Randomized Controlled Trial of Biofeedback for Fecal Incontinence

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Background & Aims: **Behavioral treatment (biofeedback) has been reported to improve fecal incontinence but has not been compared with standard care.** ***Methods:*** **A total of 171 patients with fecal incontinence were randomized to 1 of 4 groups: (1) standard care (advice); (2) advice plus instruction on sphincter exercises; (3) hospital-based computer-assisted sphincter pressure biofeedback; and (4) hospital biofeedback plus the use of a home electromyelogram biofeedback device. Outcome measures included diary, symptom questionnaire, continence score, patient's rating of change, quality of life (short-form 36 and disease specific), psychologic status (Hospital Anxiety and Depression scale), and anal manometry.** ***Results:*** **Biofeedback yielded no greater benefit than standard care with advice (53% improved in group 3 vs. 54% in group 1). There was no difference between the groups on any of the following measures: episodes of incontinence decreased from a median of 2 to 0 per week ($P < 0.001$). Continence score (worst = 20) decreased from a median of 11 to 8 ($P < 0.001$). Disease-specific quality of life, short-form 36 (vitality, social functioning, and mental health), and Hospital Anxiety and Depression scale all significantly improved. Patients improved resting, squeeze, and sustained squeeze pressures (all $P < 0.002$). These improvements were largely maintained 1 year after finishing treatment.** ***Conclusions:*** **Conservative therapy for fecal incontinence improves continence, quality of life, psychologic well-being, and anal sphincter function. Benefit is maintained in the medium term. Neither pelvic floor exercises nor biofeedback was superior to standard care supplemented by advice and education.**

Fecal incontinence is a common health care problem. A postal survey in the United Kingdom, with over 10,000 respondents, found that 5.7% of women and 6.2% of men over 40 years old report some degree of fecal incontinence, with prevalence increasing with age.[1] Overall, 1.4% of adults reported major fecal incontinence (at least several times per month).

Behavioral techniques, often considered together under the collective term *biofeedback*, have been used extensively in clinical practice to treat fecal incontinence and have been advocated to be the treatment of first choice by some investigators.[2] A systematic literature search found 46 studies published in English using biofeedback to treat adult patients complaining of fecal incontinence.[3] These studies involved a total of 1364 patients. Of those studies with data that could be analyzed, 275 of 566 patients (48.6%) were said to be cured of symptoms of fecal incontinence after biofeedback therapy and 617 of 861 patients were reported to be improved (71.7%). A separate Cochrane review of controlled studies of biofeedback and exercises for fecal incontinence concluded that "there is not enough evidence from trials to judge whether these treatments are helpful, nor which aspects of the treatment are the most helpful, and which patients are the most likely to be helped."[4]

The present study aimed (1) to determine whether biofeedback is effective compared with an attention control group, (2) to determine which elements of biofeedback are more important to clinical improvement, and (3) to determine whether patients with anal sphincter disruption are less likely to respond to biofeedback than patients with an intact sphincter. Our methodology of biofeedback has been described in detail elsewhere.[5]

Materials and Methods

The study was set in a specialist colorectal hospital that acts as a secondary and tertiary referral center. Biofeedback is the therapy of first choice for patients who do not have major anal sphincter and perineal body disruption (these patients are offered the option of surgery). The biofeedback service is nurse-led, in the context of a multidisciplinary unit. Patients normally have been examined previously by anorectal physiologic studies and anal ultrasonography before referral for biofeedback.

Abbreviation used in this paper: IQ, interquartile range.

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Table 1. Content of Therapy for the 4 Groups

	Group 1	Group 2	Group 3	Group 4
Diary and symptom questionnaire	√	√	√	√
Structured assessment	√	√	√	√
Patient teaching	√	√	√	√
Emotional support	√	√	√	√
Lifestyle modifications	√	√	√	√
Management of fecal incontinence	√	√	√	√
Urge-resistance program	√	√	√	√
Anal sphincter exercises		√	√	√
Clinic computer biofeedback			√	√
Home biofeedback unit				√

At the time of referral patients were randomized to 1 of the 2 therapists (random numbers generated by Excel function; Microsoft, Redmond, WA). Patients attending their first biofeedback assessment session were informed about the study and informed consent to enter the trial was sought. Inclusion criterion was any patient referred for symptoms of fecal incontinence, regardless of frequency or severity of incontinence. No minimum level of incontinence was required because so many patients alter their lifestyle substantially to manage their bowel and avoid frank incontinence. Exclusion criteria were: patients who previously had undergone a course of biofeedback or exercises for fecal incontinence, patients under 18 years, patients with major neurologic disease, patients with significant cognitive impairment, patients with active inflammatory bowel disease, patients who appeared significantly distressed and unable to consider informed consent issues adequately, patients assessed as needing urgent medical referral, and patients judged to have insufficient written English skills to complete the questionnaires.

