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Randomized clinical trial of intra-anal electromyographic biofeedback physiotherapy with intra-anal electromyographic biofeedback augmented with electrical stimulation of the anal sphincter in the early treatment of postpartum fecal incontinence

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KEY WORDS
Intra-anal electromyographic biofeedback therapy
Fecal incontinence
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Objective: The purpose of this study was to compare intra-anal electromyographic biofeedback alone with intra-anal biofeedback that was augmented with electrical stimulation of the anal sphincter in the treatment of postpartum fecal incontinence. A secondary aim was to examine the impact of the treatment on continence-related quality of life.

Study design: Sixty symptomatic women were assigned randomly to receive intra-anal electromyographic biofeedback or electrical stimulation of the anal sphincter once weekly for 12 weeks and to perform daily pelvic floor exercises between treatments. Therapeutic response was evaluated with a symptom questionnaire to determine continence score, anal manometry, and endoanal ultrasound scanning. Quality of life was assessed before and after treatment with a validated questionnaire.

Results: Fifty-four women completed the treatment; 52 women (96%) had ultrasonic evidence of an external anal sphincter defect. After the treatment, both groups demonstrated significant improvement in continence score ($P < .001$) and in squeeze anal pressures ($P < .04$). Resting anal pressures did not alter significantly. Quality of life improved after the completion of physiotherapy, but there were no differences in outcome between intra-anal electromyographic biofeedback and electrical stimulation of the anal sphincter.

Conclusion: Intra-anal electromyographic biofeedback therapy was associated with improved continence and quality of life in women with altered fecal continence after delivery. The addition of electrical stimulation of the anal sphincter did not enhance symptomatic outcome.

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Up to 25% of women will experience altered fecal continence after delivery as many as 50% of women who sustain a clinically recognizable third-degree tear have ongoing alteration in fecal continence.[1,2] Although symptoms of altered fecal continence are often transient, successive vaginal childbirth may lead to cumulative deterioration in anal sphincter function.[3]

Current treatment of incontinence that results from obstetric injury is centered on a combination of surgery and physiotherapy. If significant injury to the anal sphincter is identified at the time of delivery, primary surgical repair is performed. If this fails or subsequent investigation of a symptomatic patient reveals a previously undiagnosed anal sphincter tear, a secondary, or delayed, anal sphincter repair may be performed. Further treatment will center on pelvic floor rehabilitation and manipulation of bowel habit.

Biofeedback physiotherapy has been shown to be an effective treatment of fecal incontinence.[4] Biofeedback techniques adopt a behavioral approach that uses external equipment to demonstrate and alter physiologic events, with visual or auditory feedback. Biofeedback from anal sphincter muscle contraction is used to encourage patients to increase the power and endurance of external anal sphincter contraction. Symptomatic improvement rates of between 50% and 90% have been reported,[5,6] and clinical improvement has been reported to be maintained for at least 2 years after treatment.[7,8]

We have demonstrated previously that intra-anal electromyographic biofeedback treatment with electrical stimulation of the anal sphincter was more effective than biofeedback that used a transvaginal perineometer.[9] The primary aim of this study was to compare the efficacy of intra-anal electromyographic biofeedback alone to intra-anal biofeedback with electrical stimulation of the anal sphincter in the treatment of symptoms of postpartum fecal incontinence. We hypothesized that the addition of electrical stimulation of the anal sphincter would enhance neuromuscular re-education. A secondary aim of this study was to examine the impact of symptoms of postpartum fecal incontinence on quality of life (QoL) with the use of a validated questionnaire.[10]

Material and methods

Sixty consecutive women with symptoms of impaired fecal continence after obstetric injury were recruited from a dedicated Perineal Clinic at the National Maternity Hospital at 12 weeks after delivery. Patients with a history of diabetes mellitus, inflammatory bowel disease, irritable bowel disease, previous anorectal surgery, or malignancy were excluded. At the initial review, the condition of each patient was assessed with a structured bowel function questionnaire to calculate a "continence score."[11] Anal physiologic investigations consisted of anal manometry and endoanal ultrasound scans.

Patients were assigned randomly to receive standard intra-anal electromyographic biofeedback training of the pelvic floor or intra-anal electromyographic biofeedback with electrical stimulation of the anal sphincter weekly for 12 weeks by 1 of 2 physiotherapists who were blinded to the patient's manometry and ultrasound results. Randomization was achieved with computer-generated allocations in a ratio of 1:1 that were contained in sealed opaque envelopes. Endoanal surface electromyographic biofeedback and electrical stimulation of the anal sphincter were performed with an Incare PRS 9400 system connected to a 17-inch television monitor and endoanal probe (Neen Healthcare, Dereham, Norfolk, UK).

