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Effect of Biofeedback Therapy in Constipation According to Rectal Sensation

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Background/Aims: The pathophysiologic mechanism of rectal hyposensitivity (RH) is not well documented, and the significance of RH in biofeedback therapy (BFT) has not been evaluated. Thus, we aimed to assess the effect of BFT in constipated patients according to the presence of RH. **Methods:** Five hundred and ninety constipated patients (238 males and 352 females) underwent anorectal physiologic assessments. Of these, anorectal manometry was performed before and after BFT in 244 patients (63 RH and 181 non-RH patients). **Results:** The success rate of BFT was 56% in the RH and 61% in the non-RH group (p=0.604). The measurements of resting pressure, squeezing pressure, desire to defecate volume, urge to defecate volume, and maximum volume were decreased after BFT in the RH group (p<0.05), whereas only resting and squeezing pressures were decreased in the non-RH group (p<0.05). Among the RH group, individuals who responded to BFT showed decreased resting pressure, squeezing pressure, desire to defecate, urge to defecate, and maximum volume and increased balloon expulsion rate; among those who did not respond to BFT, only desire to defecate volume was improved. **Conclusions:** In constipated patients with RH, changes of anorectal manometric findings differed in comparison to patients without RH. The responses to BFT showed both anorectal muscle relaxation and restoration of rectal sensation. **(Gut Liver 2013;7:157-162)**

Key Words: Anorectal manometry; Biofeedback; Constipation; Rectum; Sensation

INTRODUCTION

Functional constipation is a common disorder that causes suffering and constitutes a substantial economic burden for patients and healthcare resources.[1] A significant proportion of these patients are managed surgically when conservative measures are not effective; however, the long-term results of surgery are often disappointing.[2] The success of other methods, such as biofeedback therapy (BFT), requires an understanding of the pathophysiologic mechanisms involved in the etiology of these conditions. Anorectal physiologic assessment may be integral in the assessment of constipated patients.[3-6] Tests of anorectal function can provide useful information on the pathophysiology of disorders that affect continence and defecation, thereby causing anorectal discomfort.[3,7-9] Among many parameters, rectal sensory perception, which can be quantified by balloon distension volume, is essential for maintaining normal continence and evacuation.

Rectal hyposensitivity (RH) has been defined as the elevation of sensory thresholds beyond the normal range, resulting in impaired or blunted rectal sensory function.[10] RH has been reported to be a predictor of poor outcome in the treatment of fecal incontinence with BFT[11] and surgery.[12] However, the underlying mechanism and clinical significance are not fully elucidated. Previously, we reported that electrical stimulation using an anal plug and BFT may improve constipation symptoms in patients with RH.[13-15] Our preliminary study suggested that RH is important in biofeedback response and that electrical stimulation of the anus may be effective in restoring rectal sensation. There have been several preliminary reports exploring the role of RH in biofeedback response.[7,16-18] However, the number of subjects was small and most studies did not evaluate changes which can be estimated quantifiably in anorectal function in response to BFT. We therefore evaluated the role of RH in BFT and the pathophysiologic mechanism of biofeedback response in constipated patients using anorectal manometry.

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MATERIALS AND METHODS

1. Patients

Of the 1,773 consecutive patients referred for physiologic investigation of constipation and treated with BFT at the Asan Medical Center, Seoul, Korea, from June 2004 to June 2009, 590 patients were evaluated by a thorough medical history and anorectal physiologic assessments involving anorectal manometry. Patients were recruited if they: 1) fulfilled the Rome II criteria for constipation; 2) were dissatisfied with conservative medical treatment (such as laxatives and/or a high-fiber diet) for constipation before start of BFT; and 3) had to complete at least three sessions of BFT. All patients answered structured questionnaires on constipation, before and after BFT. The study was approved by the institutional review board of the Asan Medical Center, University of Ulsan College of Medicine, and all patients provided written informed consent.

