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ORIGINAL CONTRIBUTIONS

Randomized, Controlled Trial of Biofeedback With Anal Manometry, Transanal Ultrasound, or Pelvic Floor Retraining With Digital Guidance Alone in the Treatment of Mild to Moderate Fecal Incontinence

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BACKGROUND: A prospective, three-armed, randomized, controlled trial was performed to assess whether pelvic floor exercises with biofeedback using anal manometry or transanal ultrasound are superior to pelvic floor exercises with feedback from digital examination alone in terms of continence, quality of life, physiologic sphincter strength, and compliance. Its secondary objectives were to assess whether there are any differences in these outcomes between biofeedback with transanal ultrasound *vs.* anal manometry and to correlate the physiologic measures with clinical outcome. METHODS: One hundred twenty patients with mild to moderate fecal incontinence were randomized into one of three treatment groups: biofeedback with anal manometry, biofeedback with transanal ultrasound, or pelvic floor exercises with feedback from digital examination alone. Commencing one week after an initial 45-minute assessment session, patients attended monthly treatments for a total of five sessions. Each session lasted 30 minutes and involved sphincter exercises with biofeedback that involved instrumentation or digital examination alone, and patients were encouraged to perform identical exercises twice per day between outpatient visits. RESULTS: One hundred two patients (85 percent) completed the four-month treatment program. Across all treatment allocations, patients experienced modest but highly significant improvements in all nine outcome measures during treatment, with 70 percent of all patients perceiving improvement in symptom severity and 69 percent of patients reporting improved quality of life. With the possible exception of isotonic fatigue time, there were no significant differences between the three treatment groups in compliance, physiologic sphincter strength, and clinical or quality-of-life measures. Correlations between physiologic measures and clinical outcomes were much stronger with ultrasound-based measures than with manometry. CONCLUSIONS: Although patients in this study who completed pelvic floor exercises with feedback from digital examination achieved no additional benefit from biofeedback and measurement with transanal ultrasound or manometry, it may be that the guidance received through digital examination alone offered patients in the pelvic floor exercise group an effective biofeedback mechanism. Contrary to our hypothesis, the use of transanal ultrasound offered no benefit over manom-

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etry, but the use of ultrasound for isotonic fatigue time and isometric fatigue contractions provided potentially important physiologic measures that require further study. This study has confirmed, through a large sample of patients, that pelvic floor retraining programs are an effective treatment for improving physiologic, clinical, and quality-of-life parameters in the short term. [Key words: Randomized trial; Incontinence; Biofeedback; Transrectal; Ultrasound]

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Fecal incontinence is a distressing and socially incapacitating condition[1,2] that affects between 2 and 7 percent of the general population,[3–5] approaching 60 percent among nursing home residents and the elderly.[4,6] Furthermore, the prevalence of fecal incontinence is likely to be an underestimate,[5] because many sufferers do not seek professional help.[7] Fecal incontinence is the leading cause of nursing home placements,[8] and the annual cost of management has been estimated to be as high as $9,771 per patient.[9]

Fecal incontinence is eight times more frequent in women,[1] the most common cause being obstetric trauma leading to direct disruption of the anal sphincter muscles or traction neuropathy affecting the pudendal nerve.[1,10,11] Although these defects can be detected with investigation in the immediate postpartum period, fecal incontinence often only manifests later in life as the sphincter ages.[11,12] The incidence of fecal incontinence has been related to age, parity,[3] and forceps delivery.[10]

Although surgery can be an effective intervention for patients with full-thickness rectal prolapse or a single anatomic defect in the external sphincter, it is not yet justified for patients with mild to moderate neuropathic fecal incontinence.[1,12] Biofeedback programs have emerged as popular and successful treatments, with reported success rates of between 50 and 92 percent[13–17] and clinical improvement lasting at least two years.[18] Much of its advantage lies in the fact that it is safe, painless, well tolerated, and does not preclude further treatment if it fails.[5] For this reason, some reviewers have concluded that biofeedback should be the treatment of first choice for fecal incontinence.[19,20]