Training was performed with the patient in the left lateral position with a full view of the monitor. Slow twitch exercises were performed by asking the patient to contract and hold the pelvic floor muscles for 5 seconds and relax for 8 seconds. This alternated with fast twitch exercises, during which the patient was asked to give 3 rapid maximal squeeze contractions in 5 seconds and then to relax for 8 seconds over a 10-minute period.

Patients who randomly received electrical stimulation were treated with the same electromyographic biofeedback regimen but received additional intra-anal neuromuscular electrical stimulation. This was performed with a standard frequency of 35 Hz with a 20% ramp modulation time. Stimulation was performed for 20 minutes with 5 seconds stimulation and 8 seconds relaxation between contractions. Stimulation was performed to an intensity that elicited an external anal sphincter contraction, with voluntary muscle contraction encouraged concurrently.

All patients performed standard Kegel exercises daily during the treatment period. Patients were reassessed at the end of the 12-week treatment protocol by anorectal manometry, and the bowel function questionnaire was repeated to facilitate comparative analysis between pre- and post-treatment continence scores. All physiologic investigations were performed by the primary investigator (R.M.) who was blinded to the individual patient treatment protocol.

The structured bowel function questionnaire was based on the presence of fecal urgency, flatal incontinence, fecal soiling, frank fecal incontinence, and any resulting impact on daily lifestyle. Based on each of these categories, a continence score was allotted; a score of 0 indicated complete continence, and a score of 20 indicated complete incontinence.[11]

Anorectal manometry was performed with a Synectics PC Polygraf Lower Gastrointestinal system (Synectics, Stockholm, Sweden), a water-perfused system with an 8-channel recording capacity. Mean maximum resting and mean maximum squeeze pressures for the anal canal

were determined by the averaging of manometric results across 3 pressure profiles.[12,13]

Endoanal ultrasound scanning was performed with each patient with a scanner (Bruel and Kjaer, Naerum, Denmark), which has a10-mHz rotating endoprobe. All scans were reported by a consultant radiologist, and injury was defined in terms of the number of quadrants of the internal and external anal sphincter circumference that were affected and whether the injury was full or partial thickness in nature.[14-16]

Baseline QoL was assessed by self-administered questionnaire at the first physiotherapy visit in a cohort of 34 patients who were seen and treated at 1 of 2 treatment sites, with the use of the Fecal Incontinence Quality of Life Scale (FIQL)[10] that produces both reliable and valid measurements in 4 domains (lifestyle, coping behavior, depression/self-perception, and embarrassment). The questionnaire was administered a second time on the completion of the final physiotherapy session.

The power calculation indicated that, from a cohort of 60 women who would be assigned randomly, 30 women in each treatment group would detect a 25% difference in outcome between the 2 treatment modalities, with a 95% statistical power ($\alpha = .05$; $\beta = .20$).

All data were stored on an IBM compatible database. Statistical analysis was performed with the Wilcoxon's rank sum test and the Mann Whitney *U* test, as appropriate, on an SPSS statistical software package (version 11; SPSS Inc, Chicago, Ill).

The study was approved by the Ethical Committees of the National Maternity and Mater Misericordiae Hospitals, Dublin, Ireland. All patients gave written informed consent.

Results

Sixty women were recruited into the trial (Table I). Thirty-two patients had symptoms of fecal incontinence after primiparous vaginal delivery, and 28 patients had symptoms after second or subsequent vaginal delivery. There were no significant differences in age, parity, or duration of symptoms between the 2 study groups.

Fifty-four patients completed the study; 26 patients were in the intra-anal electromyographic biofeedback therapy (BAlone) group, and 28 patients were in the intra-anal electromyographic biofeedback therapy that was augmented with electrical stimulation of the anal sphincter (BStim) group. Forty-seven patients (87%) had symptoms of fecal incontinence after a vaginal delivery that was complicated by recognized anal sphincter trauma. Seven women (13%) had symptoms after apparently uncomplicated vaginal delivery, 5 of which were instrumental.

The median continence score before treatment in the BAlone group was 4.5 (range, 2-11) and 4 (range, 2-14) in the BStim group. Only 2 patients (3.7%) had a normal endoanal ultrasound scan. The distribution of anal sphincter abnormality is given in Table II. There was no difference in the distribution of anal sphincter defects between the 2 groups. There was no difference in pretreatment anal manometry squeeze pressure ($P = .510$; Mann Whitney *U* test) or resting pressure ($P = .569$; Mann Whitney *U* test) between the 2 groups.

