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ORIGINAL ARTICLE

Balloon expulsion testing for the diagnosis of dyssynergic defecation in women with chronic constipation

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Abstract
Introduction and hypothesis Dyssynergic defecation can be difficult to diagnose. Anorectal manometry and defecography are often used to make this diagnosis. However, these tests are expensive and require expertise. Balloon expulsion testing may be a simple alternative. We compared balloon expulsion to anorectal manometry and defecography for diagnosing dyssynergia in women with chronic constipation.
Methods We conducted a retrospective review. All women presenting for evaluation of chronic constipation who underwent concurrent balloon testing, manometry, and defecography were included. A diagnosis of dyssynergic defecation was established by either defecography revealing prolonged/incomplete rectal evacuation and/or by manometry revealing paradoxical contraction/inadequate relaxation of the pelvic floor. Inability to expel a 50-ml balloon defined dyssynergic defecation by balloon testing. Sensitivity, specificity, and predictive values were calculated.
Results A total of 61 women met inclusion criteria. Mean age was 50 years. There were 36 women (59 %) who met Rome III criteria for dyssynergic defecation on defecography and/or manometry. Only 12 of these 36 (33 %) were similarly diagnosed by balloon testing. The sensitivity and positive predictive value of balloon testing for dyssynergia were 33 and 71 %, respectively. Of the 25 (41 %) women who did not meet Rome III criteria for dyssynergia on defecography and/or manometry, 20 (80 %) also had negative balloon testing. Thus, the specificity and negative predictive value of balloon testing for diagnosing dyssynergia were 80 and 50 %, respectively.
Conclusions In our population, balloon expulsion was not an ideal screening test for dyssynergic defecation in women with constipation. Multimodal testing is necessary for more accurate diagnosis.

Keywords Dyssynergia · Balloon expulsion · Defecography · Manometry

Introduction

Chronic constipation is a common and often debilitating condition. Approximately 63 million people in North America meet Rome criteria for chronic constipation with prevalence estimates ranging from 2 to 27 % [1]. The causes of chronic constipation are often subdivided into two broad categories: delayed transit through the colon and impaired evacuation of the rectum [2]. Impaired rectal evacuation can either be mechanical or more commonly functional. Functional defecation disorders are characterized by paradoxical contractions or inadequate relaxation of the pelvic floor muscles during attempted defecation. This is also known as pelvic floor dyssynergia or dyssynergic defecation [3]. The prevalence of dyssynergic defecation among patients with chronic constipation ranges widely depending on the study reviewed and diagnostic test used [4].

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The Rome III criteria for dyssynergic defecation are outlined in Table 1. In addition to meeting the diagnostic criteria for functional constipation, the Rome criteria require evidence, on dynamic testing, of at least two of the following: (1) impaired evacuation, (2) inappropriate contraction or impaired relaxation of the pelvic floor muscles, or (3) inadequate propulsive forces [5]. In the absence of alarm symptoms or a strong family history of colon cancer, dynamic anorectal testing is typically not necessary until patients have failed conservative treatment with dietary modification, physical therapy, or laxative therapy. This dynamic anorectal testing may include rectal balloon expulsion testing, defecography, and/or anorectal manometry. Although each of these diagnostic approaches has benefits and limitations, their testing characteristics lack rigorous evaluation and an appropriate diagnostic algorithm for pelvic floor dyssynergia is yet to be defined [4]. There is limited agreement about which test should be used to diagnose dyssynergia.

Anorectal manometry and defecography are two dynamic anorectal tests often used to make this diagnosis [4]. However, these tests are expensive and require expertise to perform. Balloon expulsion testing may be a simple and inexpensive alternative for screening if its sensitivity, specificity, and positive and negative predictive values were well known. Some prior studies in patients with functional constipation comparing balloon expulsion testing to more rigorous physiologic tests have revealed decently high specificity and negative predictive values [6]. We aimed to compare balloon expulsion testing to anorectal manometry and defecography for the diagnosis of dyssynergia in women with chronic constipation.