We had hypothesized that patients with structural sphincter damage, as identified on anal ultrasonography, might be less likely to respond to biofeedback treatment than those with a structurally intact sphincter. On this basis patients who consented and entered the study were stratified into those with an intact external and internal anal sphincter and those with some degree of anal sphincter disruption as reported on anal ultrasound. Within each of these 2 groups, patients then were randomized to 1 of 4 groups. The random numbers were generated by Excel in advance, each number was placed into an opaque brown envelope that was numbered sequentially; the therapist had no prior knowledge of group allocation to ensure minimum bias in recruitment before consent. The therapist and patient could not be blinded to treatment group once allocated. However, standard protocols were developed for each group to ensure as far as possible that all patients had the same issues covered, with only the dependent variables varying systematically between groups. Table 1 gives the content of therapy for the 4 groups. All groups received an equivalent amount of time in each treatment session.

Group 1

Patients had up to nine 40–60-minute sessions over 3–6 months with a specialist nurse offering advice on a standard range of issues such as diet, fluids, techniques to improve evacuation, a bowel training program,[5] titration of dose of antidiarrheal medication (if previously prescribed), and practical management.

Group 2

Additionally, patients were taught anal sphincter exercises verbally and by digital examination and given a leaflet on exercises. Patients were instructed to perform at least 50 maximal voluntary sustained sphincter contractions and 50 fast-twitch contractions per day.

Group 3

Additionally, patients were provided with computer-assisted biofeedback during sessions to attempt to teach the patient increased rectal sensitivity to distention, improved coordination of sphincter activity, decreased delay in sensation, and isolation of the anal sphincter, concentrating on improving both muscle strength and endurance. The external sphincter contraction pressure was shown on a computer screen.

Group 4

Additionally, patients were asked to use a home biofeedback device (DMI Medical Limited, Wigan, UK) once daily for 20 minutes. This device involves insertion of an intra-anal electromyelogram electrode, connected to a battery box, with increasing muscle contraction showing as an increased number of lights illuminated.

Outcome Measures

No single tool was found in the literature that was felt to be satisfactory for the purposes of this study. Given the lack of a gold standard and a lack of evidence from previous studies about what matters to patients with this symptom, it was decided to evaluate the outcome by using a range of subjective and objective outcome measures.

The 2 primary outcome measures were the patient's own view of the effectiveness of treatment rated as "worse," "same," "improved," or "cured," and rating of that change on an ordinal scale of −5 to +5.

Secondary outcome measures included change in anorectal physiologic tests, change in bowel symptoms as recorded by a

bowel symptom questionnaire[5] and a bowel diary,[6] change in continence as measured by a published continence score,[7] the short-form 36 generic measure of health-related quality of life and health,[8] a locally developed, unpublished, condition-specific quality of life measure, and the Hospital Anxiety and Depression scale.[9] The HAD yields separate numeric scores for anxiety and depression. The original investigators suggested that these scores could be used to categorize patients as "noncase," "borderline," or "case" for psychiatrically significant anxiety or depression and these categories were used in the present study.[9]

The physiologist performing the repeat anorectal study at the end of treatment was blinded as to group allocation and previous test results. Questionnaires only were repeated 12 months after finishing treatment. For practical reasons neither patients nor therapists, who were also the researchers and responsible for inputting the data, could be blinded as to treatment allocation. For this reason, all outcome measures (except anorectal physiologic studies) were self-completed by patients in a situation without the therapist being present.

No analysis was started until all patients had completed treatment. This was to avoid biasing the therapists, who may have changed their approach if it was known that any groups were doing better or worse than others.

Sample Size

A feasibility study[10] suggested that 67% of patients were improved or cured with standard biofeedback care in our clinic (group 3 protocol). It was not known what effectiveness the protocols for other groups would have. For a sample size calculation it was decided to compare group 1 with group 3. Because group 1 was seen as having a minimal intervention of information and advice only, it was estimated that 30% of patients in group 1 would report improvement. To show this difference with a 5% significance level and 90% power, 40 subjects would be required in each group.

The study was approved by the local research ethics committee.

Results

Patient Demographics

Figure 1 gives a flow chart of recruitment. A total of 103 eligible patients were not recruited because they refused randomization (59), could not commit to regular attendance (27), or were unwilling to complete the documentation (17 patients).