Biofeedback was initially introduced for the treatment of fecal incontinence in the 1970s as a form of operant conditioning to improve on the poor results of early pelvic floor exercise programs.[21] However, its exact mode of action remains obscure,[20–23] there is little standardization of biofeedback treatment,[14,24] and methodologically rigorous evidence for its effectiveness is lacking. A recent Cochrane systematic review identified only five randomized, controlled trials comprising a total of 109 participants that addressed the role of biofeedback for fecal incontinence, and because of their methodologic weaknesses, the reviewers were not able to reach a conclusion regarding the role of biofeedback as an effective treatment.[19] The reviewers further stressed the difficulty in the literature of dissociating between biofeedback and sphincter exercises, because most studies included both while placing emphasis on one or the other as the primary intervention. It has been suggested that some form of biofeedback measure is important to teach patients to correctly contract their anal sphincters, thus ensuring the ensuing exercises are effective.[12,23] However, the few studies that addressed this question were small and had conflicting results, either suggesting that biofeedback and exercises were more effective than exercises alone[17,22,25] or that they were not.[23]

Which physiologic measure is most effectively used as the biofeedback measure is also uncertain. Although many studies have reported good results with anal manometry–guided biofeedback, the usefulness of manometry as a measurement has been hotly debated because of its poor correlation with the clinical condition.[14,26,27] Many patients with fecal incontinence cannot voluntarily contract their external sphincter and only contract their buttock muscles, with the result that manometry may not always parallel improved anal sphincter function. In this respect, we have hypothesized that the use of transanal ultrasound as the physiologic measure during biofeedback has the advantage of enabling patients to watch the concentric contraction of their anal sphincters in real time on a monitor screen and helping them to differentiate between external sphincter and buttock muscle contractions. This may mean that they exercise more effectively.[12]

The objectives of this prospective, randomized study were as follows: 1) to assess whether pelvic floor exercises with instrument-guided biofeedback are superior to pelvic floor exercises with feedback from digital examination alone in terms of continence, quality of life, physiologic sphincter strength, and compliance; 2) to assess whether there are any differences in these outcomes between biofeedback with transanal ultrasound *vs.* anal manometry; and 3) to assess the relationship between physiologic measures and clinical outcome.

PATIENTS AND METHODS

Patients

One hundred twenty patients were included who had mild to moderate fecal incontinence with at least mild neuropathy (more than 20 percent abnormal complexes) on single-fiber, four-quadrant sampling of the external sphincter with electromyography and no anatomic defect in the external sphincter. Patients were excluded if they had a defunctioning stoma, inflammatory bowel disease, acute perianal inflammation, a potentially reversible cause of incontinence (*e.g.*, diarrhea), or untreated full-thickness rectal prolapse. All patients had initially been referred to a colorectal surgeon for investigation and management of fecal incontinence. Investigations for all patients included anal manometry, transanal ultrasound, and electromyography to confirm neuropathy and exclude anatomic defects. Management included dietary advice and medical treatment that included loperamide where appropriate. Patients were referred to the biofeedback program by the treating colorectal surgeons if they had not had success with maximal medical and dietary treatment. During the biofeedback program, patients were asked to continue their previously established treatment regimen. The approval of the Central Sydney Area Health Service Ethics Committee was obtained.

Technique

Patients with neuropathic fecal incontinence were assessed initially and finally by a research fellow blinded to the treatment group allocation. All biofeedback and pelvic floor exercise treatment sessions were conducted by an experienced clinical nurse specialist (CNS) at the Royal Prince Alfred Hospital in Sydney. The treatment sessions lasted approximately 30 minutes and were conducted one week after the initial assessment and then monthly for four months (5 treatment sessions in total). At the initial treatment session, the patient's randomization into one of three treatment groups was revealed: pelvic floor exercises, anal manometry, or transanal ultrasound. All treatments involved the patients lying in the left lateral position and performing a full set of exercises, consisting of ten five-second sphincter contractions, each at one-second intervals, repeated ten times (a total of 100 contractions). All patients were urged to perform an identical set of exercises twice per day between outpatient visits and were asked to estimate the percentage of exercises they had actually completed. This measure of home exercise compliance was self-reported and may be somewhat inflated by recall bias.

