



# Balloon Expulsion Test Does Not Seem to Be Useful for Screening or Exclusion of Dyssynergic Defecation as a Single Test

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## Background/Aims

Balloon expulsion test (BET) is regarded as a screening tool of dyssynergic defecation (DD). However, some patients with normal BET results may be treated effectively by biofeedback training. This study aims to validate BET as a single screening test.

## Methods

Two hundred and thirty-two patients who were diagnosed with functional constipation or irritable bowel syndrome with constipation who underwent anorectal manometry (ARM) and BET at Seoul National University Hospital were enrolled. We evaluated the validity of BET based on ARM and electromyography (EMG) during biofeedback training.

## Results

If  $BET \leq 1$  minute was defined as normal, sensitivity and negative predictive value (NPV) of BET in predicting paradoxical contraction based on ARM findings were 71.4% and 13.9%. If  $BET \leq 3$  minutes was defined as normal, sensitivity and NPV were 35.2% and 6.6%. Specificity and positive predictive value (PPV) of  $BET \leq 3$  minutes criteria were 84.8% and 93.3%. Same analysis was conducted in 107 patients who underwent EMG during biofeedback training. With 1-minute criteria, sensitivity and NPV of BET were 70.3% and 14.3%. With 3 minutes criteria, sensitivity and NPV of BET was 38.6% and 8.8%. Specificity and positive predictive values were both 100.0%.

## Conclusions

Based on either ARM or EMG during biofeedback training, sensitivity was at most 71.4% and NPV was less than 15.0% irrespective of whether BET was within 1 minute or within 3 minutes. BET seems to have a limitation as both a screening test for dyssynergic defecation and a simple assessment to rule out the necessity of biofeedback training.

(J Neurogastroenterol Motil 2017;23:446-452)

## Key Words

Biofeedback; Constipation; Defecation; Manometry

Received: September 20, 2016 Revised: April 2, 2017 Accepted: April 16, 2017

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## Introduction

Dyssynergic defecation is a common cause of chronic constipation.<sup>1</sup> The etiology of dyssynergic defecation is unclear, but excessive straining to expel hard stools over time may also lead to dyssynergic defecation.<sup>2</sup> Most patients with dyssynergic defecation do not respond well to laxatives, but biofeedback training works well for them compared with patients with other types of constipation. Therefore, screening of dyssynergic defecation with accuracy and giving appropriate treatment are important.<sup>3</sup>

To diagnose dyssynergic defecation, changes in pressure in the rectum and anal sphincter muscles during attempted defecation are measured by using anorectal manometry (ARM). ARM is essential for a diagnosis of dyssynergic defecation.<sup>1</sup> Normally, when a subject bears down or attempts to defecate, there is a rise in rectal pressure, which is synchronized with a relaxation of the external anal sphincter.<sup>4</sup> However, patients with dyssynergic defecation demonstrate either paradoxical anal contraction or inability to relax the anal sphincter or puborectalis muscles during attempted defecation.<sup>4,5</sup>

The balloon expulsion test (BET) is regarded as a screening tool of dyssynergic defecation in addition to ARM. The BET is easily performed and inexpensive. Therefore, it is widely used at primary care facilities.<sup>6</sup> A study reported that a diagnosis of dyssynergic defecation with the BET showed a high negative predictive value (NPV) of 97%, suggesting that when BET results were normal, dyssynergic defecation could be excluded.<sup>7</sup> However, another study reported a contradictory finding which indicated that normal results of BET do not necessarily exclude dyssynergic defecation by demonstrating that some patients with dyssynergic defecation were able to expel the balloon within 1 minute.<sup>8</sup> Currently BET within 1 minute is regarded as normal, but there is still no consensus on the standard criteria among experts.<sup>9</sup> Furthermore, some of patients who showed normal BET result can be treated effectively by biofeedback training.

