

# Investigation of Mode of Action of Biofeedback in Treatment of Fecal Incontinence

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*A study was carried out in 25 incontinent patients to evaluate some of the factors thought to be responsible for the success of retraining for fecal incontinence. Subjects were initially allocated to one of two groups; one group was trained to perceive small rectal volumes (active retraining), the other group carried out the same maneuvers but were not given any information or instruction. Active sensory retraining reduced the sensory threshold from  $32 \pm 8$  to  $7 \pm 2$  ml ( $P < 0.001$ ), corrected any sensory delay that was present ( $P < 0.004$ ), and reduced the frequency of incontinence from  $5 \pm 1$  to  $1 \pm 1$  episodes per week ( $P < 0.01$ ). Sham retraining caused a modest reduction in the sensory threshold (from  $29 \pm 9$  to  $20 \pm 8$ ;  $P < 0.05$ ) but did not significantly reduce the frequency of incontinence. Subsequent strength and coordination training did not significantly improve continence, although at the end of the study, 50% of patients had no incontinent episodes at all and 76% of patients had reduced the frequency of incontinence episodes by more than 75%. This improvement in continence was not associated with any change in sphincter pressures or in the continence to rectally infused saline but was associated with significant improvements in rectal sensation. The functional improvement was sustained over a period of two years in 16 of the 22 patients available for follow-up. In conclusion, the results support the use of retraining in the management of fecal incontinence and suggest that retraining may work by enhancing rectal sensitivity and instilling confidence.*

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**KEY WORDS:** anus; fecal incontinence; biofeedback.

Patients with fecal incontinence often suffer silently because they feel or have been told that nothing can be done to help them. The use of drugs in this condition has been inadequately studied and many patients are unsuitable for surgery. In recent years, the application of simple retraining or biofeedback techniques has been reported to improve about 70%

of incontinent patients (1), a figure that compares favorably with the results from surgery (2, 3). The reason for the good response to retraining, however, is unclear. In the absence of appropriate control data, it is possible that the improvement in symptoms after retraining may be due more to the interaction between the patient and the trainer than to changes made by the retraining methods. The proponents of the technique argue that retraining is effective because it enables patients to be more aware of the presence of fecal material in the rectum, it coordinates contraction of the external anal sphincter (EAS) with relaxation of the internal sphincter (IAS), and it improves the force of muscle contraction (1, 4-7).

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TABLE 1. CLINICAL DETAILS OF PATIENT GROUP

Pt	Age/ Sex	Stools/week	Episodes/week		Diagnosis	Anorectal surgery	PARA*	TEARS*
			Incontinence	Urgency				
1	39F	14	9	0			3	yes
2	30F	28	7	7			0	0
3	76F	24	4	7	Ulcerative colitis	Hemorrhoidectomy	4	0
4	53F	37	6	0			1	0
5	54F	6	<1	5			4	0
6	49F	24	2.2	0		Abscess drainage PAR*	4	yes
7	53F	12	1.8	9	Crohn's disease	Abscess drainage Prolapse uterus/PAR	4	yes
8	61F	10	10	6			yes	
9	35F	9	1	2		Extensive episiotomy	2	yes
10	64F	34	1	0			4	0
11	76F	15	6	0			9	0
12	47F	9	<1	0		Hemorrhoidectomy	2	yes
13	47F	4	<1	2		PAR	2	0
14	72F	24	1	3		Hemorrhoidectomy	4	0
15	65F	19	3	3		Hysterectomy	6	0
16	71F	10	1	0		PAR	2	yes
17	67F	14	1	20		Hysterectomy	8	0
18	59M	20	1	0				
19	47M	6	<1	0				
20	53M	26	19	0		Anal stretch		
21	52M	21	1	0	Back injury			
22	17M	8	5	0	Back injury			
23	51M	42	9	9				
24	63M	13	<1	7		Hemorrhoidectomy		
25	64M	18	15	0	Back injury	Hemorrhoidectomy		

\*PAR = postanal repair, PARA=number of deliveries, TEARS=perineal tears involving the sphincter during delivery.

