A Prospective, Randomized Study Comparing the Effect of Augmented Biofeedback with Sensory Biofeedback Alone on Fecal Incontinence After Obstetric Trauma

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PURPOSE: This study was designed to compare prospectively the effects of augmented biofeedback with those of sensory biofeedback alone on fecal incontinence and anorectal manometry after obstetric trauma. METHODS: A consecutive cohort of 40 females with impaired fecal continence after obstetric anal sphincter injury were recruited from a dedicated perineal clinic. Patients were randomly assigned to receive either augmented biofeedback or sensory biofeedback alone. All patients were assessed before and after twelve weeks of biofeedback training, using a fecal continence questionnaire and anorectal manometry. RESULTS: Thirty-nine of 40 females recruited completed the study. Continence scores improved in both treatment groups, but the results were better for those who received augmented biofeedback. Anorectal manometry was unchanged by sensory biofeedback, whereas anal resting and squeeze pressures increased with augmented biofeedback. No change in anal vector symmetry was observed in either group. CONCLUSION: Augmented biofeedback training is superior to sensory biofeedback alone in the treatment of impaired fecal continence after obstetric trauma. [Key words: Obstetric injury; Fecal incontinence; Biofeedback therapy]

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Fecal incontinence is a debilitating and largely unrecognized clinical problem.[1] The cause of fecal incontinence in females relates primarily to traumatic vaginal delivery, with 4 percent of females experiencing at least one episode of frank fecal incontinence after first vaginal delivery.[2] Two mechanisms of injury are generally recognized: direct disruption of the anal sphincter muscles and traction neuropathy affecting the pudendal nerves.[2, 3]

Management of obstetric-related fecal incontinence has been problematic, with an expectant approach often adopted. For those with frank incontinence and demonstrable external anal sphincter defects, early surgical repair is indicated. For those less seriously affected, standard sensory biofeedback therapy for the pelvic floor is frequently requested.

Biofeedback therapy is a behavioral technique using external equipment to demonstrate and alter physiologic events, using auditory or visual feedback. Kegel[4, 5] first described the effects of pelvic floor exercises on stress urinary incontinence postpartum. Conventional sensory biofeedback therapy for treatment of fecal incontinence now combines standard Kegel exercises with a sensory feedback signal, using either a perineometer or vaginal cones.[6]

Using such regimens, several studies have shown subjective improvement in fecal continence without objective changes in anorectal manometry.[7] It was our hypothesis that an augmented biofeedback program of electrical stimulation of the anal sphincter with

audiovisual electromyography (EMG) feedback might enhance neuromuscular reeducation, preserve and augment anal sphincter function, and enhance fecal continence. To address this hypothesis we compared prospectively the effects of augmented biofeedback therapy with those of sensory biofeedback therapy alone on fecal incontinence and anorectal manometry after obstetric trauma.

PATIENTS AND METHODS

Patient Details

Forty consecutive females with symptoms of impaired fecal continence after obstetric injury were recruited from a dedicated perineal clinic. All patients were assessed by symptom questionnaire and anorectal physiologic testing before and after a 12-week treatment period. All physiologic investigations were performed by the primary investigator (MMF), who was blinded to the individual patient treatment protocol.

Primary assessment comprised anorectal manometry, measurement of pudendal nerve terminal motor latency (PNTML) and anal endosonography.[8–10] Each patient was randomly assigned by computer (Ran List 1992, University of Texas, Houston, TX) to one of two physiotherapy treatment protocols: 1) sensory biofeedback training using a vaginal perineometer and standard Kegel pelvic floor exercises[4, 5] or 2) augmented biofeedback training of the pelvic floor combining audiovisual feedback and electrical stimulation designed to stimulate both slow twitch and fast twitch fibers.[11]

Each woman was seen weekly by separate therapists (MC, continence nurse, for those in the sensory biofeedback training group and KM, continence physiotherapist, for those in the augmented biofeedback training group). Both therapists were blinded to the individual obstetric history and results of initial anorectal physiology investigations.

All patients were advised to perform standard Kegel home pelvic floor exercises daily irrespective of treatment protocol.[4, 5] All patients were reassessed at the end of the 12-week treatment protocol by anorectal manometry and symptom questionnaire.[12]

Symptom Questionnaire

Each woman completed a symptom questionnaire modified from Pescatori *et al.*[12] to identify symptoms of impaired fecal continence. This questionnaire was then used to determine fecal incontinence scores before and after treatment.