The aim of this study was to conduct a comparative analysis of the results of the BET, ARM, and electromyography (EMG) during biofeedback training and to validate BET as a single screening test.

## Materials and Methods

### Study Design and Subjects

This is a retrospective study conducted on patients who visited

the Functional Gastrointestinal Disorders Clinic at Seoul National University Hospital between December 2012 and November 2014. We included patients with functional constipation diagnosed by the Rome III criteria who did not respond to more than 30 days of conventional laxative treatment. We also included patients who were diagnosed with irritable bowel syndrome with constipation (IBS-C) because it has been reported that an overlap of dyssynergic defecation and IBS-C is commonly present.<sup>10,11</sup> All of the included patients underwent the BET and ARM at the Motility Testing Laboratory within the Gastrointestinal Endoscopy Center of the Seoul National University Hospital. The exclusion criteria were the following: (1) inflammatory bowel disease, (2) history of gastrointestinal surgery, (3) use of drugs that may cause constipation, eg, analgesics, antidepressants, etc, (4) diagnosis of systemic disease, neurological disorders, or mental disorders which may be related to constipation, and (5) anorectal structural abnormality such as rectoceles, rectal prolapse, and intussusception.

Some of all included patients underwent EMG during biofeedback training. Biofeedback training was administered to people who had a willingness to treat, and the time and money to spend on biofeedback training.

The BET, ARM, and EMG during biofeedback training results were reviewed and demographic data including age, sex, and medication history of laxatives were obtained.

### Balloon Expulsion Test

A balloon attached to an anorectal 8-channel catheter (Mui scientific, Ontario, Canada) was inserted into the patients' lower rectum, after which the balloon was filled with 50 mL of warm water, and the patients were asked to expel it. Before the test, patients were asked to lie down in the left lateral decubitus position with the knees and hip flexed at a 90° angle, and then a catheter lubricated with jelly was carefully inserted into the rectum. After the balloon was inflated, patients moved to a toilet seat and tried to expel the balloon in a sitting position. BET results were grouped into categories depending on expulsion time. Analysis was performed for each case of 1 minute as the normal criteria and 3 minutes as the normal criteria.

### Anorectal Manometry

The patient lied in the lateral position. ARM was performed using electric manometric perfusion pump (Mui scientific) and the station pull through method was used. The pressure changes in the rectum and anus were recorded by injecting distilled water at a rate of 0.5 mL per minute using an 8-channel radial measuring tube with 8 sockets spirally spaced 0.5 cm apart. In addition, a balloon

catheter with a 3 × 6 cm latex balloon at the end of the tube was used to obtain a rectal sensory volume and a threshold value for causing rectoanal inhibitory reflex. Rectal pressure and internal anal sphincter pressure was measured during attempted defecation. Elevation of rectal pressure over 40 mmHg and relaxation of internal anal sphincter pressure over 20% from baseline were considered as normal.<sup>12-14</sup>

### Electromyography During Biofeedback Training

Biofeedback training was carried out using the surface EMG method using a visual biofeedback system (Regain 2.0; SRS Medical Systems, Inc., Redmond, WA, USA) and internal anal sensors (SenseRx, SRS medical Systems, Redmond, WA, USA). Electrodes were attached to the lower abdomen and an acryl plug was inserted into the anal canal. A distinct, not gradual, increase in EMG activity during bearing down/attempted defecation that was greater than 20.0% above resting EMG levels was defined as a paradoxical contraction.

### Statistical Methods

We made a diagnosis based on interviews conducted during patient examination and reviewed patients' records. The results of the BET, ARM, and EMG during biofeedback training were also examined by reviewing medical records. Student's *t* test was used to compare the test results, and the Chi-square test was used for comparison. The similarity in the results was measured with tau statistics, and statistical significance was determined for *P* < 0.05 and

statistical analysis was performed by using SPSS 23 (IBM Corp, Armonk, NY, USA).