This study was designed to examine prospectively some of the factors thought to be responsible for the improvement of patients undergoing retraining for fecal incontinence. To this end, we evaluated the effect of training subjects to recognize small rectal volumes before we carried out coordination or strength retraining. The sensory retraining was controlled by carrying out the same maneuvers in the same order but omitting any feedback information that would help the patient to improve performance. Finally, the response of training was assessed objectively by conducting tests of sphincter function before and after the retraining programme.

## MATERIALS AND METHODS

### Subjects

The subjects were 25 consecutive patients (eight males, ages 17–64, and 17 females, ages between 30–76), who were referred to our unit for assessment of fecal incontinence. All except one of the female patients were parous. The mean number of pregnancies was 4.2. Table 1 identifies any diseases that may be responsible for the incontinence and any anorectal surgery that had been carried out. Five patients had already undergone a postanal repair, which had failed to improve their incontinence.

Most patients had idiopathic fecal incontinence associated with abnormal perineal descent and many also had features of the irritable bowel syndrome (frequent loose motions with abdominal pain).

The objectives and details of the tests were discussed with each patient, who signed a detailed consent form, giving permission for all the procedures to be carried out. Each patient also was told that he or she could withdraw from the study at any time and that this would not prejudice subsequent care. The protocol was approved by the local ethical committee in September 1985.

### Experimental Protocol

Twenty-eight patients were originally selected for evaluation in accordance with the protocol, set out in Figure 1. After the initial tests of sphincter function were carried out, each patient was issued a diary in which to record the number of bowel movements, whether the stool was formed or unformed, and the episodes of incontinence or urgency. Urgency was defined as a precipitate desire to defecate, which may result in incontinence if a toilet were not immediately available.

Each of the original 28 patients kept the diary for a period of at least one month before any training was carried out. During this time, three patients reported no episodes of incontinence and were excluded. The remaining 25 patients (Table 1) entered phase I of the study and were allocated randomly to one of two study groups for sensory retraining. One group underwent three 20-min sessions of training, in which they were taught to recog-

