Validation of the Balloon Evacuation Test: Reproducibility and Agreement With Findings From Anorectal Manometry and Electromyography

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BACKGROUND & AIMS: **The balloon evacuation test (BET) measures the time required to evacuate a balloon filled with 50 mL water; it has been incorporated into many algorithms for diagnosis of pelvic floor dyssynergia. We aimed to assess the reproducibility of the BET, determine the upper limit of normal, and assess its concordance with evaluation of pelvic floor dyssynergia by anorectal manometry (ARM) and pelvic floor surface electromyography (EMG).**

METHODS: **The BET was tested in 286 consecutive patients with chronic constipation (mean age, 44 years; 91% female) before and after 30 days of conservative treatment at a tertiary gastroenterology clinic in Italy from March 2010 through May 2012. The BET was tested twice, 7 days apart, in 40 healthy individuals (controls: mean age, 38 years; 92% female). The 238 constipated patients who responded incompletely to conservative therapy were examined by ARM, EMG, and digital rectal examination. Forty-seven patients with conflicting ARM and BET results underwent defecography.**

RESULTS: **The balloon was evacuated within 1 minute by 37 controls (93%; 3 individuals required 1–2 minutes). Among patients with constipation, 148 (52%) passed the balloon within 5 minutes (110 passed the balloon in 1 minute, 35 passed it in 1–2 minutes, and 3 passed it in 2–5 minutes). The BET showed perfect reproducibility in 280 of the patients with constipation (98%) when a time less than 2 minutes was set as abnormal. The level of agreement between BET and ARM for dyssynergia was 78%, and between BET and EMG it was 83%. Thirty-two patients had abnormal results from the BET but normal results from ARM; 31 cases had inadequate straining (n = 11) or anatomic defects (n = 20), which could account for the abnormal findings from BET.**

CONCLUSIONS: **The BET is reliable for analysis of pelvic floor dyssynergia; the optimal upper limit of normal is 2 minutes. Findings from the BET have a high level of agreement with those from ARM and EMG.**

Keywords: Disordered Defecation; Diagnostic Test; Obstructive Defecation; Screening.

The 2 defining symptoms of constipation are infrequent stools and difficult evacuation of stools from the rectum.[1,2] The balloon evacuation test (BET) has become one of the most commonly used tests for assessing defecatory dysfunction, and in combination with anorectal manometry (ARM), it is recommended for initial assessment of patients with refractory chronic constipation.[3] The test simulates defecation and is performed by attaching a lubricated balloon to the end of a flexible catheter, inserting it into the rectum, and inflating the balloon with water to simulate a soft, formed stool. The subject sits on a toilet in privacy and attempts to evacuate the balloon. The time required to pass the balloon is the dependent measure.

The most frequently cited study on the validity of the BET was published by Minguez et al.[4] These authors defined pelvic floor dyssynergia as an obstructive defecation pattern on both ARM and defecography, and they reported how well the BET agreed with this gold standard. The negative predictive value (NPV) of the BET was 97% (ie, a normal BET could be trusted to rule out pelvic floor dyssynergia), but the positive predictive value (PPV) was only 64% (ie, one-third of patients with pelvic floor dyssynergia were able to evacuate the balloon within 60 seconds). A limitation of the study by Minguez

Abbreviations used in this paper: ARM, anorectal manometry; BET, balloon evacuation test; EMG, pelvic floor surface electromyography; NPV, negative predictive value; PPV, positive predictive value.