A total of 171 patients were recruited into the study (Table 2). There were 12 men and 159 women, with a mean age of 56 years (range, 26–85 years). They had experienced fecal incontinence for a median of 4 years (range, 2 months to 59 years). Of the 159 women, 148 (93%) were parous, with a median of 2 vaginal deliveries (range, 1–7). Of the 148 who had previous deliveries, 61 (42%) had had at least one forceps delivery, and 52 (35%) had delivered one or more babies over 4 kg of

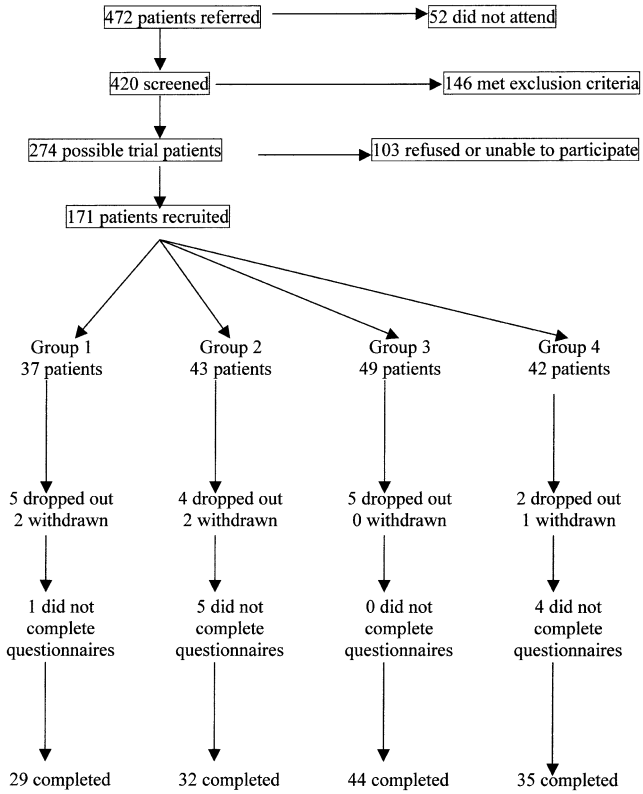

Figure 1. Flow chart of recruitment.

birth weight. Fifty-one percent had experienced one or both of an instrumental delivery or a baby over 4 kg.

Fifty-seven of the 159 women (36%) had undergone a previous hysterectomy. Twenty-four percent had a previous medical diagnosis of irritable bowel syndrome or had symptoms that fulfilled the Rome II criteria for irritable bowel syndrome.[11] Thirteen had undergone a previous hemorrhoidectomy, 6 had local procedures for hemorrhoids, 12 had anal sphincter repair, 8 had postanal repair, and 6 had surgery for rectal prolapse. One third (33%) had a history of depression severe enough to have needed medical treatment and 61% had concomitant urinary incontinence. Seventy of the patients (41%) were taking antidiarrheal medication at the time of study entry.

The median continence score was 15 (interquartile [IQ] range, 4.0). Diaries showed a median of one incontinence episode per week (IQ range, 5.0). Seventy-seven patients reported that their incontinence was a minor or small amount of stool and 79 patients reported that their incontinence was a large amount of stool (15 did not reply). Seventy-nine patients reported loss of solid stool, 77 reported liquid stool (15 did not reply).

To determine whether the recruited patients were representative of all those eligible, that is, to exclude bias in recruitment, the answers to the pre-entry questionnaires were compared between the 171 trial patients and

Table 2. Patient Characteristics Before the Study

	Group 1	Group 2	Group 3	Group 4	All patients
Number of patients	37	43	49	42	171
Sex: men/women	1/36	5/38	5/44	1/41	12/159
Age in years: mean (range)	58 (28–84)	55 (26–76)	54 (30–81)	56 (28–85)	56 (26–85)
Medical history					
Irritable bowel syndrome (Rome 11 criteria): n (%)	8 (22)	14 (33)	10 (20)	9 (21)	41 (24)
Urinary incontinence: n (%)	26 (70)	23 (53)	29 (59)	27 (64)	105 (61)
Antidiarrheal medication: n (%)	14 (38)	17 (40)	23 (47)	16 (38)	70 (41)
Depression (past or present need for treatment): n (%)	14 (38)	9 (21)	14 (29)	20 (48)	57 (33)
Continence score: median (IQ range)	16.4 (3.7)	14.4 (4.3)	15.1 (3.7)	14.8 (4.0)	15.1 (4.0)
Anorectal physiology test results					
Resting pressure: median (IQ range) cm H_2O	47 (27)	44 (56)	50 (41)	46 (35)	47 (42)
Squeeze increment: median (IQ range) cm H_2O	55 (67)	47 (53)	52 (67)	34 (26)	41 (51)
5-second squeeze increment: median (IQ range)	14 (52)	0 (40)	0 (53)	5 (22)	2.5 (38)
Anal ultrasound					
Normal: n (%)	12 (32)	13 (30)	13 (27)	9 (21)	47 (28)
Intermediate: n (%)	11 (30)	18 (42)	22 (45)	12 (29)	63 (37)
Severe damage: n (%)	12 (32)	7 (16)	13 (27)	11 (26)	43 (25)
No ultrasound available: n (%)	2 (5)	5 (12)	1 (2)	10 (24)	18 (11)

the 103 eligible patients who were not recruited. Apart from the trial group containing proportionally fewer men, there were no statistically significant differences between recruited and nonrecruited eligible patients.