### Ethical Considerations

This study was approved by the Institutional Review Board of Seoul National University Hospital and was conducted in accordance with the Declaration of Helsinki.

### Results

Based on the inclusion and exclusion criteria, 232 patients were included in this study. The mean age of patients was 61.3 years old, and 104 males and 128 females were included. The median follow-up period was 19.4 months. Of the 232 patients, 227 were taking

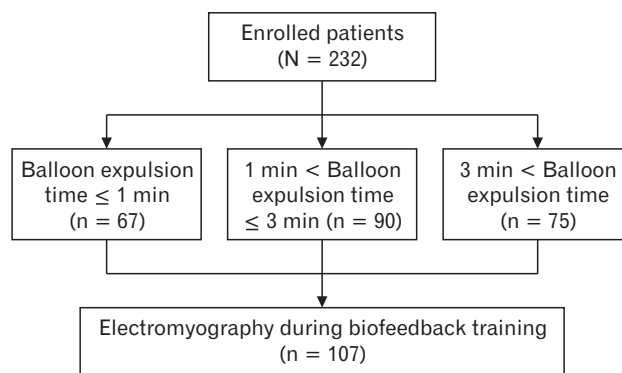


Figure. Flow chart of study design.

Table 1. Baseline Characteristics According to Balloon Expulsion Test Results

	BET (1-minute criteria)			BET (3-minute criteria)		
	Normal (n = 67)	Abnormal (n = 165)	<i>P</i> -value	Normal (n = 157)	Abnormal (n = 75)	<i>P</i> -value
Gender (male/female)	23/44	81/84	0.043	63/94	41/34	0.048
Age (yr)	60.0 ± 14.5	64.4 ± 1.2	0.033	59.0 ± 15.0	62.3 ± 13.8	0.096
Duration of laxatives use (mo)	18.0 ± 13.9	20.0 ± 13.3	0.310	19.8 ± 12.9	18.7 ± 14.7	0.589
Symptoms						
Anal pain (yes/no)	8/59	14/151	0.46	16/141	6/69	0.811
Incontinence (yes/no)	16/51	41/124	0.51	40/117	17/58	0.745
Straining (yes/no)	3/64	154/11	0.385	147/10	71/4	1.000
Hard stool (yes/no)	50/17	113/52	0.429	106/51	57/18	0.220
Incomplete sensation (yes/no)	32/35	95/70	0.192	73/84	54/21	< 0.001
Obstruction (yes/no)	15/52	52/113	0.201	44/113	23/52	0.757
Manual maneuver (yes/no)	9/57	22/143	1.000	20/137	11/64	0.684
< 3 times per week, defecation (yes/no)	19/48	49/116	0.875	43/114	25/50	0.359

BET, balloon expulsion test.

laxatives, and the mean number of laxatives used was 2.8.

All patients underwent BET and ARM. On BET, 67 and 90 patients expelled the balloon within 1 minute and between 1 and 3 minutes, respectively. The remaining 75 patients expelled the balloon after more than 3 minutes (Figure). There were no significant differences of symptoms related to defecation according to the BET results (Table 1). Among the several symptoms, 57 patients of all included patients complained of fecal incontinence as a combined symptom of constipation. These patients with fecal incontinence tended to have significantly lower resting pressures ( $40.36 \pm 21.8$  mmHg vs  $54.8 \pm 21.7$  mmHg,  $P < 0.01$ ) and squeezing pressures ( $186.9 \pm 95.3$  mmHg vs  $213.3 \pm 80.4$  mmHg,  $P = 0.041$ ) than patients who did not have fecal incontinence. The rate of patients with low anal tone was higher in patients with fecal incontinence than those without (33.0% vs 10.8%,  $P = 0.010$ ).

Of the total of 232 patients, 107 patients were tested for EMG during biofeedback training. There was no statistically significant difference in BET and ARM results between the EMG group and the non-EMG group (Table 2).