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et al is that the balloon was filled until the subject felt a desire to defecate (at an average volume of 185 mL), whereas most studies have used a balloon volume of 50 mL; this is the only published study to use such high balloon volumes. Other studies also support the utility of the BET for distinguishing rectal outlet dysfunction from other causes of constipation.[5–7] All of these studies equated outlet dysfunction with pelvic floor dyssynergia, and the BET has been incorporated into algorithms for diagnosing pelvic floor dyssynergia by many professional societies: American College of Gastroenterology,[1] American Gastroenterological Association,[2] Rome Foundation,[8] and World Gastroenterology Organization.[9]

Despite widespread adoption as a diagnostic tool, there is limited standardization of how to carry out the BET.[10] Investigators have used varying volumes of water in the balloon ranging from 25 mL[11] to whatever volume is required to produce an urge to defecate,[4] and there is little standardization about the size, shape, or type of balloon. The upper limit of normal for BET has varied from 1 minute[11] to 5 minutes.[7] The aims of this study were (1) to assess the reproducibility of the BET after a 30-day interval, (2) to define the upper limit of normal balloon evacuation time, and (3) to validate the BET by comparing it with pelvic floor dyssynergia defined by ARM and pelvic floor surface electromyography (EMG) activity. An exploratory aim was to identify factors other than pelvic floor dyssynergia that may explain failed balloon evacuation.

Methods

Study Design

The parent study for which these data form a component was designed to assess the utility of minimally invasive diagnostic tests for identifying patients with disordered defecation. This article describes a preplanned sub-study.

Consecutive patients with refractory constipation referred to a tertiary gastroenterology clinic (Hospital of Valeggio sul Mincio, Verona, Italy) were screened for inclusion in this study between March 2010 and May 2012. Patients who met inclusion criteria and consented to participate were evaluated by the BET and digital rectal examination on their initial visit. All patients were placed on conservative management and returned in 30 days to repeat the BET. Those who did not report adequate relief of constipation from the conservative management received ARM and EMG tests to characterize their pelvic floor behavior during straining. Selected patients (those for whom the BET was discordant with ARM or EMG) were also referred for defecography.

Healthy controls were recruited by advertisement and evaluated by the BET on 2 occasions 7 days apart. No treatment or diagnostic tests except a bowel diary were done.

Patients

To be eligible for the study, patients had to fulfill Rome III criteria for functional constipation.[8] These criteria require 2 or more of 6 symptoms of constipation present on at least 25% of occasions for the previous 3 months including straining, lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal obstruction/blockage, manual maneuvers to facilitate defecation, and fewer than 3 defecations per week. These symptoms should be chronic, with first onset at least 6 months previously, and loose stools should occur rarely except with the use of laxatives. Exclusion criteria were the following: (1) history of gastrointestinal resection other than appendix or gallbladder; (2) prior diagnosis of a psychotic disorder, eating disorder, or gastrointestinal cancer; (3) diagnosis of intestinal pseudo-obstruction, megarectum, or megabowel; (4) hypothyroidism; (5) taking medications known to cause constipation including narcotic analgesics, calcium channel blockers, or anticholinergic drugs; and (6) experienced adequate relief of constipation from a 30-day trial of conservative treatment.

Healthy Controls

Exclusion criteria were criteria 1–5 above or symptoms consistent with irritable bowel syndrome, functional constipation, or functional diarrhea.

Conservative Treatment

Constipated patients (but not controls) were prescribed 30 days of conservative treatment that included increased fiber up to 30 g per day, increased fluids up to 64 ounces, and increased exercise, all as tolerated, plus laxatives, enemas, or suppositories up to twice a week. After 30 days, patients were asked whether they had experienced adequate relief of constipation, and those who answered “yes” were excluded from further participation in the study.

Balloon Evacuation Test

All patients received BETs during the initial visit and after the completion of the 30-day conservative treatment. Controls underwent the repeat BET after 7 days. The BET was performed by introducing a 16F Foley catheter (Unomedical a/s, Birkerod, Denmark) covered with surgical lubricant (K-Y Jelly; Johnson & Johnson Consumer France s.a.s., Sezanne, France) into the rectum. The Foley catheter was selected because it is a standardized device available in most medical clinic settings. The drainage port of the Foley catheter was closed by an outlet plug to avoid leakage of rectal effluents. The balloon on the catheter was filled with 50 mL water at approximately 37°C. Up to 5 minutes were allowed to evacuate the balloon while sitting on a conventional