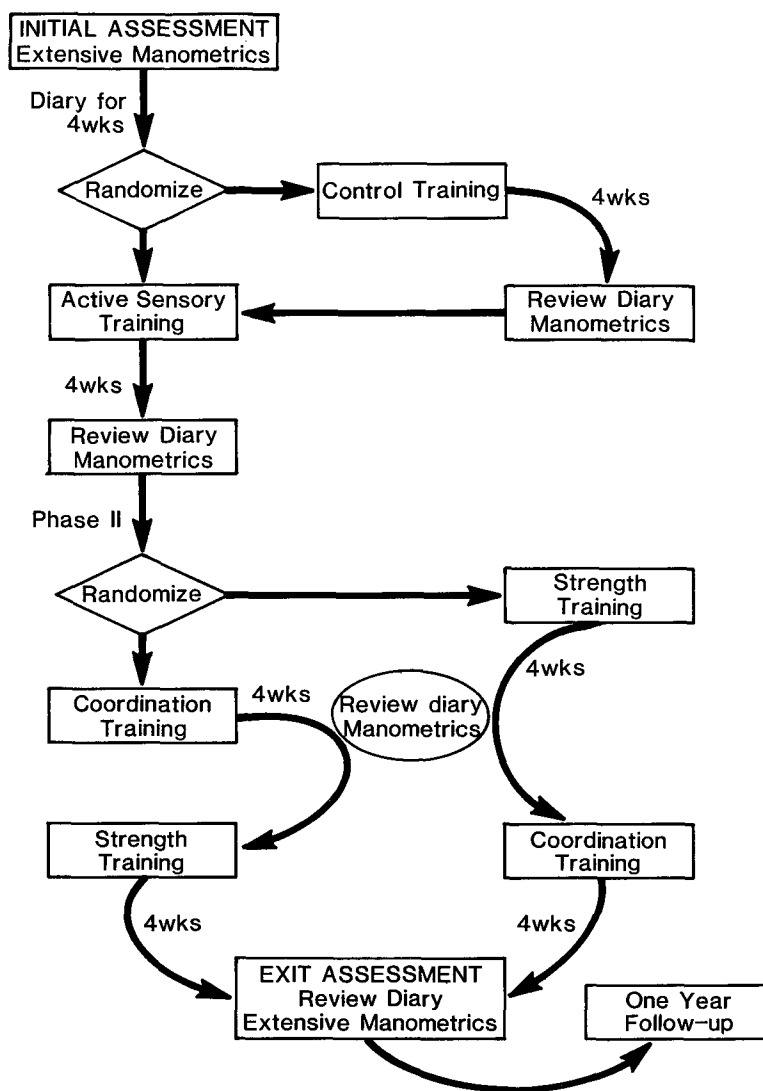


Fig 1. An outline of the protocol.

nize immediately the introduction of small volumes of air into the rectal balloon. The control group underwent the same experimental procedures in the same order, but the patients were given no instruction on how to improve their performance. At the end of one month, the degree of incontinence was assessed from the patients diaries, and rectal sensation and anal pressures were measured. The patients allocated to the control group then underwent "active" sensory retraining and were reassessed after another month.

At the end of phase I, all patients were allocated randomly to one of two groups for either strength or coordination training (phase II). Patients were crossed over at the end of one month. After a further month's assessment, sphincter function tests were carried out on each patient, irrespective of whether they were continent or incontinent.

The frequency of defecation, the consistency of the stools, and the frequency of episodes of incontinence and

urgency were assessed at each stage of the study from the information recorded on the diary cards. At the time of exit from the study, the patient's responses to the following questions were recorded: (1) Do you believe your continence has improved? (2) Do you now have more warning before an imminent incontinent episode? (3) Has your life-style changed? (4) Are you able to go out more? (5) Can you travel farther from the toilet?

Finally 22 patients were contacted two years after retraining. On this occasion, patients were asked to estimate the frequency of episodes of incontinence or urgency and to answer again the questions listed above.

#### Objective Assessment of Sphincter Function Before and After Retraining Protocol

**Station Pull-through.** Maximum basal and maximum squeeze sphincter pressures were measured using a small

multilumen water-perfused catheter inserted into the rectum and withdrawn through the sphincter at 0.5-cm stations (8). At each station, the basal pressure was recorded for 1 min, and the patient was then asked to contract the anus as hard as possible for a period of at least 20 sec.

**Measurement of Anal Responses to Rectal Distension.** Rectal contraction, relaxation of the IAS, and rectal sensation were recorded in response to distension of the rectum with serially increasing volumes of air. The patient documented the sensory responses to rectal distension by the use of a remote event marker, which was triggered every time he or she perceived rectal distension. Before proceeding with this part of the test, we confirmed that the patient could respond promptly to other stimuli such as cutaneous touch.

With the subjects lying in the left lateral position and the hips flexed to 90°, a manometric probe, consisting of a polyvinyl seven-lumen tube with an external diameter of 4 mm and bearing a terminal inflatable balloon, was inserted into the rectum. When correctly positioned, manometric side holes were situated in the anal canal at approximately 0.5, 1.0, 1.5, 2.0, 2.5, and 3.0 cm from the anal verge, and the anal pole of the rectal balloon was approximately 8 cm from the anal margin. The side holes were perfused with water at a rate of 0.4 cm/min by a low compliance pressurized perfusion system (Mui, PIP 2, Mississauga, Toronto, Canada), and pressures were measured by means of pressure transducers (Statham 2306, Oxnard, California), which were situated in each perfusion line and connected via amplifiers to a multichannel chart recorder (Hewlett Packard, 7758A, Waltham, Massachusetts).

