnormal defecography would be correctly diagnosed (specificity of 52%).

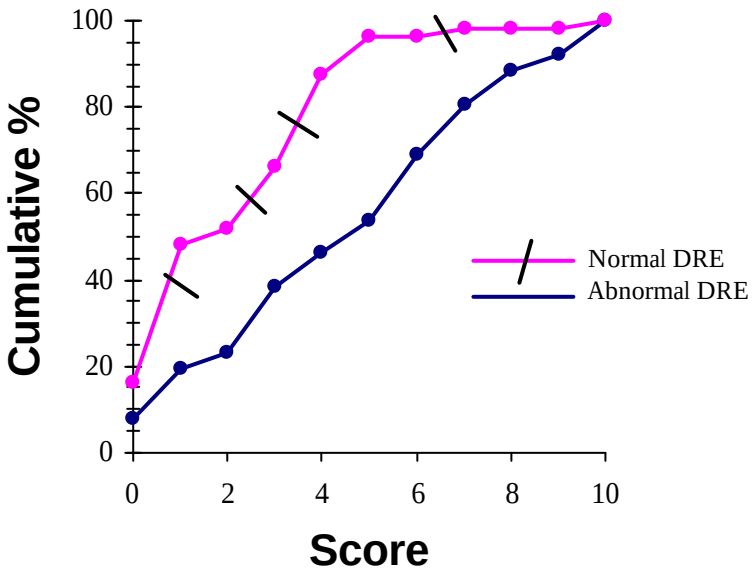

Figure 1. The cumulative distribution of patients with and without abnormal defecography, across all scores of the diagnostic rule including history of abdominal or pelvic surgery, quantification value of rectocele and constipation as assessed with the DDI.

Discussion

The aim of this study was to investigate whether the finding of an abnormal defecography in patients with descensus uteri stage II or more can be predicted by information obtained from less invasive assessments. We found that history of abdominal or pelvic surgery, QV of rectocele and constipation (as assessed by a questionnaire) are predictors of presence of abnormal defecography. The use of these few and simply obtainable parameters in the presented scoring rule enables the physician to identify a high probability group (probability > 70 % or score 8) in which 80 % have an abnormal defecography, and a low probability group (probability < 20 % or score 1) in which 84 % have a normal defecography. If gynecologists would decide not to demand a defecography for patients with a low risk of abnormal defecography (probability 0.20), in our population the number of defecographies would have been reduced by 39 %. A consequence of this decision is that in 5 (6 %) patients the diagnosis of abnormal defecography would have been missed.

Gynecologists planning surgery for a patient with genital prolapse perform defecography in case they prefer to be informed about the presence of an enterocele and/or rectal intussusception before surgery. Whether the detection of these anatomical abnormalities before surgery influences the treatment decision and improves outcome of treatment, has not been studied. As long as the exact diagnostic value of defecography has not been established, gynecologists may be expected to consider in which patients they demand for defecography and in which patients not. This consideration is also warranted because patients experience defecography as an embarrassing and bothersome procedure. To provide a tool that may help in the consideration to demand for defecography or not, we investigated whether the presence of defecographic abnormalities can be predicted in patients that are to be operated on for genital prolapse. All patients in this study had a descensus uteri grade II or more (according to the ICS classification). The observed prevalence of enteroceles (28 %) and rectal intussusception (11 %) in this study are similar to those reported by others who studied patients with genital prolapse.[2,15,16]

A defecography was defined as abnormal when an enterocele and/or rectal intussusception was detected. One may argue that a rectocele larger than 2 centimeter should also de defined as abnormal. Indeed, rectoceles of this size are considered to be an abnormal finding at defecography[17,18], but they are not likely to be missed at pelvic examination.[2,19] As a consequence, gynecologists will not have their patients undergo defecography to detect such a rectocele. Potential predictors of abnormal findings at

defecography were medical history, findings at pelvic examination, defecation and micturation symptoms. The predictive values of 19 parameters were studied. The predictive value of history of abdominal or pelvic surgery was studied as several studies have related the presence of an enterocele to previous abdominal or pelvic surgery.[20-22] We decided to analyze the quantification value of descensus uteri, cystocele and rectocele rather than their stage, as a quantified measurement is more precise. As pelvic examination has been shown to have a poor diagnostic performance to detect an enterocele or a rectal intussusception[2,3,23,24], we did not score the presence of either of these anatomical abnormalities at pelvic examination. The predictive value of defecation symptoms was evaluated, as many studies have shown a relation between these symptoms and abnormal defecography.[3,19,25-27] In contrast to these studies, we used a questionnaire to assess the prevalence of defecation symptoms. The main advantage of a questionnaire is that it assesses the presence of symptoms in a more standardized way than an interview does. The decision to study also the predictive value of micturition symptoms, was based on studies that have related the formation of an enterocele to damage of the pudendal nerve.[21,28] As micturition symptoms may result from damage of the pudendal nerve[29,30], the presence of micturition symptoms could predict the presence of abnormal defecographic findings.

A history of abdominal or pelvic surgery was an important predictor of abnormal defecography. It has been suggested that enterocele development following pelvic surgery may result from damage to the pudendal nerve and pelvic floor musculature.[21,28] Alternatively, abnormal defecography after abominal or pelvic surgery may result from constipation, which can be caused by damage to the pelvic floor innervation during surgery. The pelvic floor could then descend and become funnel-shaped, causing the anterior wall to incur most of the expulsive forces which may ultimately lead to rectal intussusception.[31,32]

Rectocele at pelvic examination appeared to be another important predictor of abnormal defecography. This confirms earlier findings that both enterocele and rectal intussusception are associated with a rectocele.[31,33] The observation that constipation was a predictor of abnormal defecography, confirms the findings of others who have related constipation to both the presence of an enterocele and a rectal intussusception.[2,19,25-27] As the questionnaire used in this study to assess the prevalence of defecation symptoms is new (results of validation studies have been recently submitted), one may question the validity of the measurements. However, all definitions used were based on the literature

and are widely accepted in the field.[34-36] None of the studied micturation symptoms appeared to importantly predict abnormal defecography.

Validation of the model by bootstrapping techniques demonstrated that the prediction rule is robust. However, before implementating the model in clinical practice, the actual performance of this scoring rule should be proven by using this rule in another group of women with descensus uteri.[13,37]

In conclusion, this study shows that a diagnostic model based on findings obtained from a non-invasive diagnostic work-up, can predict the presence of an abnormal defecography. Practitioners should realize that defecography is an invasive and embarrassing procedure to undergo. As a consequence, they are obliged to strongly consider for each individual case whether a defecography is warranted or not. Our prediction model may importantly contribute to this consideration.

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