The Long-term Clinical Efficacy of Biofeedback Therapy for Patients With Constipation or Fecal Incontinence

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Background/Aims
There has been a controversy regarding the usefulness of biofeedback therapy for functional constipation or fecal incontinence. This study was performed to investigate the long-term clinical efficacy of biofeedback therapy.

Methods
Sixty-four patients with constipation or fecal incontinence received biofeedback therapy for 4 weeks. Symptom improvements were evaluated immediately after the completion of biofeedback therapy and during the follow-up period of about 12 to 64 months.

Results
Twenty-five patients in the constipation group [mean age of 52.1 years, 16 men (64.0%)] received 6.2 sessions of biofeedback therapy. Improvement of constipation after the completion of biofeedback therapy was as follows: major response (or improvement) in 3 patients (12.0%), fair in 6 (24.0%), minor in 11 (44.0%) and none in 5 (20.0%). Among 9 patients who showed major or fair improvement, 8 patients (88.9%) maintained the symptom improvement through the long term follow-up periods. Thirty-nine patients in the fecal incontinence group [59.7 years old, 15 men (38.5%)] received 6.8 sessions of biofeedback therapy. Improvement of incontinence after the completion of biofeedback therapy was as follows: major improvement in 6 patients (15.4%), fair in 14 (35.9%), minor in 14 (35.9%), and none in 5 (12.8%). All 11 patients with major or fair improvement maintained the symptom improvement to the end of follow-up periods.

Conclusions
Symptom improvements after biofeedback therapy were disappointing in both the constipation and incontinence group. However, when the symptom improvements were classified as major or fair, the improvements continued for at least a year. (J Neurogastroenterol Motil 2010;16:177-185)

Key Words
Biofeedback, Therapy, Constipation, Fecal incontinence
Introduction

Constipation and fecal incontinence are common disorders in gastrointestinal area. These disorders are rarely life threatening, but could interfere with the quality of life and on individuals’ self-image. Biofeedback therapy has been introduced as a method to treat these functional gastrointestinal disorders, especially for functional fecal incontinence and constipation by pelvic dyssynergia. This treatment modality has been reported to be effective, although there have been arguments over the studies on biofeedback therapy which were sometimes not controlled and had methodological problems.

Constipation is a common disorder with a prevalence of 2-27% in adults. Most of these patients could be treated with conservative treatments such as high fiber diet and/or laxatives. However patients with severe constipation who do not respond to medications seek for further medical care. Biofeedback therapy has been effective for constipation by pelvic floor dyssynergia with the success rates of 60 to 80%. The biofeedback therapy is usually not effective for slow transit constipation. However, in slow transit constipation with pelvic floor dyssynergia, so-called mixed-type functional constipation, it has been effective as it is in normal transit constipation. Some investigators insisted biofeedback therapy to show clinical benefits even with slow transit constipation. In a recent controlled long-term follow-up study, the clinical benefits of biofeedback therapy in patients with pelvic floor dyssynergia were maintained for a long time.

Fecal incontinence could be defined as an involuntary passage of fecal materials after at least 4 years of age. The prevalence of fecal incontinence is 2 to 17% and has been reported to increase among women, aged, and disabled. Although fecal incontinence is not a life threatening disorder, it could lead to various social and psychological problems. Choosing treatment strategy is based on the specific cause of fecal incontinence. When constipation occurs by a trauma to the anal sphincters during an obstetric procedure, or a surgical procedure, surgical modality is the first choice of treatment. The surgical treatment is shown to be highly effective in the short-term follow-up studies, whereas the results of long-term follow-up were questionable. When conservative treatment fails or when surgical correction is not amenable, other therapeutic modalities are needed. Biofeedback therapy is a non-invasive and easily feasible option which has been used for fecal incontinence over several decades. Numerous published studies support it as the first choice of treatment for fecal incontinence. These studies have reported a success rate of about 70% (between 40 to 100%). However, in a recently randomized-controlled study, biofeedback therapy was not more helpful than supportive cares, such as life-style modification, drug treatment, or emotional support. Furthermore, instrumental feedback as well as non-instrumental feedback such as digital guidance could not prove any additional benefit of biofeedback therapy in a randomized-controlled trial. A well-designed controlled study is needed to clarify the efficacy of biofeedback therapy in patients with fecal incontinence.