Table I Patient characteristics in 30 patients who were assigned randomly to receive biofeedback alone and 30 patients assigned randomly to receive biofeedback with electrical stimulation of the anal sphincter

Characteristic	BAlone group	BStim group	*P* value
Median age (y)*	35 (23-39)	32 (22-42)	.574
Median parity (n)*	1 (1-3)	1 (1-3)	.182
Mode of delivery (n)			.705
Spontaneous vaginal delivery	19	15	
Vacuum extraction	2	5	
Forceps	6	4	
Vacuum/forceps	3	6	
Failure to complete program (n)	4	2	

* The range is given in the parentheses.

After treatment, there was a similar improvement in symptoms in both groups (Table III). The median continence score in the Bstim group after the completion of therapy was 2 (range, 0-10; $P < .001$; Wilcoxon's rank sum test). After treatment, the median continence score in the BAlone group was 2 (range, 0-10; $P < .001$; Wilcoxon's rank sum test). There was a median change in continence score of 2 (range, 0-8) in the BAlone group and 2 (range, 0-4) in the Bstim group ($P = .583$; Mann Whitney *U* test). Fourteen patients (26%) became completely asymptomatic, 6 patients (24%) in the BAlone group compared with 8 patients (28%) in the BStim group. Overall 8 women (15%) reported no benefit from treatment (5 patients in the BStim group and 3 patients in the BAlone group; $P = .451$, chi-squared test).

After treatment, there was a significant improvement in the anal squeeze pressure and in the anal squeeze pressure increment in both groups. There was no change in anal canal resting pressure after treatment in either group (Table II).

Thirty-four patients completed both the QoL questionnaires. Bivariate correlations between continence scores and all FIQL scales were found to be significant ($P < .001$) with coping/behavior, which shows the strongest inverse relationship with symptom score and the weakest with depression/self perception. Improvements in both symptoms of fecal incontinence and QoL measures were observed after the completion of physiotherapy (Table III). Improvement in the embarrassment domain was not significant.

Table II Nature of ultrasound defects in 54 women who were assigned randomly to receive either biofeedback alone or biofeedback with electrical stimulation of the anal sphincter

Defect	External anal sphincter (n)	Internal anal sphincter (n)
No defect	2 (3.7%)	20 (37%)
≤1 Quadrant defect	45 (83%)	20 (37%)
>1 Quadrant defect	7 (13%)	14 (26%)
Partial thickness defect	28 (52%)	27 (50%)
Full thickness defect	24 (44%)	7 (13%)

Table III Continence scores and manometric findings before and after treatment in the biofeedback alone group and in the augmented feedback group

	BAlone group (n = 26)			BStim group (n = 28)		
Variable	Before treatment	After treatment	*P* value	Before treatment	After treatment	*P* value
Median continence score	4.5 (2-11)	2 (0-10)	<.001	4 (2-14)	2 (0-10)	<.001
Median resting pressure (mm Hg)	29 (11-54)	31 (8-64)	.308	28 (4-43)	30 (2-66)	.32
Median squeeze pressure (mm Hg)	44 (20-83)	59 (25-110)	.047	42 (6-71)	47 (17-91)	.004

The range is given in the parentheses.

Table IV Changes in FIQL scores after treatment

FIQL domain	Median score before treatment	Best possible score (%)	Median score after treatment	Best possible score (%)	Change	*P* value
Lifestyle	3.8 ± 2.70	95	3.9 ± 2.3	97.5	0.1	.008
Coping/behavior	2.88 ± 3.00	72	3.22 ± 2.56	80.5	0.34	<.001
Depression/self perception	3.64 ± 3.43	82.2	3.86 ± 2.86	87.1	0.22	.006
Embarrassment	3.33 ± 3.00	83.3	3.67 ± 3.00	91.8	0.34	.123

Comment

This study shows that intra-anal electromyographic biofeedback therapy is associated with a significant improvement in the symptoms of postpartum fecal incontinence. In both arms of the trial, there were improvements in continence scores and anal canal squeeze pressures but no improvement in anal resting pressures. Augmenting standard intra-anal electromyographic biofeedback therapy with electrical stimulation of the anal sphincter did not achieve better results than biofeedback alone. We acknowledge the absence of a placebo group in this trial. The decision not to include a placebo group was based on the evidence in the current literature that biofeedback physiotherapy is an effective treatment for fecal incontinence.[8] We felt it was difficult to justify no treatment for symptomatic women who already were 12 weeks after delivery.