Table 1 Rome III criteria for functional defecation disorders[a]

Criteria
1. The patient must satisfy diagnostic criteria for functional constipation[b]
2. During repeated attempts to defecate must have at least two of the following:
(a) Evidence of impaired evacuation, based on balloon expulsion test or imaging
(b) Inappropriate contraction of the pelvic floor muscles (i.e., anal sphincter or puborectalis) or less than 20 % relaxation of basal resting sphincter pressure by manometry, imaging, or EMG
(c) Inadequate propulsive forces assessed by manometry or imaging

EMG electromyography

[a] Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

[b] Diagnostic criteria for functional constipation must include ≥2 of the following: (1) straining during at least 25 % of defecations, (2) lumpy or hard stools in at least 25 % of defecations, (3) sensation of incomplete evacuation for at least 25 % of defecations, (4) sensation of anorectal obstruction for at least 25 % of defecations, (5) manual maneuvers to facilitate at least 25 % of defecations, (6) fewer than three defecations per week. In addition, loose stools must be rarely present without the use of laxatives and there must be insufficient criteria for irritable bowel syndrome

Materials and methods

We conducted a retrospective cross-sectional study assessing women presenting with chronic constipation to the Division of Gastroenterology and Hepatology at Indiana University between January 2012 and January 2013. Any woman who underwent concurrent balloon expulsion testing, anorectal manometry, and defecography for a primary indication of chronic constipation was included in the analysis. Men, women who did not undergo all three tests, and women who did not have chronic constipation as the primary indication for testing were excluded from the analysis. This study was fully approved by the Institutional Review Board at Indiana University.

Eligible patients were identified by querying the electronic medical record used for data storage and analysis of all manometric studies (ProvationMD 5) at the Motility Lab at Indiana University Hospital. This allowed us to identify all high-resolution anorectal manometry studies conducted between January 2012 and January 2013. All of these patients also had balloon expulsion testing as part of their anorectal physiologic testing as this is the standard practice of our Gastroenterology Division. This group of patients was then cross-referenced against the Indiana University electronic imaging record (Synapse) to determine which patients also had defecography within a 3-month time frame. The results of all three diagnostic tests were reviewed to obtain pertinent clinical information and results were recorded. The ability to collect secondary demographic and clinical data was limited as clinical charts were not available for review. However, age, indication for testing, and specifics regarding manometry and defecography findings were available for review.

A diagnosis of dyssynergic defecation was then established by either defecography revealing prolonged/incomplete rectal evacuation and/or by anorectal manometry revealing paradoxical contraction/inadequate relaxation of the pelvic floor consistent with Rome III criteria. Defecography was performed in the seated position on a radiolucent commode and sequential fluoroscopic images were interpreted by one of two radiologists experienced in the technique. The small bowel was opacified with oral ingestion of barium liquid. The urinary bladder was opacified with 50 ml of Cystografin. A barium gel was inserted into the vagina and a barium paste, the consistency of stool, was inserted into the rectum. Static and dynamic images of the lateral pelvis were then obtained. Fluoroscopy was used to evaluate the evacuation phase with digital serial acquisition at 1 frame/s for 30 s. Prolonged or incomplete rectal evacuation (dyssynergic defecation) on

defecography was defined as the inability to evacuate at least two thirds of a rectal contrast enema within 30 s of attempted defecation, as previously described by Halligan et al. [7], unless the interpreting radiologist felt that contrast retention was independently caused by a significant structural abnormality, such as a large rectocele.