Investigations

Anorectal physiologic studies were available for 159 patients at study entry and showed median manometric resting and squeeze pressures below the normal range, but with a large variation (Table 2). Median resting pressure was 47 cm H_2O (range, 5–145; normal range in our unit, 60–160 cm H_2O). Median squeeze increment was 41 cm H_2O (range, 0–288; normal range in our unit, 50–220 cm H_2O).

Anal ultrasound results were available in 153 patients. The anal ultrasound was classified[12] as normal when there was no structural sphincter damage (47 patients, 28%). Severe damage was a full-length defect in either internal or external anal sphincter or both (43 patients, 25%). All other patients, that is, those with partial disruption, scarring, or degeneration on ultrasound, were classified as intermediate (63 patients, 37%). Stratification for randomization was on the basis of a normal sphincter vs. any abnormality of the sphincter (including partial disruption or degeneration). The 18 patients with no ultrasound available were allocated arbitrarily to the normal sphincter arm. This feature of sphincter integrity on ultrasound was for purposes of stratification only. They were distributed evenly throughout all 4 groups. Those patients without a scan were excluded from the analysis of outcome in relation to scan findings.

Randomization

Thirty-seven patients were randomized to group 1, 43 to group 2, 49 to group 3, and 42 to group 4. The 4 randomized groups did not differ significantly for demographics and nearly all other parameters. A difference was found in reported urgency on the bowel symptom questionnaire, with group 3 more likely to have no urgency (6 patients with no urgency, as opposed to 0 or 1 in the other groups, $P = 0.028$). Passive soiling was more frequent in groups 1 and 2 ($P = 0.005$). Amount of leakage was distributed evenly.

The only statistically significant difference found in physical parameters was in pretreatment squeeze pressure, this being particularly low in group 4 ($P = 0.018$). Ultrasound appearances were distributed equally between groups.

Patients Completing Study Protocol

A total of 140 patients completed the trial protocol and the repeat outcome measures at the end of the trial. A further 16 patients dropped out (9.4%), 5 were withdrawn because they developed a need for urgent medical treatment, and 10 completed the protocol but did not return any questionnaires (Figure 1). There was no significant difference between the groups in completion rates ($P = 0.13$, Fisher exact test). Patients had a median of 5 sessions (range, 1–9), always with the same therapist.

Patient Assessment of Outcome—Primary Outcome Measure

The primary outcome measure for this study has been analyzed and reported on an intention-to-treat ba-

sis, with noncompleters assumed to remain unchanged. Patients were asked to give a global rating of symptom change since starting treatment (worse, same, improved, or cured). There was no significant difference in rating between the 4 groups ($P = 0.54$, Fisher exact test; Figure 2).

Patients were asked to rate the change in their bowel control since starting treatment on a scale from −5 to +5. The median change was +3 for group 1, +2 for group 2, +3 for group 3 and, +0.5 for group 4, a statistically significant difference between the 4 groups ($P = 0.048$, Kruskal–Wallis test; Figure 3). This significant difference was owing to group 4 showing a poorer outcome (expected to show a better outcome) than groups 1–3.

Patients were asked to rate their satisfaction with the results of treatment on a scale from 0–10. There was no significant difference in rating between responders in the 4 groups ($P = 0.52$, Kruskal–Wallis test). The median satisfaction was 8 (IQ range, 4).

Bowel Frequency and Continence

Patients reported between 1–9 bowel actions per day. The groups did not differ in relation to bowel frequency and symptoms of incontinence before treatment. After treatment there was no difference between the groups in frequency of bowel actions per day ($P = 0.71$, Kruskal–Wallis test), reported length of time they could usually resist the urge to defecate, stool form, frequency of urge incontinence, frequency of postdefecation soiling, or passive fecal incontinence. After treatment there was no significant difference between groups for overall rating of bowel control on a scale of 0–10 ($P = 0.68$, Kruskal–Wallis test). According to the bowel diary there was no difference between the groups on bowel actions per week, frequency of accidents, or pads used per week at the end of treatment (Table 3).