After a basal recording period of at least 15 min, the rectal balloon was serially inflated with 1, 2, 5, 10, 20, 30, 40, 50, 60, 80, and 100 ml air. Each inflation was maintained for 1 min and a gap of at least 1 min was allowed before the next inflation. Rectal distension usually causes a rectal sensation, a transient increase in rectal pressure, and a decrease in the anal pressure, best seen in the innermost anal channels and caused by relaxation of the internal anal sphincter. Once the initial inflations were completed, several inflations of short duration were used to identify the lowest rectal volume that the patient could sense (sensory threshold), and the delays between balloon inflations and the reporting of sensation for each volume (sensory delay) were noted. Sensory delay was defined as a delay between the onset of the stimulus and the perception of sensation of at least 2 sec.

**Saline Continence Test.** Continence to a rapid infusion (60 ml/min) of 1500 ml warmed saline into the rectum was determined using the technique we have previously described (8, 9). The total volume of retained saline and the volume that had been infused prior to leakage of 10 ml saline (first leak volume) were noted.

### Sensory Retraining

Three 20-min training sessions were carried out within three days. Before each training session, the current sensory threshold was established by a series of brief inflations beginning with the lowest sensed volume from

the previous session. The patient was asked to identify immediately a rectal volume above the threshold using a remote event marker connected to the recorder and was informed of any sensory delay greater than 1 sec from the introduction of the volume into the balloon. This volume then was reintroduced repeatedly until the patient was able to perceive it promptly. Once the sensory delay was eliminated, a volume of between 65% and 75% of the sensory threshold usually was felt easily. This was introduced, and the patient was told when he or she failed to perceive the balloon inflation and the stimulus repeated with a 3- to 5-sec warning. As the patient learned to recognize the new stimulus, the balloon was inflated with decreasing volumes and the patient taught to recognize sequentially smaller stimuli. After each training session, the new sensory threshold was recorded. Then, at the following session, approximately 50% of this new threshold was given to verify the absence of sensation at this level and a new sensory threshold was established. The subsequent volumes were multiples of the first until the patient responded correctly. Once the volume was sensed, subsequent volumes were decreased by 25–35%. The success of each training session in improving continence was determined from the diary cards at the first visit following completion of the training (approximately four weeks).

Patients randomized to the control group were subjected to similar training sessions, during which the same maneuvers were carried out, but no information about their performance was given and nor any instruction as to how to correct their defective perception.

**Training to Improve Strength of External Sphincter.** Three 20-min sessions were carried out within three days. With the manometric catheter in place, the patient was asked to generate a maximum squeeze pressure. The technique was altered by trial and error, and as the squeeze gained speed and strength, the patient was encouraged to maintain the contraction for at least 20 sec. This could be done satisfactorily without visual feedback from the recording. The patient was then instructed to carry out a well-defined exercise program to enhance muscle strength and endurance over the next month. This consisted of at least four structured periods of exercise a day, each period consisting of four squeezes lasting 20 sec and separated by rest periods of 20 sec.

### Coordination Training

Three training sessions were carried out within three days using the seven-lumen catheter assembly described above. The patients were instructed to respond to balloon inflation by prompt contraction of the voluntary pelvic floor muscles. The goal of coordination training was to achieve a maximum voluntary squeeze in less than 0.5 sec from the time of balloon inflation and to control the consequent relaxation phase by continued conscious contraction of the sphincter so that the anal pressure did not fall below preinflation values. The lowest volume that the patient could sense reliably was used as the stimulus. The patient was informed about a slow onset of contraction and would practice short bursts of muscle contraction until the delay in response was reduced.