High-resolution anorectal manometry was performed and interpreted by one of three gastroenterologists experienced in the technique. A solid-state manometry catheter (Given ManoView System) with 12 circumferential sensors and a 4-cm balloon was placed through the anus with the patient in the left lateral position with the following configuration: 2 sensors inside the rectum and 10 circumferential sensors, at 0.6-cm increments, across the pressure zone of the anal canal. After 1 min of rest, anal resting and squeeze pressures were calculated and then bearing down maneuvers (attempted defecation) were performed at least twice. Dyssynergic defecation was diagnosed on high-resolution anorectal manometry with findings on attempted defecation of either: (1) increased rectal pressure with paradoxical increase of anal sphincter pressure, (2) impaired generation of rectal pressure with paradoxical increase of anal sphincter pressure, (3) increase in rectal pressure with inadequate (<20 %) anal sphincter relaxation, or (4) impaired generation of rectal pressure with inadequate (<20 %) anal sphincter relaxation [8].

A finding of dyssynergic defecation on either of these studies was then defined "presence of disease." This was then compared to the result of the balloon expulsion test performed in the seated position on a bedside commode. Inability to expel a 50-ml water-filled balloon from the rectum within 120 s of attempted defecation defined dyssynergic defecation by balloon expulsion testing. We were then able to perform sensitivity, specificity, and predictive value calculations comparing results of the balloon test to presence of disease. These were our primary outcomes. In addition, the result of the balloon expulsion test was compared to dyssynergic defecation defined by defecography alone and by anorectal manometry alone and similar calculations were performed. Also, rate of agreement between defecography and high-resolution anorectal manometry was assessed using the kappa statistic. Finally, prevalence of dyssynergia by each testing modality was calculated. Statistical analysis was performed using SPSS 22 statistical software.

Results

A total of 61 women referred for chronic constipation underwent concurrent balloon expulsion testing, defecography, and high-resolution anorectal manometry during our study period. The mean age of participants was 50 years (SD 16). All subjects had a primary indication of chronic constipation as the reason for testing. The majority of patients, 56 %, had all three tests performed on the same day, thus limiting the spectrum bias that can arise when evaluating diagnostic tests on a highly selected group (i.e., when the decision to proceed with a secondary test is based on the results of an initial test). In our population, the prevalence of dyssynergic defecation varied considerably based on the test used to establish the diagnosis. The lowest prevalence rate was seen with balloon expulsion testing at 28 % (17 of 61 women). The prevalence of dyssynergia was slightly higher with defecography at 33 % (20 of 61 women) and considerably higher with anorectal manometry at 46 % (28 of 61 women).

Of these 61 women, a total of 36 (59 %) met Rome III criteria for dyssynergic defecation on defecography and/or anorectal manometry, thereby meeting criteria for presence of disease. Only 12 of these 36 women (33 %) were similarly diagnosed by balloon expulsion testing. Thus, the sensitivity and positive predictive value of balloon expulsion testing for dyssynergia according to Rome III criteria were 33 and 71 %, respectively. Of the 25 (41 %) women who did not meet Rome III criteria for dyssynergia on defecography and/or anorectal manometry, 20 (80 %) also had negative balloon testing. Thus, the specificity and negative predictive value of balloon expulsion testing for excluding dyssynergia were 80 and 50 %, respectively (Table 2).

In addition, the result of the balloon expulsion test was also compared to dyssynergic defecation defined by defecography alone (Table 3) and by anorectal manometry alone (Table 4). In these instances, the testing characteristics of balloon expulsion for diagnosing dyssynergia were not significantly better than when the two gold standard tests were combined. The sensitivity and positive predictive value of balloon expulsion testing for diagnosing dyssynergia compared to defecography alone were 50 and 59 %, respectively. The specificity and negative predictive value of balloon expulsion testing for excluding dyssynergia compared to defecography alone were 83 and 77 %, respectively. The sensitivity and positive predictive value of balloon expulsion testing for diagnosing dyssynergia compared to anorectal manometry alone were 32 and 53 %, respectively. The specificity and negative predictive value of balloon expulsion testing for excluding dyssynergia compared to anorectal manometry alone were 76 and 57 %, respectively.

Finally, the measure of agreement between defecography and high-resolution anorectal manometry for diagnosing dyssynergic defecation in women with chronic constipation was found to be quite poor with a kappa statistic of 0.190.