## Balloon Expulsion Test Results and Anorectal Manometry Findings

Among 232 patients, 199 patients showed incomplete relaxation or paradoxical contraction of anal sphincter on ARM, while 33 patients showed normal findings. Table 3 shows the concordance between results of BET and presence of paradoxical contraction on ARM. If balloon expulsion within 1 minute was defined as normal, sensitivity and NPV of BET for predicting dyssynergic pattern of anal sphincter were 71.4% and 14.9%, respectively. Specificity and positive predictive values (PPV) were 30.3% and 86.1% (Table 4). If balloon expulsion within 3 minutes was also defined as normal, sensitivity and NPV were 35.2% and 17.8%, respectively. Specificity and PPV were 84.8% and 93.3%, respectively (Table 4).

Of 232 patients, 71 patients showed inadequate propulsive force (ie. decreased or insufficiently elevated of rectal pressure), whereas 161 patients showed increases in rectal pressure in the normal range (Table 3). If balloon expulsion within 1 minute was defined as normal, the sensitivity, specificity, PPV, and NPV of BET for predicting inadequate propulsive force, which was deter-

**Table 2.** Anorectal Manometric Findings of Electromyography Group and Non-electromyography Group

	EMG group (n=107)	Non-EMG group (n=125)	P-value
Resting pressure (mmHg)	53.3 ± 20.9	49.7 ± 23.8	0.233
Squeezing pressure (mmHg)	208.9 ± 76.2	205.3 ± 91.2	0.745
Sustained duration (sec)	33.8 ± 14.0	33.7 ± 14.4	0.971
Minimal volume (mL)	35.3 ± 19.5	39.8 ± 27.9	0.168
Urgency volume (mL)	108.2 ± 52.3	112.7 ± 53.0	0.518
Maximal volume (mL)	165.3 ± 64.8	174.3 ± 62.9	0.289
Bearing down rectal pressure (mmHg)	74.3 ± 39.2	78.1 ± 49.3	0.535
Bearing down anal sphincter pressure (mmHg)	85.2 ± 59.5	73.1 ± 45.3	0.081
Defecation index	1.2 ± 1.1	1.4 ± 1.1	0.255

EMG, electromyography.

**Table 3.** Concordance Between Balloon Expulsion Test and Anorectal Manometry Results

BET (min)	Anal sphincter contraction during attempted defecation			Rectal pressure during attempted defecation		
	Normal relaxation	Paradoxical contraction or < 20% relaxation	Total	Normal elevation	Decreased or insufficiently elevated rectal pressure	Total
≤ 1	10	57	67	44	23	67
1 < BET ≤ 2	2	11	13	7	6	13
2 < BET ≤ 3	16	61	77	60	17	77
> 3	5	70	75	50	25	75
Total	33	199	232	161	71	232

BET, balloon expulsion test.

**Table 4.** Validity of Balloon Expulsion Test Based on Anorectal Manometry and Electromyography Findings

	ARM (paradoxical contraction or incomplete relaxation)	ARM (inadequate propulsive force)	ARM (total findings)	EMG (paradoxical contraction)
BET (1-minute criteria)				
Sensitivity (%)	71.4	72.8	66.1	70.3
Specificity (%)	30.3	35.4	27.9	83.3
PPV (%)	86.1	81.2	24.9	98.6
NPV (%)	14.9	25.4	68.9	14.3
BET (3-minute criteria)				
Sensitivity (%)	35.2	37.1	37.1	38.6
Specificity (%)	84.8	69.4	69.4	100
PPV (%)	93.3	30.7	30.7	100
NPV (%)	17.8	75.2	75.2	8.8

ARM, anorectal manometry; EMG, electromyography; BET, balloon expulsion test; PPV, positive predictive value; NPV, negative predictive value.

mined by using ARM, were 72.8%, 35.4%, 81.2%, and 25.4%, respectively (Table 4). If balloon expulsion within 3 minutes was also defined as normal, the sensitivity, specificity, PPV, and NPV of BET were 37.1%, 69.4%, 30.7%, and 75.2%, respectively (Table 4).