Pelvic Floor Exercises With Feedback From Digital Examination

Patients performed a full set of exercises under the supervision of the CNS who, guided by digital per anal examination of the external sphincter, ensured that the patients were contracting the anal sphincter adequately.

Biofeedback With Transanal Ultrasound

All treatment sessions were performed with an 1849 TRUS probe (Brüel and Kjær, Nærum, Denmark) and a 7-MHz transducer protected by a rigid plastic anal cone, encased in a disposable condom, and inserted with the aid of lubricant. Patients were taught how to contract the anal sphincters while watching the real-time ultrasound display on the monitor screen, and a full set of exercises were performed during each treatment session. The use of this method for biofeedback has been described in more detail elsewhere[12] and involves patients watching on the ultrasound monitor as a clearly visible black ring shrinks and then vanishes on contraction of the external anal sphincter, representing the internal anal sphincter as it is concentrically withdrawn inside the focal range of the 7-MHz radial probe. To monitor progress and provide feedback, external sphincter isotonic fatigue time and isometric fatigue contraction measures (described below) were taken at the beginning of each session.

Biofeedback With Anal Manometry

All treatment sessions were performed with a Peritron-Precision Perineometer one-channel catheter system (Cardio Design, Perth, Australia) that measured contractions on a cone inserted 5 cm into the anal canal. Patients were taught how to contract and relax the anal sphincters while attending to the pressures generated in the anal canal, and a full set of exercises were performed during each treatment session. To monitor progress and provide feedback, resting and maximal squeeze pressures were recorded at the beginning of each session. It is thought that resting pressures represent internal anal sphincter tone, and squeeze pressures represent the external anal

sphincter contraction, but external anal sphincter contraction may be difficult to distinguish from buttock muscle contraction.

Outcome Measures

At the initial and final assessments, the following measures were recorded by a research fellow blinded to the patient's treatment allocation group:

1. St. Mark's Hospital fecal incontinence score (full continence = 0; complete incontinence = 13).[28]
2. Pescatori fecal incontinence score (full continence = 0; complete incontinence = 6).[29]
3. Patient's self-assessment of fecal incontinence severity using a visual analog scale (0 is no incontinence problems; 10 is "the worst it could be").
4. Investigator's assessment of fecal incontinence severity using a visual analog scale (0 is no incontinence problems; 10 is "the worst it could be").
5. Quality-of-life measure using Direct Questioning of Objectives,[30] in which patients were encouraged to select several objectives affected by their incontinence and rate each for its importance to them and their current ability to meet it. The result is a scale from 0 (no quality of life) to 10 (full quality of life).
6. Resting and maximal squeeze anal canal manometric pressures in millimeters of mercury.
7. Isotonic fatigue time, or the time in seconds from the beginning of the external sphincter contraction to the first sign of fatigue as visualized on transanal ultrasound. The use of this measure has been described previously[12,31] and is operationally defined as the duration of squeeze until the internal anal sphincter first returns into the focal range of the 7-MHz ultrasound probe.
8. Isometric fatigue contractions, defined as the number of successfully completed five-second contractions that can be achieved before the five-second contraction cannot be maintained, as visualized on transanal ultrasound.[12]

When patients did not complete the full biofeedback program, the last recorded outcome measures were recorded as their final score.

Patient Allocation and Blinding

Patients were randomized centrally before the start of the trial with a chart of random numbers and sealed opaque envelopes containing the study group allocation for each sequential patient. The initial and final assessments were conducted by a research fellow not involved with the patients' treatment and who was blind to the patients' allocation. By necessity, the CNS and patients were not blind to the treatment allocation.