The aim of this study was to evaluate both the short-term and long-term efficacy of biofeedback therapy, and to identify the predicting variables associated with success of the treatment in a single center in South Korea.

Materials and Methods

1. Subjects

Sixty-four patients with constipation or incontinence were consecutively enrolled in Seoul National University Bundang Hospital from June 2003 to January 2008. Twenty-four patients had constipation and 39 had fecal incontinence. Patients who completed less than 4 biofeedback sessions were excluded from the analysis.

2. Methods

Detailed medical history was taken to evaluate the duration of symptoms including any previous operation or trauma history. Before the biofeedback therapy, the physiological parameters were evaluated by anorectal manometry, balloon expulsion test and colonic transit testing. For the patients with fecal incontinence, transanal ultrasonography was performed to assess pathophyslogic status of the anal sphincter.

1) Anorectal manometry with balloon expulsion test

Before anorectal manometric evaluation, bowel preparation was performed by 2 pills of dulcorax suppository. Anorectal function testing was performed in the left-lateral position with the hips flexed to 90°. Anorectal manometry was performed using the water-perfusion technique with an 8-channel Micro Tip catheter (Medtronic) connected to a perfusion pump in the left-lateral position. The physiological parameters included the anal canal resting pressure, squeezing pressure, compliance, defecation index, resting and squeezing vectogram, and rectoanal inhibitory reflex. Rectal sensation was assessed by the inflation of a latex bal-
loon with an air flow of 1 mL per second, and the threshold volumes for the first minimal sensation, desire to defecate, urge, and maximal tolerance were determined. The balloon expulsion test was carried out with 50 mL water filled balloon in the following order: the catheter was lubricated and inserted to the rectum, and then the balloon was filled with a 50 mL of water at room temperature. The patients were instructed to sit on a commode chair in a usual defecation position and to pass out the balloon. After waiting for 5 minutes, patients who could not pass the balloon across the anal canal were considered to have failed the balloon expulsion test.

2) Colon transit time

The colon transit time was measured using radio-opaque markers (Kolomark\textsuperscript{TM}, M.I.Tech., Pyongtaik, Korea). The subjects ingested one capsule containing 20 radio-opaque markers in the morning at 24-hour intervals for three consecutive days; 2 simple abdominal radiographs in the supine position were obtained on day 4 and day 7. Localization of the radio-opaque markers was determined by identifying the relations to landmarks of bony structure.\textsuperscript{24} That is, the markers located to the right side of the vertebral spinous processes above a line from the fifth lumbar vertebra to the right pelvic outlet were assigned to the right colon, and the markers inferior to a line from the pelvic brim on the right and anterior superior iliac crest were assigned to the left colon, and the markers above an imaginary line from the fifth lumbar vertebra to the anterior superior iliac crest were assigned to the left colon, and the markers inferior to a line from the pelvic brim on the right and the superior iliac crest on the left were considered to locate in the recto-sigmoid colon and rectum. The markers were counted by the superior iliac crest on the left were considered to locate in the markers inferior to a line from the pelvic brim on the right and anterior superior iliac crest were assigned to the left colon, and the markers above an imaginary line from the fifth lumbar vertebra to the anterior superior iliac crest were assigned to the left colon, and the markers inferior to a line from the pelvic brim on the right and the superior iliac crest on the left were considered to locate in the recto-sigmoid colon and rectum. 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A p-value of less than 0.05 was considered statistically significant. Data were analyzed using the SPSS statistical software package (SPSS 15.0 for Windows, SPSS Inc., Chicago, IL, USA).