## BIOFEEDBACK FOR FECAL INCONTINENCE

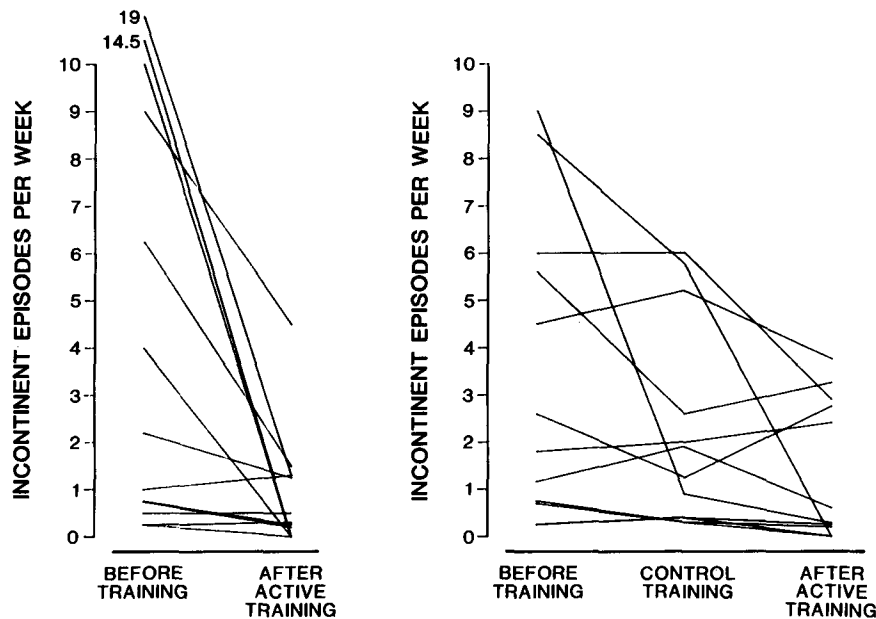


Fig 2. A diagram of the changes in incontinence episodes per week before and after either active or sham retraining.

### Statistical Analysis

An analysis of variance was used to evaluate differences in sphincter pressures and in responses to rectal distension or increases in intraabdominal pressure between the groups. If the analysis of variance showed statistical significance, the Student's *t* test was used to determine the levels of significance. Differences between the percentages of patients in each group that responded to training were assessed by chi-square test.

### RESULTS

**Sensory Retraining.** After active sensory retraining, the frequency of incontinent episodes was reduced in all except two patients ( $P < 0.05$ ) and incontinence was abolished in four patients (Figure 2) (Table 2). The frequency of defecation also was

reduced slightly ( $P < 0.05$ ) (Table 2), but there was no significant difference in the frequency of urgency. In contrast, only five of 12 patients showed a reduction in the incidence of incontinent episodes after sham training ( $P > 0.1$ ), and incontinence was not abolished in any patient (Figure 2). There were no significant changes in the frequencies of either defecation or urgency after sham training. However, when we compared the two groups of patients, the responses to active training were not significantly different from the responses to sham training.

After the patients allocated to the control group underwent a subsequent period of active sensory retraining, incontinence was abolished in three patients and further reduced in another four. Thus, at

TABLE 2. EFFECT OF ACTIVE AND SHAM SENSORY RETRAINING ON ANORECTAL FUNCTION IN INCONTINENT\* PATIENTS

	Group randomized to active retraining (N = 13)		Group randomized to sham retraining (N = 12)		
	Before	After	Before	After	After active
Stools/week	16.5 ± 2.3	14.2 ± 1.6†	19.0 ± 3.4	19.0 ± 3.6	17.6 ± 3.1
Incontinent episodes/week	5.3 ± 1.7	0.9 ± 0.3†	3.4 ± 0.9	2.3 ± 0.6	1.4 ± 0.4†
Urgency episodes/week	1.8 ± 0.7	2.2 ± 1.4	4.4 ± 1.8	3.9 ± 1.3	2.8 ± 0.9
Sensory threshold (ml)	32.3 ± 7.6	6.6 ± 2.1†	29.2 ± 9.4	19.5 ± 7.1†	7.7 ± 2.2†
Sensory delay (sec)	5.0 ± 1.3	0 ± 0†	4.2 ± 0.9	3.7 ± 1.3	1.0 ± 0.3
Basal pressure (cm H <sub>2</sub> O)	57 ± 8	53 ± 6	58 ± 9		51 ± 9
Squeeze pressures (cm H <sub>2</sub> O)	132 ± 24	141 ± 24	109 ± 18		117 ± 15