2. Anorectal manometry and balloon expulsion test

Before anorectal manometry, patients were asked to empty their bowels. To measure resting and maximal anal sphincter pressures, a radial eight-channel anorectal water-perfused catheter was placed into the rectum at a level 6 cm above the anal verge and automatically pulled by a catheter-pulling system at the rate of 1 cm per second. The catheter was connected to a Mui eight-channel water perfusion system (Medtronics Inc., Minneapolis, MN, USA), and the anal sphincter pressure was measured three times. A spiral eight-channel anorectal water-perfused catheter with a balloon was subsequently placed in the anal canal, and both resting pressure and squeezing pressure were measured again. The balloon on the tip of the catheter was gradually inflated with 10 mL of air, and the rectoanal inhibitory reflex, minimal volume for desire to defecate, urgency volume, and maximal tolerable volume were measured. Polygram Net® (Medtronic Inc.) software was used to analyze anorectal manometry results. Based on previous institutional findings[15] and unpublished data, we arbitrarily defined impaired rectal sensation as a rectal sensory threshold volume of desire to defecate >90 mL. Our unpublished data was estimated by 22 healthy volunteers (mean age, 38.5±10.4; male/female, 15/7). Mean volume of desire to defecate in 22 healthy volunteers was 84.5±41.3 mL, so the upper limit of normal for volume of desire to defecate was 90 mL for the anal electrosensory threshold. The balloon expulsion test was performed using a balloon catheter with eight spirally arranged channels. About 50 mL of warm water was placed in the balloon and the patient was requested to evacuate the balloon. Expulsion of the balloon within 5 minutes was defined as successful.

3. BFT

One specialized therapist offered biofeedback training consisting of surface electromyography performed during sham defecation in a sitting position, followed by individual education of patients about the mechanism of defecation, the gastrocolic reflex, the structure of the anus and rectum, constipation, and the concept of BFT. Patients began biofeedback training, using Orion Platinum biofeedback equipment (SRS Medical Systems Inc., Redmond, WA, USA), under the instruction of the therapist. During the training, therapist used latex balloon filled with water which was inserted to the rectum for helping the sensation of filling and the initiation of defecation, especially in patient with impaired rectal sensation. Each session of BFT usually lasted 40 to 60 minutes. Before and after BFT, all patients answered structured questionnaires about constipation. Completed questionnaires provided scores of global defecatory satisfaction and explored six aspects of constipation symptoms: number of defecations per week, straining during defecation, lumpy or hard stools, incomplete evacuation, sensation of anorectal obstruction, and manual maneuvers to facilitate defecation. The primary outcome measure to evaluate the effectiveness of BFT for constipation was self-reported global defecatory satisfaction score, recorded on a scale of 0 to 10, with 0 being worst and 10 being best. Successful BFT was defined as a ≥3-point improvement in global defecatory satisfaction scale.

4. Statistical analysis

Continuous variables are reported as medians and ranges, and categorical variables as relative frequencies. Continuous variables were compared using Student's t-test or the Mann-Whitney U test, and categorical variables using the chi-square test or Fisher's exact test. A $p<0.05$ was considered statistically significant. All statistical analyses were performed using the SPSS version 12.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

1. Characteristics of RH and non-RH patients

The 590 patients who underwent anorectal manometry had a median age of 58 years (interquartile range, 47 to 68 years). Of these, 168 patients (28%) had RH (Table 1). Among all 590 patients, 458 had underlying diseases, including brain diseases (n=39) such as infarction, hemorrhage, and meningitis; spinal trauma (n=70); low abdominal surgery (n=90) such as transabdominal hysterectomy, cesarean delivery, and prostatic surgery; diabetes mellitus (DM) (n=83); Parkinson's disease (n=22); hemorrhoid operation (n=79); and other diseases (n=255). Eighty-seven patients had a combination of two or more diseases. The characteristics of the RH and non-RH patients are summarized in Table 1. Median age and the proportion of male, overall underlying disease, DM, and combined disease was higher in RH group than non-RH group ($p<0.05$).

2. Anorectal manometric findings

Anorectal manometry was performed before and after BFT in

244 patients; of these, 63 (26%) had RH and 181 (74%) did not. Manometric findings and responses to BFT are summarized in Table 2. Resting pressure and squeezing pressure was lower and balloon expulsion rate was higher after BFT, however, other parameters had no significant changes.