Statistical Considerations

Sample Size. We calculated that a sample size of 40 per treatment arm would be required to detect a decrease in incontinence scores of 20 to 30 percent, a result consistent with our experience of biofeedback treatment.[12] This sample size would be sufficient to distinguish a median drop of four points on the St. Mark's Fecal Incontinence Scale in an effective treatment from an expected two-point drop as a result of placebo effect using a two-tailed alpha of 0.05 and a power of at least 0.85 for three independent groups. Given that there were three study groups of 40 patients each, a total of 120 patients were planned for this study.

Statistical Analysis. All data were entered into an Excel spreadsheet and then imported into SPSS® version 9.0 (SPSS Inc., Chicago, IL) for further analysis. The change in outcome scores between the three treatment groups were compared with the Kruskal-Wallis test, and overall pretreatment and posttreatment measures were compared with Wilcoxon signed-rank tests. Finally, a Spearman correlation was conducted to assess the relationship between changes in the four physiologic measures and five measures of clinical or quality-of-life outcome. Because of the number of statistical tests conducted, a *P* value threshold of 0.01 was adopted for determining significance.

RESULTS

Demographic characteristics of the patients and their self-reported treatment compliance are presented in Table 1. Patients reported an overall compliance rate of 83 percent for completing exercises between treatment sessions and achieved a program completion rate of 85 percent, yielding 102 patients who completed the four months of treatment.

The outcome measures before and after treatment for each of the three treatment groups are presented in Table 2. The pretreatment clinical and physiologic measures were similar to those reported by other biofeedback treatment programs.[2,26,32–35] Chi-squared and Kruskal-Wallis testing (data not shown) was conducted to confirm effective randomization and exclude baseline differences, with no significant

Table 1.
Characteristics of Patients and Treatment Compliance

	TRUS (n = 40)	Manometry (n = 39)	Pelvic Floor (n = 41)	Total (n = 120)
Average age (yr)/(SD)	60.1 (13.7)	63.4 (13.6)	62.7 (11.0)	62.0 (12.8)
No. male (%)	5 (12.5)	3 (7.7)	5 (12.2)	13 (10.8)
Exercise compliance (%)	86.4	82.7	79.9	83.0
No. completed (%)	36 (90)	31 (79)	35 (85)	102 (85)

TRUS = transanal ultrasound; SD = standard deviation.

Table 2.
Pretreatment and Posttreatment Outcome Measures for Each of the Three Treatment Groups

Outcome Measure	Transanal Ultrasound (n = 40)		Manometry (n = 39)		Pelvic Floor (n = 41)	
	Initial	Final	Initial	Final	Initial	Final
Pescatori (0–6)	5 (4, 6)	4 (3, 5)	5 (4, 5)	4 (3, 5)	5 (4, 5)	4 (4, 5)
St. Mark's (0–13)	8 (7, 10)	7 (3, 9)	9 (7, 11)	6 (4, 10)	9 (7, 11)	8 (5, 10)
Self-rating (0–10)	5.3 (4, 6.8)	3.6 (1.5, 5.3)	4.9 (4.1, 7.5)	4.0 (0.9, 5.8)	5.5 (3.7, 7.2)	3.5 (1.9, 5.7)
Investigator rating (0–10)	6 (4.5, 7)	3.7 (2.1, 6.8)	6.1 (4.4, 7.4)	3.7 (2.6, 7.5)	6.7 (5, 7.6)	4.5 (3.2, 7.3)
Quality of life (10–0)	3.8 (2.7, 5.6)	6.3 (5, 8.6)	5 (3, 6.4)	6.5 (4, 7.9)	4.2 (3.5, 5.3)	6.7 (5, 7.1)
Rest pressure (mmHg)	38 (33, 51)	44 (34, 57)	38 (33, 47)	45 (37, 55)	45 (39, 52)	48 (38, 57)
Squeeze pressure (mmHg)	80 (60, 101)	95 (77, 121)	73 (59, 92)	78 (70, 106)	90 (57, 100)	90 (67, 120)
Isotonic fatigue time (sec)	13 (8, 21)	27 (15, 42)	10 (5, 20)	21 (11, 31)	15 (9, 16)	15 (10, 31)
Isometric fatigue contractions (n)	6 (5, 7)	9 (6, 13)	5 (4, 7)	8 (6, 10)	5 (4, 6)	8 (6, 10)

Figures are median (25th, 75th percentiles).