After treatment there was no statistically significant difference between the groups' continence score (Table 3, $P = 0.54$, Kruskal–Wallis test). There was no significant difference between the groups in the proportion taking antidiarrheal medication; in total 68 were taking medication and 68 were not (4 not recorded), and these numbers were distributed evenly between the groups ($P = 0.71$, Pearson χ^2 test). Fifty percent were taking medication after treatment, compared with 41% before entering the study (no difference between groups before or after treatment).

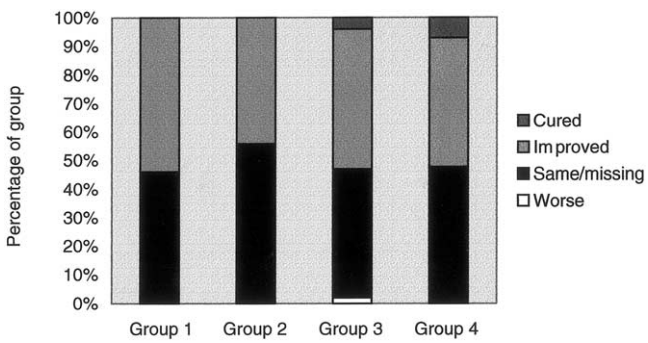

Figure 2. Patients' rating of the results of treatment. Intention to treat analysis: those dropping out or not completing questionnaires were counted as the same.

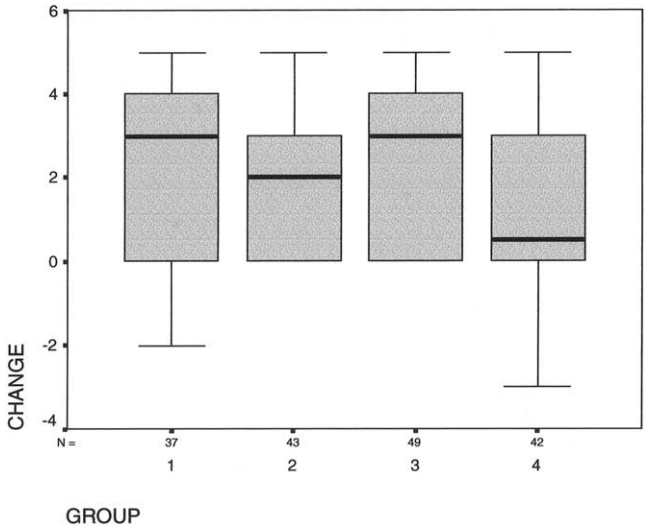

Figure 3. Patients' rating of change. Intention to treat analysis: those dropping out or not completing the questionnaires counted as zero. *Solid black line*, median for group; *box*, IQ range; *thin bars*, whole range of responses.

Other Outcomes

Anorectal physiologic tests were repeated in 88 patients (the remainder declined repeat tests: those who declined repeat tests were not statistically different from those who agreed to repeat tests, either in baseline physiologic measurements nor in rating of the effect of treatment). After treatment there were no statistically significant differences in manometric pressures between groups (Table 3).

Every domain of the condition-specific quality-of-life questionnaire was compared between the 4 groups using Fisher exact test. After treatment there was no significant difference between groups for any domain or the total score. There was no statistically significant difference between the groups in any domain of the short-form 36.

There was no significant difference between the groups in anxiety or depression scores after treatment ($P = 0.53$ for anxiety and $P = 0.46$ for depression, Kruskal–Wallis test). There was no significant difference in anxiety or depression category (case, borderline, or noncase) between the groups ($P = 0.64$ for anxiety, Pearson's χ^2 test and $P = 0.50$ for depression, Fisher exact test).

Table 3. Symptoms and Test Results After Treatment

	Group 1	Group 2	Group 3	Group 4	All patients
Completed protocol and questionnaires	29 (78%)	32 (74.4%)	44 (90.0%)	35 (83.3%)	140 (82.0%) $P = 0.13$ (FT)
Rating of bowel control (0–10 scale): median (IQ range)	6 (3)	7 (2.5)	6 (5)	6 (3)	6 (3) $P = 0.68$ (KW)
Diary bowel actions per week: median (IQ range)	10 (8)	11 (11)	9 (8)	10 (11)	10 (8) $P = 0.58$ (KW)
Diary accidents per week: median (IQ range)	1 (2)	0 (2)	0 (3)	0 (3)	0 (3) $P = 0.51$ (KW)
Diary pad changes per week: median (IQ range)	1 (2)	0 (0)	0 (2)	0 (1)	0 (1) $P = 0.26$ (KW)
Continence score: median (IQ range)	13 (6.5)	11 (6)	13 (7)	14 (11)	13 (7) $P = 0.54$ (KW)
Anorectal physiology test results					
Resting pressure: median (IQ range) cm H_2O	50 (18)	49 (43)	66 (36)	54 (45)	54 (33) $P = 0.48$ (KW)
Squeeze increment: median (IQ range) cm H_2O	71 (67)	60 (103)	46 (43)	37 (40)	54 (49) $P = 0.12$ (KW)
5-second squeeze increment: median (IQ range) cm H_2O	35 (70)	37 (44)	30 (45)	35 (50)	30 (45) $P = 0.70$ (KW)

FT, Fisher exact test; KW, Kruskal–Wallis test.