In the RH group, resting pressure, squeezing pressure, desire to defecate volume, urge to defecate volume, and maximum volume were significantly decreased after BFT, whereas only resting pressure and squeezing pressure were significantly de-

Table 1. Characteristics of RH and Non-RH Patients

Characteristic	Total (n=590)		
	RH (n=168)	Non-RH (n=422)	p-value
Median age (range), yr	62 (48–70)	55 (45–67)	0.007
Sex, F:M	85:83	267:155	0.005
Underlying disease*	144 (86)	314 (74)	0.003
Brain disease	14 (8)	25 (6)	0.288
Spinal trauma	21 (13)	49 (12)	0.763
Low-abdominal surgery†	32 (19)	58 (14)	0.106
Diabetes mellitus	31 (18)	52 (12)	0.053
Parkinson	10 (6)	12 (3)	0.072
Hemorrhoid operation	23 (14)	56 (13)	0.321
Other disease‡	78 (46)	177 (42)	0.321
Combined disease§	35 (21)	52 (12)	0.009

Data are presented as number (%).
RH, rectal hyposensitivity; F, female; M, male.
*Total percentage can exceed 100% because of combined diseases; †Transabdominal hysterectomy, Cesarean delivery, and prostatic surgery; ‡Breast cancer, lung cancer, hepatocellular carcinoma, biliary disease, thyroid disease, and heart disease; §More than two underlying diseases.

Table 2. Anorectal Manometric Findings after Biofeedback Therapy (BFT) in All Patients

	Total (n=244)		
	Before BFT	After BFT	p-value
Resting pressure, mm Hg	55.5±24.8	51.2±23.6	0.002
Squeezing pressure, mm Hg	182.2±84.6	172.1±81.9	0.002
Sustained pressure, mm Hg	5.9±4.1	6.1±4.2	0.436
Sphincter length, cm	3.9±0.7	3.8±0.8	0.302
High pressure zone length, cm	2.3±0.7	2.3±0.7	0.146
Rectoanal inhibitory reflex	17.0±11.1	19.9±23.2	0.075
Cough reflex	218.2±113.4	215.1±98.7	0.502
Minimum volume, mL	10.8±3.6	10.5±3.4	0.480
Desire to defecate volume, mL	64.2±42.9	64.3±43.3	0.902
Urge to defecate volume, mL	119.3±60.7	113.5±47.1	0.166
Maximum volume, mL	150.0±81.3	143.6±47.4	0.261
Compliance	7.3±14.3	6.1±6.2	0.231
Defecation index	18.6±104.6	12.2±81.6	0.462
Balloon expulsion, success/failure	165/78 (68)	207/36 (85)	<0.001

Data are presented as mean±SEM or number (%).

Table 3. Anorectal Manometric Findings after Biofeedback Therapy (BFT) in the Rectal Hyposensitivity (RH) and Non-RH Groups

	RH group (n=63)		Non-RH group (n=181)	
	Before BFT	After BFT	Before BFT	After BFT
Resting pressure, mm Hg	54.8±25.5	47.1±20.6*	56.7±24.5	52.7±24.5†
Squeezing pressure, mm Hg	172.3±67.9	162.0±70.7‡	185.3±89.7	175.7±85.3§
Sustained pressure, mm Hg	5.0±2.7‖	5.3±2.7	6.2±4.5	6.4±4.5
Sphincter length, cm	3.8±0.6	3.8±0.7	3.9±0.7	3.8±0.8
High pressure zone length, cm	2.3±0.6	2.3±0.7	2.3±0.7	2.3±0.7
Rectoanal inhibitory reflex	21.4±12.4¶	23.3±17.5	15.4±10.2	18.7±24.8
Cough reflex	231.2±130.9	221.5±81.2	213.6±106.5	212.9±104.4
Minimum volume, mL	11.2±4.6	10.8±5.2	10.7±3.1	10.4±2.4
Desire to defecate volume, mL	125.9±36.1	89.1±52.3#	42.7±15.5	55.8±36.1**
Urge to defecate volume, mL	163.9±37.7	133.7±45.1††	106.2±59.9	107.6±46.1
Maximum volume, mL	188.5±35.8	162.7±44.1‡‡	140.9±86.3	139.1±47.2
Compliance	7.6±7.6	7.8±7.7	7.2±16.1	5.4±5.4
Defecation index	14.1±92.9	22.8±123.6	20.2±108.7	8.4±59.6
Balloon expulsion, success/failure	38/24 (61)	49/13 (79)§§	127/54 (70)	158/23 (87)‖‖

Data are presented as mean±SEM or number (%).
*p=0.001 vs before BFT in the RH group; †p=0.055 vs before BFT in the non-RH group; ‡p=0.047 vs before BFT in the RH group; §p=0.017 vs before BFT in the non-RH group; ‖p=0.015 vs before BFT in the non-RH group; ¶p=0.001 vs before BFT in the non-RH group; #p=0.000 vs before BFT in the RH group; **p=0.000 vs before BFT in the non-RH group; ††p=0.000 vs before BFT in the RH group; ‡‡p=0.000 vs before BFT in the RH group; §§p=0.019 vs before BFT in the RH group; ‖‖p=0.000 vs before BFT in the non-RH group.

creased without differences of sensory volume in the non-RH group (Table 3).