Table 3.
Mean Change in Outcome Measures for Each Treatment Group

Outcome Measure	TRUS	Manometry	Pelvic Floor	*P* Value
Pescatori (0–6)	−1.06	−0.68	−0.57	NS
St. Mark's (0–13)	−2.14	−1.94	−1.6	NS
Self-rating (0–10)	−1.94	−2.23	−1.97	NS
Investigator rating (0–10)	−1.47	−1.12	−1.55	NS
Quality of life (10–0)	2.6	1.69	2.01	NS
Rest pressure (mmHg)	2.54	6.84	2.8	NS
Squeeze pressure (mmHg)	11.66	10.45	10.69	NS
Isotonic fatigue time (sec)	32.42	8.94	8.69	NS
Isometric fatigue contractions (n)	1.58	3.79	3.11	NS

TRUS = transanal ultrasound; NS = not significant.
Kruskal-Wallis test, n = 120, $P < 0.01$.

differences found between treatment groups in any demographic or pretreatment outcome variable.

An additional Kruskal-Wallis test (Table 3) comparing the change in pretreatment and posttreatment outcome measures found no significant differences in treatment effect between the three treatment groups in any of nine outcome variables. However, the mean improvement for isotonic fatigue time with the ultrasound group (32 seconds) was greatly higher than with the other two modalities (9 seconds); the *P* value for this difference was 0.0336. A third Kruskal-Wallis test (data not shown) also failed to find significant differences in the nine posttreatment outcome measures between treatment groups, although the *P* value for posttreatment isotonic fatigue time was 0.0493.

Across all three treatment allocations, patients enrolled in a program of pelvic floor exercises experienced modest but highly significant improvements in all nine outcome measures during treatment (Table 4), with 70 percent of all patients reporting decreased symptom severity on the visual analog scale and 69 percent of patients reporting improved quality of life on the Direct Questioning of Objectives.

Finally, Table 5 displays only the statistically signif-

Table 4.
Improvement in Outcome Measures Between Initial and Final Assessment

Outcome Measure	Pretreatment	Posttreatment	*P* Value	% Who Improved
Pescatori (0–6)	5 (4, 5)	4 (4, 5)	<0.0001	45.8
St. Mark's (0–13)	9 (7, 11)	7 (4, 10)	<0.0001	56.7
Self-rating (0–10)	5.1 (4.1, 7.2)	3.8 (1.5, 5.6)	<0.0001	70
Investigator rating (0–10)	6.3 (4.7, 7.4)	4.5 (2.5, 7.2)	<0.0001	64.2
Quality of life (10–0)	4.4 (3, 5.9)	6.5 (5, 8)	<0.0001	69.2
Rest pressure (mmHg)	41 (34, 51)	45 (35, 56)	0.0015	33.6
Squeeze pressure (mmHg)	76 (60, 99)	90 (70, 116)	<0.0001	24.4
Isotonic fatigue time (sec)	12 (8, 20)	21 (11, 35)	<0.0001	17.5
Isometric fatigue contractions (n)	5 (4, 7)	8 (6, 10)	<0.0001	15

Figures are median (25th, 75th percentiles). Wilcoxon signed-rank test, n = 120, $P < 0.01$.