Comparison of All Trial Patients Before and After Treatment

Given the finding that there were no differences between the groups, the groups were analyzed together to examine the effect of therapy on the whole cohort of randomized patients.

There was a statistically significant increase in resting (median, 49–55; $P = 0.002$), squeeze increment (median, 41–54; $P = 0.001$), and 5-second squeeze increment (median, 0–30; $P = 0.001$) pressures in those patients undergoing repeat testing. Involuntary squeeze was unchanged, as were threshold, urge, and maximum tolerated volumes to rectal balloon distention.

Answers to the Bowel Symptom Questionnaire were compared before and after treatment for the whole cohort. Patients experienced a significant reduction in bowel actions per day from a median of 2.5 before treatment to 2.0 after treatment ($P \leq 0.001$, Wilcoxon signed ranks test). Using the McNemar test for paired categoric data, there was a significant increase in the length of time defecation could be deferred ($P \leq 0.001$), and stools were more likely to be firmer ($P = 0.05$); the frequency of urge incontinence decreased ($P \leq 0.001$), as did that of postdefecation ($P \leq 0.001$) and passive incontinence ($P = 0.005$); incontinence was likely to be more liquid rather than solid ($P \leq 0.001$) and lower volume ($P \leq 0.001$) after treatment. There was a nonsignificant trend for patients to be less likely to wear a pad ($P = 0.06$). They were more likely to be able to control flatus ($P \leq 0.001$). Patients were likely to rate the overall impact on quality of life lower after treatment ($P \leq 0.001$).

Patients were less likely to report difficulty with evacuation after treatment than before ($P = 0.002$, McNemar test). Patients were asked for a global rating of bowel control on a scale of 0–10. The median score improved from 4 before treatment to 7 after treatment ($P \leq 0.001$, Wilcoxon signed rank test).

According to the bowel diary there was a statistically significant reduction in bowel actions from a median of 14 to 10 ($P < 0.001$), accidents (2 to 0, $P < 0.001$), and pads (1 to 0, $P < 0.001$, all Wilcoxon signed rank test) used per week. It should be noted that the diary was poorly completed after treatment, with a high percentage of missing data (5% before, 39% after), so these results should be viewed with caution.

Response to each domain of the condition-specific quality of life questionnaire was compared before and after treatment using the McNemar test. There was a significant improvement in nearly all domains. The total score on this questionnaire was compared before and after treatment. There was a significant reduction (improvement) in scores after treatment for the 109 patients with both questionnaires from a median of 15 to a median of 8 ($P \leq 0.001$, Wilcoxon signed rank test) (possible range, 0–77). On the short-form 36 there was a significant positive change in vitality, social functioning, and mental health scores in 111 trial patients who completed both questionnaires (Wilcoxon signed rank test), and all subscale scores increased (improved) or stayed the same.

Responses to the Hospital Anxiety and Depression scale showed a significant decrease (improvement) in both anxiety ($P \leq 0.001$) and depression ($P = 0.001$) scores for the trial patients as a whole group (Wilcoxon signed rank test, n = 122). There was a significant positive change in the anxiety category toward being a noncase ($P = 0.01$, McNemar test), but no change in the depression category ($P = 1.00$, McNemar test).

There was a decrease (improvement) in continence scores, from a median of 15 (IQ range, 4.0) to 13 (IQ range, 7.0) ($P \leq 0.001$, Wilcoxon signed rank test). There was no significant change in the number of patients using antidiarrheal medication before and after treatment ($P = 0.09$, McNemar test).

Correlates of Outcome

No clear associations were found between patients' subjective rating of outcome and any of the predetermined possible predictors of outcome (main presenting complaint [urge incontinence vs. passive soiling], therapist, age, previous history, parity, weight, smoking, prior anorectal physiology test results, continence score [severity], anxiety and depression, or previous rating of bowel control). The only exceptions were age over 60 years (more positive rating of outcome) and body mass index (higher weight being associated with poorer outcomes). In particular, outcome did not relate to structural integrity of the anal sphincter on anal ultrasound. Patients with normal sphincters, intermediate disruption, and severe disruption were compared in their rating of outcome on the -5 to $+5$ scale. There was no correlation ($P = 0.48$, Pearson correlation). Whether patients had been exercising or not did not correlate with outcome (group 1 compared with groups 2–4) or whether they had biofeedback (groups 1 and 2 compared with groups 3 and 4).