Results

1. Characteristics of patients

Total of 64 patients were enrolled; 25 patients had constipation (39.1%) and 39 patients had fecal incontinence (60.9%) (Table 1). The mean age was 52.1 ± 18.6 years in the constipation group and 59.7 ± 16.7 years in the fecal incontinence group. There were more males (64.0%) than females (36.0%) in the constipation group and more females (61.5%) than males (38.5%) in the fecal incontinence group (p = 0.046). The bowel movement frequency was 2.5 ± 1.8 per week in the constipation group and 4.8 ± 2.1 per day in the fecal incontinence group (Table 1).

2. Clinical efficacy of biofeedback therapy

The mean follow-up period was 49.6 ± 12.0 months in the constipation group and 34.5 ± 13.8 months in the incontinence group, respectively. Improvement of constipation after completion of biofeedback therapy was noted by the following order: major improvement in 3 patients (12%), fair in 6 (24%), minor in 11 (44%), and none in 5 (20%). Among 9 patients who showed major or fair improvements (responder group), 8 patients (88.9%) maintained the symptom improvements through the long-term follow-up periods. Among 39 incontinence patients, improvements of incontinence after completion of biofeedback therapy are as follows: major in 6 patients (15.4%), fair in 14 (35.9%), minor in 14 (35.9%), and none in 5 (12.8%). Among 11 patients who showed major or fair improvements (responder group), all maintained the symptom improvements through the long-term follow-up periods.

3. Biofeedback therapy sessions

The average number of sessions for biofeedback therapy was 6.2 times in the constipation group and 6.8 times in the incontinence group. No significant difference was observed among the responder group in regard to the frequency of biofeedback sessions in both the constipation and incontinence patients.

4. Anorectal physiological parameters

Analysis was performed between the responder and non-responder group in either constipation or incontinence group. In the constipation group, no significant differences were found between the responder and non-responder group at baseline with regard to demographic variables such as age, symptom duration, and bowel frequency (Table 2). However, female responded more fairly to biofeedback therapy than male (p = 0.031) (Table 2). Also there were no significant differences between the responder and non-responder group with regard to the physiologic parameters such as resting pressure and squeezing pressure, although the defecation index was lower in the non-responder group (p = 0.041) (Table 3). There were no differences in the minimal volume, urgent volume and critical volume in measuring the rectal sensory threshold, while the desire to defecate volume was smaller in the responder group. No differences in colon transit time and balloon expulsion test before biofeedback therapy.

Table 2. Characteristics of Patients With Constipation at the Initial Enrollment and Comparison Based on the Response to Biofeedback Therapy

|                     | Responder (n = 25) | Non-responder (n = 39) | p-value |
|---------------------|-------------------|------------------------|---------|
| Gender (male/female) | 16/9              | 24/13                  | 0.031   |
| Age (yr) 58.8 ± 7.9 | 48.3 ± 21.8       | 0.552                  |
| Bowel frequency (wk) | 2.3 ± 1.7         | 2.6 ± 1.9              | 0.740   |
| Symptom duration (mo) | 240.4 ± 212.6     | 126.9 ± 113.9          | 0.428   |
| Biofeedback therapy (sessions) | 7.2 ± 2.8 | 6.6 ± 2.9 | 0.527   |

7Major improvement (more than 80% symptom resolution) or fair improvement (symptoms less than 50%), 8Mild improvement (symptoms remained more than 50%) or none (unresponsive to the biofeedback therapy), 9Frequency of defecation during 1 week. Bold style indicates statistical significance.
were noted (Table 3).

In the fecal incontinence group, there were no significant differences between the responder and non-responder group with regard to the physiological parameters; with the exception on the squeezing pressure before biofeedback therapy (Table 4). The responder group showed higher squeezing pressure than the non-responder group \( (p = 0.027) \).

Follow-up anorectal manometry test was performed in 3 patients of the constipation group and 13 patients of the incontinence group after completion of biofeedback therapy. Adequate analysis for the physiological parameters before and after biofeedback therapy was not able in the constipation group due to the small sample size. In the incontinence group, the squeezing pressure increased significantly after biofeedback therapy in the responder group as opposed to the non-responder group. There were no significant differences in the resting pressure and minimal sensory volume before and after biofeedback therapy (Table 5).