Patients with postpartum incontinence frequently have difficulty in initiating and co-ordinating voluntary contraction of the pelvic floor muscles, which may be partly due to a loss of cortical awareness.[17] The rationale for inclusion of electrical stimulation in this study was to facilitate the biofeedback response by enhancing patient awareness of anal sphincter and puborectalis contraction and motor unit recruitment.[18] This view is supported by recent evidence that sacral nerve stimulation improves fecal continence without changing anal sphincter pressures.[19] Repeated muscle contraction improves muscle strength and retards atrophy. In addition, chronically stimulated muscle assumes the properties of slow motor units, which increases muscle endurance.[20]

Observed increases in anal squeeze pressures reflect an enhanced ability to contract the external anal sphincter. Sustained sphincter contraction has been postulated to diminish large bowel peristalsis and even induce retrograde peristalsis, which allows continence to be preserved until the defecatory urge ceases.[21] The lack of change in resting pressure reflects the contribution to resting tone by the internal anal sphincter, an involuntary muscle not susceptible to voluntary retraining.

Solomon et al[22] have recently shown, in a study of patients with mild-to-moderate fecal incontinence, that biofeedback with digital guidance was as good as bio-

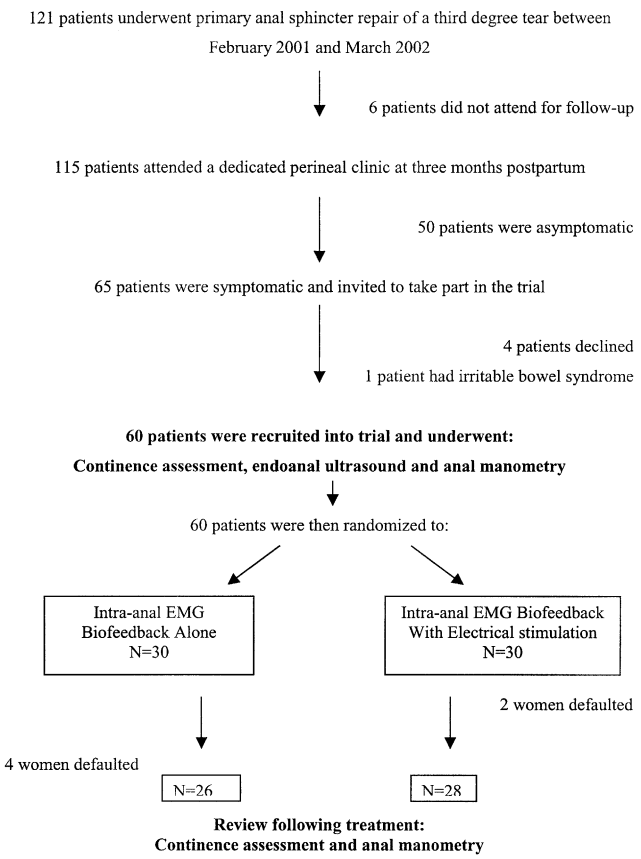

Figure Study design. *EMG*, Electromyographic.

feedback with ultrasonography or manometry; electromyographic biofeedback was not used. They point out that pelvic floor exercises alone may be as effective as biofeedback-assisted techniques. Indeed, Norton et al[23] found that exercises and biofeedback did not enhance the effect of standard nursing advice and support. Notwithstanding these observations, the great majority of women in the current study achieved significant improvement in symptoms, although biofeedback has been shown to be less effective in patients with large external anal sphincter defects.[9]

Continence depends not just on anal sphincter integrity but also on the interplay of bowel habit, colonic motility, and cortical awareness. There also appears to be a psychologic component that may respond to supportive counseling regarding the symptoms and cause of fecal incontinence. This in itself can be a powerful tool. The results of the trial by Norton et al[23] support the hypothesis that the beneficial effects that were observed for biofeedback in fecal incontinence may relate more to the relationship with the therapist and to the advice that was given than to the technical aspects of biofeedback therapy.

After treatment, QoL improved across all domains and was significant in the lifestyle, coping/behavior, and depression/self perception domains. The improvement in the embarrassment domain was not significant, and some women actually worsened. This may reflect longer duration since childbirth. Women may tolerate the embarrassment that is caused by incontinence better in the early postpartum period; however, persistent difficulty as they resume their working and social lives may lead to more embarrassment, despite improving symptoms.

Continence is a complex physiologic function, the alteration of which may have dramatic effect on QoL. Biofeedback physiotherapy, as used in the current study, has a useful role in the treatment of postpartum fecal incontinence. The question of whether biofeedback is superior to standard pelvic floor exercises with intensive counseling and support remains to be determined fully. In addition there is a need for further long-term follow-up and investigation of the impact of symptoms and treatment on QoL. These aspects must be addressed if we are to understand the true role of pelvic floor biofeedback physiotherapy.

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