When the RH group was subdivided into those who did and did not respond to BFT, we found that resting pressure, squeezing pressure, desire to defecate volume, urge to defecate volume, and maximum volume were decreased and balloon expulsion rate was increased in responders, whereas only desire to defecate volume was improved in nonresponders (Table 4).

3. Outcomes of BFT

Of overall 244 patients, BFT was successful in 145 patients (59%); 35 patients in the RH (56%) and 110 patients in the non-RH (61%) group. Global satisfaction scales after BFT were 3.03±2.49 in RH group and 3.17±2.49 in non-RH group without significance (p=0.59).

The secondary outcomes of BFT were measured by structured questionnaires about constipation in RH and non-RH groups. There were no significant differences about the results with six aspects of constipation symptoms: number of defecations per week, straining during defecation, lumpy or hard stools, incomplete evacuation, sensation of anorectal obstruction, and manual maneuvers to facilitate defecation between RH group and non-RH group after BFT.

DISCUSSION

RH is described as a diminished reception of rectal distension and has been reported in 18% to 68% of constipated patients.[4] However, its clinical implication remains unclear. To assess the role of RH in response to BFT, we analyzed the effects of BFT in constipated patients with or without RH and evaluated anorectal physiologic parameters by anorectal manometry. RH was diagnosed in 28.5% (168/590) of constipated patients who performed BFT. In patients diagnosed with RH, BFT resulted in decreasing desire to defecate volume, urge to defecate volume, and maximal volume compare to non-RH patients. Moreover, responders to BFT with RH showed improvements in these parameters and increased balloon expulsion rate. With these results, we can consider that restoration of rectal sensations is one of the mechanism of BFT in RH patient.

The pathophysiologic mechanisms of RH are unknown, although they may be due to alterations in the pelvic and anorectal afferent nerves, mechanoreceptors of the rectal wall, rectoanal reflexes, or brain-gut interactions.[19,20] Anorectal manometry can be used to estimate various rectal functions quantitatively. However, since the thresholds used to diagnose RH are unclear,[21-24] differences in rectal distension methodology indicate that the actual volumes required to diagnose RH should not be universally applied, with individual units establishing their own normal ranges.[23] We included RH patients with elevated desire to defecate volume >90 mL in anorectal manometry, based on the previous collective experience of our institution and unpublished data.[15] However, previous studies of rectal sensory impairment have used a variety of thresholds.[10,21,22] Our

Table 4. Anorectal Manometric Findings after Biofeedback Therapy (BFT) in Rectal Hyposensitivity (RH) Responders and Nonresponders

	RH responders (n=42)		RH nonresponders (n=21)	
	Before BFT	After BFT	Before BFT	After BFT
Resting pressure, mm Hg	52.4±21.8	43.9±20.2*	59.5±31.7	53.4±20.2
Squeezing pressure, mm Hg	165.9±61.6	152.4±64.1†	187.8±78.5	181.3±80.6
Sustained pressure, mm Hg	4.7±2.5	5.1±2.5	5.5±2.9	5.5±3.1
Sphincter length, cm	3.7±0.6‡	3.7±0.7	4.0±0.5	4.1±0.7
High pressure zone length, cm	2.1±0.6§	2.1±0.6	2.6±0.5	2.5±0.8
Rectoanal inhibitory reflex	20.9±11.2	23.8±19.9	22.4±14.8	22.4±11.8
Cough reflex	221.2±141.3	205.7±81.8	246.7±106.8	252.3±72.2
Minimum volume, mL	10.9±3.7	10.2±1.5	11.7±6.2	11.9±8.7
Desire to defecate volume, mL	120.9±33.0‖	80.5±46.2¶	135.7±40.7	106.2±60.5#
Urge to defecate volume, mL	163.9±40.8**	127.2±45.9††	178.9±36.6	153.1±35.3
Maximum volume, mL	184.2±34.9‡‡	158.6±42.0§§	208.7±33.6	183.1±43.5
Compliance	6.8±5.4	7.3±4.7	9.1±10.7	8.9±11.8
Defecation index	20.7±113.6	12.8±72.9	11.1±1.2	42.6±189.4
Balloon expulsion, success/failure	26/16 (62)	34/7 (83)‖‖	12/9 (57)	15/6 (71)