5. Transanal ultrasound

For the incontinence group, the status of anal sphincters was evaluated by transanal ultrasound. The anal canal was noted to be normal in all patients. However, the ultrasound was not able to detect the extent of the sphincter defects accurately.

### Table 3. Physiological Parameters of the Patients With Constipation at the Initial Enrollment and Comparison Based on the Response to Biofeedback Therapy

|                          | Responder \( n = 9 \) | Non-responder \( n = 16 \) | p-value |
|--------------------------|-----------------------|-----------------------------|---------|
| Anorectal manometry findings |
| Resting pressure (mmHg)  | 52.2 ± 30.2           | 48.6 ± 13.8                 | 0.789   |
| Squeezing pressure (mmHg)| 137.6 ± 61.5          | 127.2 ± 55.3                | 0.640   |
| Defecation index         | 2.86 ± 3.46           | 1.03 ± 0.81                 | 0.041   |
| Minimal volume (mL)      | 33.3 ± 14.1           | 44.6 ± 18.5                 | 0.147   |
| Desire to defecate volume (mL) | 71.1 ± 10.3 | 88.3 ± 18.5                 | 0.019   |
| Urgent volume (mL)       | 127.1 ± 19.8          | 150.0 ± 49.3                | 0.402   |
| Critical volume (mL)     | 162.2 ± 23.3          | 205.0 ± 89.0                | 0.423   |
| Colon transit time (hr)  | 61.3 ± 49.9           | 62.2 ± 38.0                 | 0.910   |
| Balloon expulsion test   | 7/2                   | 10/3                        | 0.962   |

*Major improvement (more than 80% symptom resolution) or fair improvement (symptoms remained more than 50%) or none (unresponsive to the biofeedback therapy), †Rectal pressure during straining/anal residual pressure during straining. Bold style indicates statistical significance.

### Table 4. Characteristics and Physiological Parameters of Patients With Fecal Incontinence at the Initial Enrollment and Comparison Based on the Response to Biofeedback Therapy

|                          | Responder \( n = 20 \) | Non-responder \( n = 19 \) | p-value |
|--------------------------|-----------------------|-----------------------------|---------|
| Number (%)               | 20 (51.3)             | 19 (48.7)                   | 0.265   |
| Gender (male/female)     | 6/14                  | 9/10                        |         |
| Age (yr)                 | 62.0 ± 15.5           | 57.1 ± 18.1                 | 0.412   |
| Bowel frequency (/day)   | 5.1 ± 2.1             | 4.4 ± 2.1                   | 0.290   |
| Symptom duration (mo)    | 31.6 ± 50.2           | 45.3 ± 65.1                 | 0.365   |
| Biofeedback therapy (sessions) | 6.5 ± 2.9 | 5.7 ± 2.6                   | 0.579   |
| Anorectal manometry      |
| Resting pressure (mmHg)  | 27.6 ± 14.3           | 24.2 ± 15.1                 | 0.366   |
| Squeezing pressure (mmHg)| 125.4 ± 48.9          | 91.2 ± 43.7                 | 0.027   |
| Minimal sensory volume (mL) | 30.5 ± 13.9 | 34.1 ± 20.9                 | 0.749   |

*Major improvement (more than 80% symptom resolution) or fair improvement (symptoms less than 50%), †Mild improvement (symptoms remained more than 50%) or none (unresponsive to the biofeedback therapy). Bold style indicates statistical significance.

### Table 5. Changes of Manometric Parameters Before and After Biofeedback Therapy in Patients With Fecal Incontinence

|                          | Before biofeedback | After biofeedback | p-value |
|--------------------------|--------------------|-------------------|---------|
| Resting pressure (mmHg)  |
| Responder \( n = 7 \)   | 32.7 ± 14.4        | 22.8 ± 15.0       | 0.171   |
| Non-responder \( n = 6 \)| 19.6 ± 8.5         | 18.1 ± 16.2       |         |
| Squeezing pressure (mmHg)|
| Responder \( n = 7 \)   | 118.2 ± 23.8       | 142.7 ± 35.7      | 0.019   |
| Non-responder \( n = 6 \)| 90.8 ± 37.1        | 79.8 ± 38.2       |         |
| Minimal volume (mL)      |
| Responder \( n = 7 \)   | 25.7 ± 9.7         | 33.3 ± 16.3       | 0.235   |
| Non-responder \( n = 6 \)| 25.0 ± 9.2         | 34.2 ± 15.1       |         |

Bold style indicates statistical significance.
Several treatment modalities have been adopted for syndromes (25%), slow transit constipation (13%), and the mixed type (59%), followed by pelvic floor dysynergia with the most common subtype (3%).