Table 5.
Correlations Between Physiologic and Clinical Outcome Measures

Outcome Measurement		Pretreatment		Posttreatment		Change Score	
Physiologic	Clinical	Rho	*P* Value	Rho	*P* Value	Rho	*P* Value
Fatigue time	Pescatori			−0.3	0.0008		
	St. Mark's	−0.26	0.005	−0.39	<0.0001	−0.26	0.0036
	Self-rating			−0.42	<0.0001	−0.3	0.0008
	Investigator rating	−0.25	0.0064	−0.34	0.0002		
	Quality of life	0.24	0.01	0.29	0.0014	0.26	0.0042
Fatigue contractions	Pescatori			−0.29	0.0015		
	St. Mark's	−0.32	0.0004	−0.31	0.0007		
	Self-rating			−0.47	<0.0001		
	Investigator rating	−0.32	0.0005	−0.3	0.0009		
	Quality of life	0.43	<0.0001	0.31	0.0005	0.35	0.0001
Squeeze pressure	Self-rating	−0.28	0.0019				

Spearman's rho correlation, n = 120, $P < 0.01$.

icant correlations between physiologic measures and clinical outcome measures for pretreatment, posttreatment, and change scores with treatment. Only one manometry-based measure correlated with clinical outcomes (pretreatment squeeze pressure and treatment self-assessment of severity). The ultrasound-based measures, however, were strongly correlated with clinical outcomes, especially with posttreatment self-assessment of severity (0.42 for isotonic fatigue time and 0.47 for isotonic fatigue contractions).

DISCUSSION

This is the first large and methodologically rigorous study investigating whether a program of pelvic floor exercise with manometry or transanal ultrasound biofeedback measures offers any advantage over feedback with digital guidance alone in the short term. Patients in the present study who completed pelvic floor exercises that included digital guidance achieved no additional benefit from the addition of biofeedback instrumentation or measures that used transanal ultrasound or manometry. However, this does not suggest that biofeedback plays no role. Part of the pelvic floor exercise protocol involved digital examination of the external sphincter by the CNS to ensure adequate contraction. The digital examination itself may have offered the patient an effective biofeedback mechanism. Previous studies have confirmed a strong correlation between digital examination findings and formal manometry.[36,37] Therefore, pelvic floor exercises with digital guidance might be considered as equivalent to biofeedback with manometry, albeit with significantly reduced equipment and training costs, an important consideration given the high prevalence of fecal incontinence yet limited availability of biofeedback treatment programs. For the patients in the present study, the use of biofeedback instrumentation offered no additional advantage over pelvic floor exercises with digital guidance alone.

Second, contrary to our hypothesis,[12] with the possible exception of isotonic fatigue time, the use of transanal ultrasound as the physiologic measurement for biofeedback offered patients no additional benefit over the more traditional treatment with manometry. Because isotonic fatigue time is an ultrasound-based measurement that was recorded during every session for the treatment group allocated to transanal ultrasound, it is not surprising that their improvement in this measure could be greater than for other treatment groups. However, many studies have remarked on the low correlation between physiologic measures and clinical outcomes or have questioned the clinical relevance of physiologic measures entirely.[13,17,22,23] In the present study, manometry-based measures were largely unrelated to clinical outcomes, whereas the ultrasound-based measures of isotonic fatigue time and isometric fatigue contractions yielded significant correlations with multiple clinical outcomes. Although these correlations with ultrasound-based measures were not sufficient to yield a statistically significant difference in clinical outcome for the transanal ultrasound group, the potential importance of these measures, and thus biofeedback programs that use techniques such as transanal ultrasound that may improve them, has been reinforced by other studies that suggest that fatigue rate and duration of anal squeeze may be significant predictors of clinical outcomes.[13,17] Further research is needed to elucidate the value of isotonic fatigue time and isometric fatigue contractions as outcome measures and the role of biofeedback programs that use transanal ultrasound.

Finally, the present study has confirmed, through a large sample of patients, that exercise-based pelvic floor retraining programs are an effective treatment for improving physiologic, clinical, and quality-of-life parameters, with 70 percent of patients perceiving improvement in symptom severity or quality of life, a range consistent with previous studies.[15,16] However, the effectiveness of traditional pelvic floor exercises alone without any form of biofeedback and the exact mechanisms of clinical improvement remain unassessed. Further research is required to isolate the individual contributions of the exercises alone, digital guidance, dietary or lifestyle advice, and counseling by a concerned technician and to determine the longer-term outcomes.

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