\*Results are expressed as mean ± SEM.

†Significantly lower than value before training ( $P < 0.05$ ).

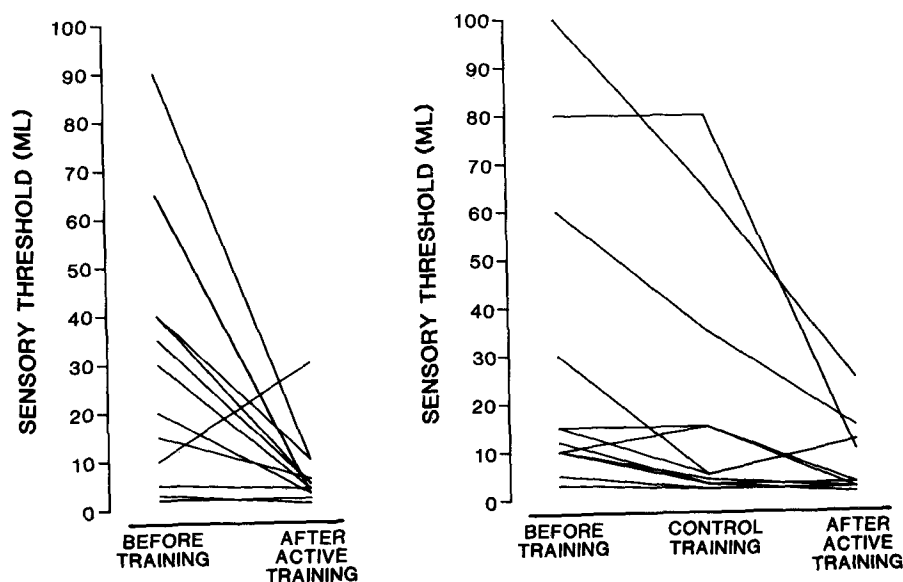


Fig 3. A diagram of the changes in sensory threshold before and after either active or sham retraining.

the end of phase I, the frequency of incontinence was abolished in seven patients (28%) and reduced by at least 75% in another three. Only three patients showed an increase or no change in the number of incontinent episodes. The frequency of defecation also was reduced (Table 1), but there was no change in the episodes of urgency.

The improvement of incontinence following active sensory training was associated with an improvement in rectal sensitivity, although not all patients with improved sensation had improved incontinence. Seven of the 13 patients allocated to the active retraining group had sensory thresholds greater than 20 ml before training, and five patients had a sensory delay. By comparison, not one of a series of 35 healthy controls tested in our laboratory

exhibited a sensory delay or had a sensory threshold greater than 20 ml (10). Sensory retraining reduced the sensory threshold in all but one patient ( $P = 0.01$ ) (Figure 3) and eliminated the sensory delay in all of the patients in whom it was present. Sensory retraining did not alter the basal and squeeze pressures.

Four of the 12 patients allocated to the sham training group had sensory thresholds above 20 ml and, although sham training significantly reduced the sensory threshold ( $P < 0.05$ ) (Table 3), three patients continued to have thresholds greater than 20 ml (Figure 3). The subsequent active retraining further reduced the sensory threshold (Table 2) and, after this period, only one patient had a threshold greater than 20 ml.