Multiple logistic regression using the same factors found none significant at the 5% level, but depression ($P = 0.08$) and body mass index ($P = 0.07$) had a suggestion of an influence, but did not alter results when adjusted for independently.

Results at 1-Year Follow-up

Patients were sent all questionnaires again 1 year after finishing treatment or dropping out. Nine patients had surgery for persistent fecal incontinence, 1 patient had developed cancer, and 1 patient had moved and was not followed-up.

Overall, replies were available at 1 year for 106 of the remaining possible 160 patients (66%). Of those who replied at 1 year, 11 had not done so immediately after the end of the study or dropping out, giving 95 paired responses at both points in time. Among those who did reply, early changes were largely sustained, with only a slight decrease in efficacy. As with the results immediately after treatment, no differences could be detected between the groups on any of the questionnaires at 1 year. Virtually all parameters remained significantly improved from pretreatment values, although there was some decrease in efficacy (e.g., satisfaction decreased from a median of 8 immediately after to a median of 7 out of a maximum score of 10 at 1 year). At 1 year 74% of those who returned questionnaires felt that their bowel control was improved compared with before treatment.

Discussion

This was an evaluation of different elements of conservative bowel care. Unexpectedly, the hypothesis that biofeedback would enhance the therapeutic effect compared with standard care with advice was not upheld. Sixty percent of patients with fecal incontinence entering the study reported that undergoing this treatment had improved their symptoms. However, unexpectedly, group 4, who had the most intensive input, rated the least degree of improvement and there was little difference between the other groups, with exercises and biofeedback not enhancing the effect of nursing advice and support. Improvement was largely sustained at 1 year.

The main mechanism may have been health seeking, assessment or intervening per se, the therapeutic relationship, or the general advice on diet, use of medication, bowel habit, and lifestyle common to all groups. A recent review of studies of biofeedback for fecal incontinence has suggested that "it may be critical that a therapeutic relationship be established so that incontinent patients are able to discuss their experiences openly with the clinician to facilitate treatment."[13] The present results would support the hypothesis that the beneficial effects observed for biofeedback in fecal incontinence may relate more to the relationship with the therapist and to the advice given rather than to the more technical aspects of therapy.

Patients decreased their bowel frequency, had less urgency, firmer stools, and less urge incontinence after treatment. Urgency is associated with looser stools.[14] They may have had less urgency because the stool was firmer, for some because of medication and diet. Alternatively, less panic could slow gut transit and thereby lead to firmer stool. All aspects of bowel control measured on the bowel symptom questionnaire improved significantly, except pad wearing. The latter represents confidence rather than frequency of accidents for most patients. Before treatment 47% said that their bowel control restricted their life "quite a lot" or "a great deal"; this decreased to 20% after treatment.

Patients reported greater satisfaction with treatment than the extent of improvement as assessed by the objective measures of the severity of fecal incontinence would indicate. This suggests that there may have been an improvement in coping mechanisms. Benefits were general as well as specific—not only did symptoms improve, but psychologic state and quality of life improved also.

The finding that the majority of patients were improved by treatment is in line with most other studies of

biofeedback[3] and expert opinion. Whatever outcome measures have been used, and whatever therapy was given under the name of biofeedback, the majority of studies have claimed a 70%–80% response rate. An overall cure and improvement rate of 72% was found in the studies in a systematic review.[3] Similar results are reported whatever method of biofeedback is used and one review has suggested that "it is possible that it does not matter which treatment intervention is used."[13] However, none of these studies had a no-biofeedback group as in the present study, and few have compared different methods directly.

Although anal sphincter function improved in all groups, this included even those who had not been taught exercises, suggesting a general awareness and sensitization rather than benefit from specific exercises. Increased resting pressure is difficult to explain because exercise should not affect the smooth muscle internal anal sphincter, which is responsible for 80% of resting tone in the anal canal.[15] The ability to sustain a squeeze for 5 seconds was improved. This lessening of fatigue may be more important than the maximum peak of the squeeze in the ability to resist the urge to defecate. Since the start of this study, more sophisticated ways to assess fatigue rate have been proposed.[16] Heymen et al[13] have suggested that any intervention in the anorectal area could sensitize the patient to improve control regardless of the method of feedback; this would, however, not explain why group 1 did equally well as the other groups. It must be noted that group 4 started with a significantly lower squeeze increment than other groups, and this may have influenced outcome.