Discussion

In this retrospective review of 61 women presenting to a single institution with symptoms of chronic constipation and undergoing concurrent testing for dyssynergic defecation, balloon

Table 2 Balloon expulsion testing vs presence of disease

Sensitivity=33 % Specificity=80 % Positive predictive value=71 % Negative predictive value=50 %		Dyssynergic defecation by anorectal manometry and/or defecography (presence of disease)	
		Yes	No
Dyssynergic defecation by balloon expulsion (test)	Yes	12	5
	No	24	20

expulsion was not an ideal screening test when compared to defecography and anorectal manometry. Although this test may be a simple and inexpensive alternative for screening for dyssynergia, it does not seem to be an accurate way to exclude this diagnosis. Accurate diagnosis is important because dyssynergic defecation can be effectively treated with pelvic floor physical therapy with sensory biofeedback [9]. While many patients with functional constipation may benefit from the empiric application of standard physical therapy practices such as pelvic floor muscle exercises and bowel education, patients with dyssynergia will often require more advanced techniques, including instrumented biofeedback. In addition, given that dyssynergia, perineal laxity, and prolapse often occur concomitantly in women with chronic constipation [10], establishing this diagnosis and offering appropriate treatment before any pelvic floor repair is essential. Appropriate preoperative treatment may significantly reduce the risk of recurrence of prolapse after surgical repair when persistent straining from dyssynergic defecation coexists. Physical therapy should always be offered as first-line treatment in women with concomitant dyssynergia and prolapse.

In our population, the overall prevalence of dyssynergia diagnosed by any single, abnormal, dynamic physiologic test ranged from 28 to 46 %, with balloon expulsion testing at the low end of that range. These prevalence rates are fairly consistent with those identified by Videlock et al. in their recent meta-analysis evaluating abnormal findings associated with dyssynergic defecation across testing modalities [4]. In that study, the overall prevalence of dyssynergia ranged from 15 to 53 %, depending on the diagnostic test utilized. They identified a pooled prevalence for abnormal balloon expulsion testing of 43 % which is slightly higher than the 28 % prevalence rate seen in our study. There were 19 studies evaluating balloon expulsion in their meta-analysis and this difference may be related to the heterogeneous populations included as well as the variety of definitions used for abnormal balloon expulsion testing.

At 33 and 71 %, respectively, the sensitivity and positive predictive value of balloon expulsion testing in our study for diagnosing dyssynergia were quite low when compared to diagnosis by either defecography and/or anorectal manometry. In addition, at 80 and 50 %, respectively, the specificity and negative predictive value of balloon expulsion testing for diagnosing dyssynergia were also low when compared to gold standard diagnosis by either defecography and/or anorectal manometry. None of these testing characteristics improved significantly when diagnosis by balloon expulsion testing was compared to diagnosis by defecography alone or anorectal manometry alone. The very low sensitivity and poor negative predictive value were largely driven by an extremely high false-negative rate, with 24 of the 36 women who met criteria for presence of disease having a negative balloon expulsion test. Thus, given this high false-negative rate, balloon expulsion testing may be an unreliable method to exclude the diagnosis of dyssynergic defecation. These findings are consistent with those of Bordeianou et al. in their recent study of 125 patients with functional constipation [11]. They established the diagnosis of pelvic floor dyssynergia by defecography and found a prevalence rate of 51 % (63 of 125). Only 33 of these 63 women also had abnormal balloon expulsion testing, resulting in a sensitivity of 52 % and a false-negative rate of nearly 50 %. They concluded that normal balloon expulsion testing does not exclude the presence of dyssynergia on defecography. In contrast, Minguez et al. prospectively evaluated 130 patients with functional constipation and had different results [6]. They chose to establish the diagnosis of pelvic floor dyssynergia in patients who showed an obstructive pattern of defecation by means of defecography plus anorectal manometry. They found a low prevalence of pelvic floor dyssynergia of 18 % (24 of 130). Of these 24