In a large epidemiological study, normal transit constipation was the most common subtype according to the results of physiological testing. Normal transit constipation was the mixed type according to the results of physiological testing.29 Biofeedback therapy has been accepted as the treatment of choice for pelvic floor dysynergia and fecal incontinence due to its clinical efficacy. However, there continues to be controversies regarding its efficacy. First, most of the clinical findings were found to be based on the uncontrolled studies. In addition, many of the studies had methodological limitations, such as the differences in the criteria used to define successful outcome, the heterogeneity of the participants studied, and the different variables considered during the assessments. Furthermore, some studies did not show biofeedback therapy to be more effective than conservative treatments especially in patients with fecal incontinence22,23 and childhood functional constipation.24 However, the more important issue would be about the effects of biofeedback therapy to be maintained or not. As biofeedback therapy is a relatively inexpensive and non-invasive modality, it could be considered as the first-line therapy in patients with refractory anorectal disorders when its efficacy is predicted to be maintained for a long time interval.

Discussion

Biofeedback therapy has been reported to be an effective treatment for functional anorectal disorders such as functional constipation and functional fecal incontinence over the past few decades.2,27 Biofeedback therapy has been accepted as the treatment of choice for pelvic floor dysynergia and fecal incontinence due to its clinical efficacy. However, there continues to be controversies regarding its efficacy. First, most of the clinical findings were found to be based on the uncontrolled studies. In addition, many of the studies had methodological limitations, such as the differences in the criteria used to define successful outcome, the heterogeneity of the participants studied, and the different variables considered during the assessments. Furthermore, some studies did not show biofeedback therapy to be more effective than conservative treatments especially in patients with fecal incontinence22,23 and childhood functional constipation.24 However, the more important issue would be about the effects of biofeedback therapy to be maintained or not. As biofeedback therapy is a relatively inexpensive and non-invasive modality, it could be considered as the first-line therapy in patients with refractory anorectal disorders when its efficacy is predicted to be maintained for a long time interval.

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Constipation could be classified into normal-transit constipation, pelvic floor dyssynergia, slow-transit constipation, and the mixed type according to the results of physiological testing.29 In a large epidemiological study, normal transit constipation was the most common subtype (59%), followed by pelvic floor dysynergia (25%), slow transit constipation (13%), and the mixed type (3%).30 Several treatment modalities have been adopted for constipation such as life-style modification, medications, biofeedback therapy, injection of botulinum toxin,31 sacral nerve stimulation,32 anorectal electrical stimulation,33 and surgical treatment.34 Biofeedback therapy has been studied mainly in patients with pelvic floor dyssynergia. This disorder, which has also been called as anismus, an outlet obstruction or spastic pelvic floor syndrome, is a type of constipation characterized by a failure to relax the puborectalis muscle, the external and internal anal sphincter muscle during the straining for defecation. In recent controlled studies, Chiarioni et al.8,10 reported biofeedback as an effective treatment for pelvic floor dysynergia superior to laxatives with the improvement to be maintained for a long-term follow interval, while the effect was not found in cases of slow transit constipation. Biofeedback therapy was more effective than conservative treatments or sham feedback treatment in patients with pelvic floor dyssynergia.35 Altogether these studies suggest biofeedback therapy to be highly effective for pelvic floor dysynergia with the effects being long-lasting. Furthermore, some studies reported the effectiveness of biofeedback therapy for slow-transit constipation,11,12 which was shown by the improvement of cerebral cortex activity controlling colon motility.35,36 In the present study, we applied biofeedback therapy for refractory constipation patients regardless of the constipation type. The effect of biofeedback therapy was found in 36% of constipation patients with 88.9% of the responder group maintaining the symptom improvements for the long follow-up intervals. The lower outcome of biofeedback therapy just after the completion of biofeedback therapy may have originated from the broad category of participants including those with slow-transit constipation. Furthermore, defecation index, which is specific for pelvic floor dyssynergia,26 was significantly lower in the non-responder group. Again these results could be due to the broad indication of biofeedback therapy with the relatively old participants in our study. Several studies have evaluated the variables associated with successful outcome.8,10,37 Park et al.37 reported the defecation index and pelvic floor dyssynergia as factors influencing the response by multivariate analysis. Other investigators have suggested milder constipation, less frequent abdominal pain, digital facilitation, slow transit, and the defecation index to be associated with successful outcome. But not a common specific variable emerged when a critical review was performed.3 In our study, the rectal sensory parameters showed relatively lower pressures and volumes in the responder group and desire to defecate volume was also significantly lower in the responder group than in the non-responder group. In other words, the non-responder group showed higher minimal volume, desire to defecate volume, urgent volume, and critical volume than the responder group and the difference in desire to defecate volume was statistically significant. Furthermore, similar trend was observed in the follow-up anorectal manometry test after completion of biofeedback therapy. Urgent volume after biofeedback therapy was statistically higher in the non-responder group (180 mL vs. 140 mL, p
Clinical Efficacy of Biofeedback Therapy