We also analyzed the sensitivity, specificity, PPV, and NPV of BET compared with total ARM findings (based on paradoxical contraction and insufficient increase of rectal pressure). If balloon expulsion within 1 minute was defined as normal, sensitivity and NPV of BET for predicting functional defecation disorder were 66.1% and 68.9%, respectively. Specificity and PPV were 27.9% and 24.9%, respectively (Table 4). If balloon expulsion within 3 minutes was also defined as normal, sensitivity and NPV were 37.1% and 75.2%, respectively. Specificity and PPV were 69.4% and 30.7%, respectively (Table 4).

### Balloon Expulsion Test Results and Electromyography During Biofeedback Training

Analysis was also conducted in 107 patients who underwent EMG during biofeedback training. The average number of biofeedback training was 4.3 sessions. The presence or absence of paradoxical contraction in the EMG was determined in the first session of biofeedback training. One hundred and one patients showed paradoxical anal contraction, whereas 6 patients showed normal anal contraction. Concordance between time-to-balloon expulsion and the EMG results regarding anal sphincter contraction was observed with  $\tau_b = 0.253$  ( $P = 0.005$ ; Table 5). If balloon expulsion within 1 minute was defined as normal, the sensitivity, and NPV of BET in predicting paradoxical contraction shown were 70.3% and 14.3%, respectively. Specificity and PPV were 83.3% and 98.6%, respectively (Table 5). In contrast, if balloon expulsion

**Table 5.** Concordance Between Balloon Expulsion Test and Electromyography During Biofeedback Training

BET (min)	EMG, anal sphincter		
	Normal relaxation	Paradoxical contraction	Total
≤ 1	5	30	35
1 < BET ≤ 2	1	4	5
2 < BET ≤ 3	0	28	28
> 3	0	39	39
Total	6	101	107

EMG, electromyography; BET, balloon expulsion test.

within 3 minutes was defined as normal, the sensitivity, and NPV of BET was 38.6% and 8.8%, respectively. Specificity and PPV were both 100% (Table 4).

### Discussion

The BET is simple and easy to perform, and its effectiveness as a screening tool to diagnose dyssynergic defecation has been demonstrated in several studies.<sup>8</sup> However, in the clinical setting, some patients present dyssynergic movement of the anal sphincter or puborectalis muscles during simulated defecation training, although their BET results are normal. In the present study, among the 107 patients who received biofeedback training, 33 patients showed improvement of their symptoms during defecation and paradoxical anal contraction during EMG on biofeedback training. Among the 33 patients, 8 patients expelled the balloon within 1 minute and 16 patients expelled the balloon within 3 minutes. Thus, we re-evaluat-

ed the significance of BET in diagnosing patients with dyssynergic defecation.

Recently, several studies have adopted balloon expulsion within 1 minute as the criteria to define normal results on BET.<sup>15-18</sup> However, in the present study, the sensitivity of BET with the 1-minute criteria was not high enough to predict dyssynergic defecation comparison based on ARM or EMG during biofeedback training. With the 3 minutes criteria, sensitivity was even lower. Thus, although the 1 minute criteria may be more significant than the 3 minutes criteria, unlike the previous studies, BET seems to have a limitation as a screening test for dyssynergic defecation.

The NPV of BET was 14.0% and 17.8% with 1 minute and 3 minutes as the normal criteria, respectively, which was very low. Thus, even if BET is normal, dyssynergic defecation cannot be excluded. Therefore, based on BET as a single test, disregarding dyssynergic defecation or exclusion of the necessity of biofeedback training seems to be unreasonable. According to the 3 minutes criteria of BET based on ARM and EMG during biofeedback training, PPVs were 93% and 100%, respectively. This result could mean that patients who cannot expel the balloon within 3 minutes may have dyssynergic defecation.