TABLE 3. ANORECTAL FUNCTION BEFORE AND AFTER PHASE I AND II RETRAINING\*

	Initial	After phase I	After phase II
Stools/week	17.8 ± 2.0	15.8 ± 1.7†	14.6 ± 1.6†
Incontinent episodes/week	6.1 ± 0.9	3.4 ± 0.8	2.5 ± 1.0†
Urgency episodes/week	3.0 ± 0.9	2.5 ± 0.9	4.9 ± 1.0
Basal pressure (cm H <sub>2</sub> O)	57 ± 6	51 ± 5	52 ± 5
Squeeze pressure (cm H <sub>2</sub> O)	120 ± 14	117 ± 12	129 ± 14
Sensory threshold (ml)	37.3 ± 34.9	6.4 ± 6.8†	3.1 ± 3.2†
Threshold for IAS relaxation (ml)	40 ± 6	Not done	62 ± 8
Saline retained	1180 ± 90	Not done	1169 ± 103
First leak (ml infused)	519 ± 98	Not done	433 ± 130
Patients with >10 ml leak	18		13

\*Results are expressed as mean ± SEM.

†Significantly different compared with initial value ( $P < 0.05$ ).

## BIOFEEDBACK FOR FECAL INCONTINENCE

TABLE 4. COMPARISON OF OBJECTIVE TESTS OF SPHINCTER FUNCTION IN THOSE RESPONDING TO RETRAINING AND THOSE WHO FAILED\*

	<i>Success (N = 19)</i>		<i>Failure (N = 6)</i>	
	<i>Initial</i>	<i>Final</i>	<i>Initial</i>	<i>Final</i>
Sensory threshold (ml)	31 ± 30	3 ± 1†	18 ± 9	3 ± 1†
Basal pressure (cm H <sub>2</sub> O)	60 ± 28	54 ± 25	51 ± 32	45 ± 31
Squeeze pressure (cm H <sub>2</sub> O)	121 ± 66	132 ± 60	120 ± 97	122 ± 106
Retained saline (ml)	1194 ± 101	1152 ± 113	1135 ± 213	1197 ± 283
First leak (ml)	540 ± 126	520 ± 160	470 ± 165	140 ± 56

\*Results are expressed as mean ± SEM.

†Significantly different from initial value.

Four patients in the sham training group exhibited a sensory delay. One corrected after sham training and two more improved after active sensory retraining.

**Effect of Phase II.** All patients entered and completed phase II of the study. The number of patients who reported a cure (no incontinent episodes for one month) or an improvement (25% of the original frequency of incontinent episodes) were approximately doubled after phase II. After both phase I and phase II, 12 of 25 patients (48%) considered themselves "cured," and seven patients were "improved." One patient suffered an increase in incontinent episodes, and five patients experienced no real change. Combining these figures gave an overall success rate with regards to incontinence of 76%. Similar figures were obtained for urgency (60% cured, 12% improved, 72% successful). There was very little change in the frequency of defecation between phase I and phase II of the study (Table 3).

**Qualitative Response to Retraining.** When interviewed at the end of the study, all patients with documented success were pleased with their improvement. Five of the six patients who had no real reduction in incontinent episodes also felt they had experienced some improvement; they all believed that: (1) they had more warning prior to an episode of incontinence, and (2) they felt more confident and able to venture out of their house more.

**Objective Assessment of Sphincter Function.** The only significant change in anorectal function at the end of the four-month assessment period was an improvement in the sensory perception of a balloon in the rectum (Table 3). There were no significant differences in the rectal volumes required to produce anal relaxation or to sustain relaxation for a period of 1 min. Basal and squeeze pressures did not change. Continence to rectally infused saline also was not improved; both the first leak volume and the total volume that could be retained at the

end of the study were not significantly different from values obtained at the beginning of the study (Table 3), although fewer patients leaked during the test. There were no significant differences in initial or final sphincter pressures or saline continence between those patients in whom training succeeded (cured or improved) and those in whom it failed (Table 4).