Data are presented as mean±SEM or number (%).
*p=0.001 vs before BFT in the response group; †p=0.009 vs before BFT in the response group; ‡p=0.005 vs before BFT in the nonresponse group; §p=0.016 vs before BFT in the nonresponse group; ‖p=0.053 vs before BFT in the nonresponse group; ¶p=0.000 vs before BFT in the response group; #p=0.027 vs before BFT in the nonresponse group; **p=0.007 vs before BFT in the nonresponse group; ††p=0.001 vs before BFT in the response group; ‡‡p=0.046 vs before BFT in the nonresponse group; §§p=0.007 vs before BFT in the response group; ‖‖p=0.039 vs before BFT in the response group.

diagnostic criterion, desire to defecate volume, is the most important parameter used for patients with RH, and simple criteria can be applied more easily in clinical practice. However, further studies are needed to determine the optimal criteria for the diagnosis of RH.

This present report showed that the median age and the proportion of male was higher in RH group. With these results, we can think that RH may have relationship with decreased rectal elasticity due to old age and male is prone to RH than female. Of our patients, 78% had underlying diseases, but it was unclear whether these concomitant disorders affected the development of constipation or RH. Many congenital and acquired factors may be associated with RH, although causality has not been definitively established.[4] Defects of the rectal afferent pathway include various neuropathic disorders such as peripheral and central disruption, which may lead to RH.[4] Peripheral nerve injury can occur during pelvic surgery, particularly hysterectomy, resulting in RH[25-27] and central disruption may occur following spinal trauma.[4] Of our RH patients, 11% had undergone transabdominal hysterectomy and 13% had spinal trauma suggesting that their disorders might contribute to the development of RH.

Uncontrolled studies have reported improvements in 50% to 71% of subjects undergoing BFT,[5,28-30] and a recent controlled trial showed that BFT resulted in greater improvements at 1 year than laxatives.[31] We observed symptomatic improvements in 56% of patients in the RH group, 61% of patients in the non-RH group, and 59% overall. We also found that improvement of balloon expulsion with BFT was matched by improvements in physiologic parameters of anorectal function. Anorectal manometric indices, such as resting and squeezing pressures, improved significantly after BFT, and the success rate of balloon expulsion increased from 69% to 85% after BFT treatment, from 61% to 79% in the RH group and from 70% to 87% in the non-RH group. This was similar to a previous report,[17] which showed improvements in anal resting pressure and sensational threshold after BFT. Although desire to defecate, urge to defecate, and maximum volume were not decreased after BFT in all patients, all three improved significantly in the RH group. Before BFT, responders in the RH group had shorter sphincter and high pressure zone lengths, and lower desire to defecate, urge to defecate, and maximum volumes than nonresponders in the RH group. After BFT, many parameters improved in responders with RH, but only desire to defecate volume improved in nonresponders with RH. There results suggest that adequate stimulation of the rectum by BFT may effectively decrease the threshold of rectal sensation in patients with RH, thus reducing the volume of fecal materials in the rectum and decreasing anal resting pressure. In non-RH group, desire to defecate volume was increased after BFT and only desire to defecate volume was increased in both responders and nonresponders after BFT without difference about volume. This change can be thought that rectal hypersensitivity is recovered after BFT in patients with nonimpaired rectal sensation, however, the mechanism is unclear.

The limitations of our study include the referral bias to a tertiary care center, previous medication history, comorbid illnesses, and underlying conditions related to RH which can affect to the result of BFT. Furthermore, this study was not a randomized study and patient compliance in answering questionnaires was not controlled thoroughly because some patients showed an unwillingness to participate even after providing informed consent.

In conclusion, we have found that RH plays a role in response to BFT at the parameters of desire to defecate volume, urge to defecate volume, and maximal volume, even though, the response rate is similar between RH group and non-RH group. The major effects of BFT in patients with RH can be considered as the restoration of rectal sensation with changes of anorectal manometric findings and the anorectal muscle relaxation. In responders with RH, many parameters improved after BFT, but only desire to defecate volume improved in nonresponders with RH. Additional studies in larger patient populations are required to determine the clinical benefit of anorectal manometry in patients with RH.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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