The reason why our results are different with the results of previous studies that reported high NPV and sensitivity of BET might be the inclusion of patients who complain of fecal incontinence as a combined symptom of constipation. Patients with fecal incontinence secondary to fecal impaction were reported to demonstrate impaired balloon expulsion.<sup>19,20</sup>

In another literature, 86% of patients with fecal incontinence have little difficulty with balloon expulsion.<sup>20,21</sup> A study showed 92% of patients with fecal incontinence could expel the balloon and the mean expulsion time was 50 seconds.<sup>22</sup> In the present study, 57 patients of all included patients complained of fecal incontinence as a combined symptom of constipation. Sixty-one percent of the patients with combined fecal incontinence could expel the balloon within 1 minute, but were diagnosed with dyssynergic defecation according to ARM or EMG during biofeedback training. These findings suggest that a substantial proportion of constipated patients with fecal incontinence might show false negative results of BET.

A previous study argued that 2 minutes would be an appropriate upper limit in the BET.<sup>23</sup> However, in the present study, the portion of patients who expelled the balloon between 1 and 2 minutes after insertion was only 5%. Therefore, the 2 minute criteria do not seem to change results significantly.

Among 107 patients who received biofeedback training based on EMG, 39 exceeded 3 minutes in expelling the balloon, and

all of them showed paradoxical contraction of the anal sphincter on EMG. Several reasons why the BET predicted EMG results during biofeedback training more accurately than ARM could be suggested. First, it has to do with different patient postures for ARM and for EMG taken during biofeedback training. EMG is performed in the sitting position, whereas ARM is performed in the left lateral decubitus position. A study reported that an assessment of bowel movements could be made most appropriately in the sitting position.<sup>24</sup>

This study has several limitations. First, only 46% of the total patients received biofeedback training with EMG. This study performed through a retrospective analysis of data from routine clinical practices in a single tertiary care center, in which biofeedback training with EMG was performed in patients with suspicious dyssynergic defecation and did not improve despite continuous treatment with laxatives for 1-3 months or relapsed after tapering of laxatives. As a result, not all of the BET results could be compared with EMG during biofeedback training and this could lead to another selection bias. However, it was judged that the selection bias was minimized, since there was no statistically significant difference between the EMG group and Non EMG group in BET and ARM results, as above mentioned. Second, other diagnostic tests that might be helpful to diagnose dyssynergic defecation, such as defecography or colon transit times, were not performed. This was because of patients' preference and poor accessibility to those exams. Defecography is useful in identifying anatomical abnormalities, such as paradoxical contraction of the puborectalis muscles.<sup>25,26</sup> However, the technique of defecography is incompletely standardized and has limited reproducibility in terms of anorectal angle measurements.<sup>27</sup> Furthermore, there were risks of X-ray exposure and barium impaction, even though these risks are minimal.<sup>28</sup>

In conclusion, sensitivity of BET was at most 71.4% and NPV of BET was less than 15% in predicting paradoxical anal contraction or inadequate propulsive force when estimated from ARM or EMG during biofeedback training irrespective of BET criteria. BET seems to have a limitation as both a screening test for dyssynergic defecation and a simple assessment to rule out the necessity of biofeedback training.

**Financial support:** None.

**Conflicts of interest:** None.

**Author contributions:** Kyoung Sup Hong planned the study, designed the protocol, and contributed to the screening and pe-

riodic visits of the patients; Joo Sung Kim and Hyun Chae Jung contributed to the screening and periodic visits of the patients; Jooyoung Lee analyzed the data; Kyoung Sup Hong and Jooyoung Lee contributed to the writing of the manuscript; Kyoung Sup Hong, Joo Sung Kim, and Hyun Chae Jung reviewed and edited the final manuscript; and all authors reviewed and approved the final manuscript.

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