Possibly the expectation of benefit and the credibility of treatment is important.[17] There has been much previous work on beneficial effects of giving information to patients.[18] It has been suggested that, far from being dismissed as placebo, this should be harnessed.[19] People can get better because they believe they will.[17] This treatment was conducted in a specialist hospital, which may have led to high expectations and enhanced treatment effect.[20]

Other methods of biofeedback might have yielded different results. The 3-balloon system sensory retraining commonly used in American studies was expensive and not easily available, but some studies have suggested that this is the most useful element of biofeedback therapy.[21] The present study used equipment easily available to specialist continence services in the United Kingdom because this is the modality most likely to be used in current clinical practice.

A previous review found that 49% of patients were cured of fecal incontinence in studies that stated this outcome.[3] This was not replicated in the current study, with only 4.6% of responders judging themselves as cured at the end of therapy and 6% at 1 year. This may be because few other studies asked patients for their opinion on this, or that the present treatment was not as effective as others in completely alleviating symptoms. Many studies have taken episodes of incontinence on a bowel diary as their primary outcome measure. By this criterion 47% of those returning a diary in this study were cured after treatment (i.e., recorded no accidents for the week). It is interesting that one of the studies showing the lowest response rate was one of the few that asked patients directly to rate their subjective change.[22] An international working party on functional gastrointestinal disorders has recommended that "the most important outcomes in the treatment of [functional gastrointestinal disorders] FGIDs are those that reflect the patient's symptoms. Since individual symptoms can vary from patient to patient and from time to time, a measure of overall change in symptoms should be the primary outcome criterion...generally accepted validated outcome measures are lacking."[23] A consensus conference held after the start of the present study recommended that the primary outcome measure in studies of treatment for functional gastrointestinal disorders should be the patient's self-reported relief of symptoms, preferably as a continuous or ordinal-scaled measure, especially because these are understood easily by patients and have face validity.[24]

Given that very few studies have used any form of control, and none has included a no-treatment group, this may support the present results in finding that it is intervening per se, rather than the nature of that intervention that makes a difference. One recent small study (34 patients) had a similar design to the present study, but without a no-biofeedback group. There was no difference between 4 groups receiving different biofeedback protocols, and a significant reduction in incontinence in all 4 groups. The groups may, however, have been too small to detect a difference.[25]

Change was independent of all the variables examined for correlation, except age and body mass index. As with other studies[26,27] prior anal sphincter function as measured by manometry test results did not predict outcome and a change in parameters measured by these tests was not correlated with success or failure. If an initial resting or squeeze pressure was below the normal range, normalizing this did not equate to an improvement in rating of bowel control. Others have suggested that duration of

squeeze is more important than maximum strength[28,29] and 5-second squeeze was nearly doubled from a median of 30 cm H_2O to 50 cm H_2O. However, this was not different between those who exercised (groups 2–4) and those who did not (group 1). In common with other studies,[30] pudendal neuropathy did not predict response, although others have suggested that severe pudendal neuropathy precludes response to biofeedback.[31]

Anal ultrasonography findings did not determine outcome, nor did previous anal surgery. This is in contrast to the findings in our previous study,[10] in which patients with an abnormal ultrasound did less well, but supports the findings of others that outcome is independent of ultrasound findings.[27,30] Initial continence scores did not correlate with outcome, suggesting that initially severe symptoms (greatest capacity to benefit) or initially milder symptoms (least capacity to benefit but maybe easier to resolve) do not predict subjective benefit from this treatment.

As at the end of treatment, there was no difference between the groups at 1 year, suggesting that none of the protocols had a better-lasting efficacy than the others.

There have been few other studies that have followed-up patients after the end of the period of treatment with biofeedback. Ryn et al,[22] using anal electromyelography plug biofeedback, found that 22 of 37 patients (60%) rated their result as good or very good immediately after treatment; at a median of 44 months later (range, 12–59 mo) 15 patients (41%) still rated the result as good or very good.[22]

Study Limitations

This study did not have any minimum frequency of fecal incontinence required for entry. This may mean that some of the patients had minimal symptoms and so were more amenable to treatment than participants in other studies. Although randomization did achieve an even spread throughout the 4 groups, this may have masked any differential effect of exercises or biofeedback. Additionally, a high proportion of patients did not undergo repeat anorectal physiology testing, a limitation on the finding that there was no difference between the groups. The study was conducted in a national specialist hospital, and it is not known if the results are generalizable.

Clinical Implications

The results of this study suggest that the majority of patients with symptoms of fecal incontinence may be subjectively improved by conservative nurse-led management. Addition of anal sphincter exercises, computer-assisted biofeedback, and a home biofeedback device did not enhance the effect of this management. Patients with anal sphincter disruption are not excluded from this benefit. It is, however, a time-consuming, labor-intensive intervention. When making an informed decision about choice of therapy for fecal incontinence, patients should be offered the choice of conservative management.

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