Table 3 Balloon expulsion testing vs dyssynergic defecation by defecography

Sensitivity=50 % Specificity=83 % Positive predictive value=59 % Negative predictive value=77 %		Dyssynergic defecation by defecography (presence of disease)	
		Yes	No
Dyssynergic defecation by balloon expulsion (test)	Yes	10	7
	No	10	34

Table 4 Balloon expulsion testing vs dyssynergic defecation by anorectal manometry

Sensitivity=32 % Specificity=76 % Positive predictive value=53 % Negative predictive value=57 %		Dyssynergic defecation by anorectal manometry (presence of disease)	
		Yes	No
Dyssynergic defecation by balloon expulsion (test)	Yes	9	8
	No	19	25

women, 21 also had abnormal balloon expulsion testing, resulting in a high sensitivity of 88 % and a low false-negative rate of 12 %. They concluded that balloon expulsion is a useful screening tool for excluding dyssynergia in patients with functional constipation. The strict criteria of abnormality on both defecography and manometry for establishing the diagnosis of dyssynergia certainly explains the lower prevalence rate in this study. This may have resulted in a fairly restrictive cohort of 24 patients with dyssynergia and subsequently an increased likelihood of positive balloon expulsion testing. Conversely, we may have overestimated the prevalence of dyssynergia in our study population by establishing the presence of disease with positive findings on either of the more complex physiologic tests. This may have resulted in bias which decreased the likelihood of positive balloon expulsion testing.

Given that a diagnostic algorithm for pelvic floor dyssynergia is not well defined and there is no consensus about which test should be used to diagnose dyssynergia, we also chose to assess overall agreement between our two diagnostic tests—anorectal manometry and defecography. In our study population, the agreement between these two studies for diagnosing dyssynergia was poor at 0.190. This is consistent with recent prospectively collected data that found poor association among the various diagnostic tests for dyssynergia as well as with data from Videlock et al.'s meta-analysis and with expert opinion [4, 10, 12]. This discordance is likely related to the extensive variability inherent in the performance and interpretation of these studies. While anorectal manometry is performed with the patient in the left lateral position and relies on pressure measurements, defecography is performed while seated and relies on two-dimensional radiographic images. Thus, it remains unclear which of these diagnostic tests should be used as a first line to make the diagnosis of dyssynergia and to direct the recommendation for treatment. We believe they are complimentary tests that provide different anatomic and physiologic information, intended to be used in conjunction with clinical history.

Limitations of this study include the retrospective design and small number of patients. In addition, although women presented with severe enough symptoms that their physicians felt testing was warranted, the diagnosis of functional constipation was not confirmed by Rome III criteria. However, we did use Rome III criteria to establish our definitions of dyssynergic defecation on defecography and anorectal manometry. Also, all diagnostic tests in our study were carried out and interpreted by physicians experienced in and comfortable with these complex diagnostic modalities. This level of expertise may not be universally available.

In conclusion, it remains unclear which diagnostic test(s) should be used to establish the diagnosis of dyssynergic defecation in women with chronic constipation. This significantly limits our ability to direct the recommendation for treatment. This may be due to the complex pathophysiology and phenotypic variability of outlet obstruction related to pelvic floor dyssynergia, and multimodal testing may be necessary for more accurate and nuanced diagnosis. For instance, while abnormal balloon expulsion testing may be sensitive enough to detect significant impairment of pelvic floor relaxation, more modest impairment or issues with rectal propulsion may go undetected. Further investigation, preferably with multicenter studies and clearly defined diagnostic criteria, is needed to determine the validity of each of these tests and would improve our ability to develop a diagnostic algorithm.

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Author contributions Dr. Kassis: protocol development, data collection and analysis, manuscript writing/editing, final approval. Dr. Wo: data acquisition, manuscript editing, final manuscript approval. Dr. James-Stevenson: data acquisition, manuscript editing, final manuscript approval. Dr. Maglinte: Data acquisition, manuscript editing, final manuscript approval. Dr. Heit: data analysis, manuscript editing, final manuscript approval. Dr. Hale: protocol development, manuscript editing, final manuscript approval.

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