**Long-term Follow-up.** Twenty-two of the original 25 patients were questioned two years after retraining. One patient refused to respond to the follow-up questionnaire, one patient had died, and one patient had gone to live abroad. Three patients had proceeded to surgery: two for postanal repair and one for colostomy. Of the remaining 19, 17 had originally improved and all of them said that the improvement had been sustained; six had had no episodes of incontinence and another three experienced "accidents" less than once a month. Only two patients showed no reduction in incontinence episodes but even these said that their quality of life had improved in that they had more time to reach the toilet and they felt sufficiently confident to go out of their houses.

## DISCUSSION

The results of this study confirm the impression gained from previous studies (1, 3-5, 7) that retraining techniques can cause a marked improvement in incontinence episodes in approximately 70% of patients. Unlike previous studies, however, we could not demonstrate that this improvement was associated with any significant change in any of the objective indices of sphincter function. What, therefore, is the physiological basis, if any, for this improvement? One factor appears to be an improvement in sensory awareness. Retraining significantly reduced both the sensory threshold and the delay in perception following the application of the

stimulus, such that by the end of the study only one patient had a sensory threshold above 20 ml (compared with 12 before retraining), and no patient had a sensory delay. The significant improvements in both incontinence and in sensory awareness took place during the phase of sensory retraining, although further improvement in continence took place during the subsequent period of strength and coordination training. The benefits of improved sensation may be: (1) a longer warning from the entry of stool into the rectum to impending defecation, (2) enhanced perception of a smaller stool, and (3) awareness of stool in the rectum before reflex internal sphincter relaxation takes place. This improvement in awareness was probably responsible for the patients' observations that they felt they had more warning of possible incontinence and they felt more confident in taking part in social activity and in venturing longer distances from the toilet.

Our results, however, indicate that sensation is probably not the only factor related to the improvement in continence. Incontinence was eliminated in only four patients after sensory training alone; another three were cured after phase II. Four of the 13 patients, who improved as a result of sensory retraining, had quite normal sensory thresholds and no sensory delay and there were no changes in anal pressures. Finally, even those patients who failed to improve their incontinent episodes reduced sensory thresholds. Perhaps improvement was related to increased feeling of control and confidence.

Six of 12 patients reduced the number of incontinent episodes and nine of 12 reduced the sensory threshold after sham retraining. Can the very fact that tests are being carried out improve sensory awareness without any input from the investigator? Was the improvement in continence related to a reduction in anxiety and an increase in confidence? Whatever the reason, it appears that direct intervention is helpful but not obligatory to improve continence and rectal sensation. Indeed, 10% of the patients, who were originally selected for retraining were "cured" of their incontinence during the period between the initial assessment and the start of the training. However, it would be a mistake to discount the importance of the feedback, since only those in the active group showed a significant improvement in incontinence, and subsequent active retraining after a period of sham training improved both sensation and continence in those patients who had not improved during sham training

anal control. Finally, only one patient eliminated the delay in sensation without specific instruction. Subsequent active training eliminated the delay in all but one patient.

The phase of muscular and coordination training did not significantly alter the frequency of incontinent episodes, although a greater number of patients were cured or improved after all phases of retraining were complete. The observations that neither anal pressure nor the saline continence were improved suggest that (1) the symptomatic improvement of 19 of 25 patients was not related to changes in motor function and (2) improvements in sensation have little effect on continence to a large volume of saline.

In conclusion, it is gratifying that a relatively brief period of retraining can improve fecal continence in many patients for up to two years. Although the study favors the notion that retraining may work by enhancing rectal sensitivity, there is also some support for a nonspecific effect on well-being and confidence. Sensory retraining is quick, safe, inexpensive, requires no sophisticated equipment, can easily be learned by unskilled health workers, and in these respects compares favorably with surgery and drugs.

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