Randomized, controlled, and blinded trials have not shown the superiority of biofeedback therapy compared to standard care supplemented by advice and education. In addition, non-instrumental feedback using simple digital insertion was equally as effective as instrumental biofeedback therapy. In spite of these limitations of biofeedback therapy, recent studies have concluded biofeedback-induced improvement to be maintained for a long time interval after treatment. There continues to be controversy on the use of biofeedback therapy for fecal incontinence, which may account for the reluctance in clinical use and the need for well-designed controlled studies to assess its efficacy. In our study, the clinical effect of biofeedback therapy was observed in 20 patients (51.3%) among 39 participants. Similar to other recent data, all patients who responded to biofeedback therapy have maintained the improvement on the most recent follow-up by telephone interview in the present study. Again the low response rate in the present study may have been due to the broad range of participants including anal sphincter defects caused by surgical procedures. Variables which tend to negatively affect the clinical outcome were reported to be the underlying neurological impairment and the heterogeneity of study group, as in our data. No objective factors has been identified in a critical review of many studies to date. Some studies have shown the improvement of manometric parameters after biofeedback therapy. However, most of the data points to inconsistencies between subjective improvement and objective parameters such as manometric changes. In our study, a high anal squeezing pressure was an indicator for a good response (p = 0.027). In addition, the responder group showed increases in the anal squeezing pressure after biofeedback therapy (p = 0.019). These results in the incontinence group suggest patients with mild anorectal pathophysiology to present with a good response to biofeedback therapy as in the constipation group. We could not find any other objective parameters than the anal squeezing pressure which correlated with the clinical efficacy evaluated by the anorectal manometry after completion of biofeedback therapy.

In our study, there are several methodological problems. First of all, we did not use the Rome II or Rome III criteria. Instead, biofeedback was performed in patients with either constipation or incontinence who did not respond to conservative medical therapy such as life-style modifications and medications. Second, the criteria for the evaluation of clinical efficacy were rather subjective. Successful outcome was defined depending on the patient’s subjective report. Third, follow-up periods were variable. However, as biofeedback therapy has not been estab-
lished as a standard therapy for constipation or incontinence and the response rate has been known to be inconsistent, it might be a valuable attempt to analyze the efficacy of biofeedback therapy in the crude patient group and share the experience of one institution.

In conclusion, biofeedback therapy in our study showed low successful outcome, but the clinical efficacy was maintained for a long time once the patients responded to the therapy. As patients with mild anorectal pathophysiology show good response to biofeedback therapy, it must be considered as the first therapeutic modality for functional anorectal disorders before they advance into more serious cases.

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