Anal Manometry

Anal vector manometry using a Synectics PC Polygraf HR™ (Synectics Medical, Enfield, Middlesex, U.K.) lower gastrointestinal manometry system was performed at recruitment and after completion of therapy. Mean maximum resting pressure and mean maximum squeeze pressure were determined by averaging manometric results across three pressure profiles. Mean squeeze increment pressure was then calculated by subtraction of mean maximum resting pressure from mean maximum squeeze pressure values. An index of anal canal pressure symmetry, the vector symmetry index, was calculated using a formula derived from Perry *et al.*[8]

Pudendal Nerve Terminal Motor Latency

PNTML was measured using a St. Mark's Hospital electrode (Dantec, Skovlunde, Denmark).[9] A stimulus of 50 V for 0.1 ms was delivered at one pulse per second, and the shortest reproducible latency was recorded on an MS91 EMG machine (Medelec™, Old Woking, Surrey, U.K.). The PNTML was considered prolonged if greater than 2.4 msec.[9]

Anal Endosonography

Anal endosonography was performed using a Bruel and Kjaer 10 MHz rotating transanal endoprobe.[10] Endosonographic injury was graded for both the external and internal anal sphincters according to whether the injury was full or partial thickness and the number of quadrants involved.

Sensory Biofeedback Training

The training program was explained, demonstrated and monitored by an experienced continence nurse (MC). Patients were given sensory pelvic floor feedback training lasting 30 minutes each week for twelve weeks. The training program comprised exercises designed to improve awareness and strength of the pelvic floor muscles and included static (slow twitch) and dynamic (fast twitch) exercises.[4, 5] Biofeedback was achieved using a Peritron™ Precision Perineometer (Cardio design, Pty Ltd, Perth, Australia). The perineometer was inserted into the vagina and fast twitch exercises were performed by asking the patient

to perform short maximum contractions, aiming to achieve 20 contractions of six to eight seconds duration, with ten seconds relaxation between. Slow twitch contractions were performed by asking the patients to lift and squeeze the perineometer and to hold the contraction for as long as possible, aiming to achieve a contraction of at least 30 seconds duration. These exercises were performed in the supine position and biofeedback was used to encourage improvement in previous readings.

Augmented Biofeedback Training

Augmented biofeedback training, which combined audiovisual feedback and electrical stimulation, was performed using an Incare PRS 9300™ system connected to a 17 inch TV monitor and endoanal probe (Hollister, Libertyville, IL). The endoanal probe was used to perform both electrical stimulation and audiovisual feedback through surface EMG recording with a 25-μV catchment range.

Training was performed with the patient lying in the left lateral position with a full view of the monitor. Static (slow twitch) and dynamic (fast twitch) exercises were alternated over a 15-minute period comprising 13-second cycles (5 seconds activity and 8 seconds rest). The beginning of each 13-second cycle was announced by a buzzer sound.

Slow twitch exercises were performed by asking the patient to contract and hold the pelvic floor muscles for five seconds and relax for eight seconds. This alternated with fast twitch exercises during which the patient was asked to give three rapid maximum squeeze contractions in five seconds and then relax for eight seconds (Fig. 1).

Electrical stimulation was then performed using low-frequency 20-Hz and high-frequency 50-Hz settings to target static (slow twitch) and dynamic (fast twitch) fiber activity with a 20 percent ramp modulation time. Low frequency stimulation at 20 Hz was performed for ten minutes with five seconds stimulation and eight seconds relaxation between contractions. High-frequency stimulation was performed using 50 Hz for eight seconds with a 30-second rest period between stimulations. This long rest period was used between stimulations to avoid muscle fatigue.[13]

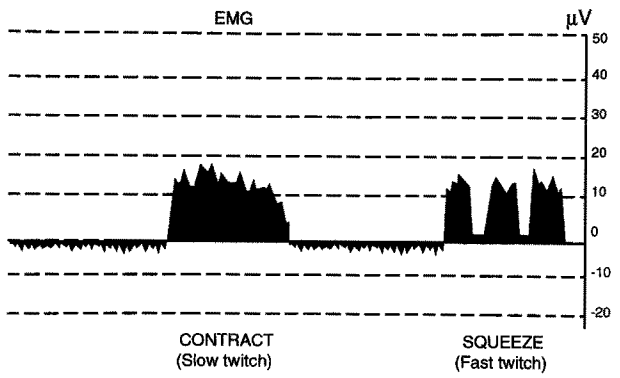

Figure 1. Augmented biofeedback therapy combining electrical stimulation and audiovisual biofeedback.

Statistical Analysis

All data were stored on an IBM-compatible Microsoft Access database (Microsoft, Flushing Meadows, NY). Statistical analysis was performed using the Wilcoxon's rank sum test as appropriate on an SPSS™ for Windows statistical software package (SPSS Inc., Chicago, IL).

Ethics

This study was approved by the Ethical Committee of the National Maternity Hospital, Dublin. All patients gave their written informed consent.

RESULTS

Mean age for the study group was 32 (range, 18–48) years, and mean duration of symptoms was four (range, 3–28) months. Thirty-seven patients developed symptoms of impaired fecal continence after primary repair of recognized obstetric anal sphincter disruption, whereas onset of symptoms in the remaining three patients followed traumatic instrumental delivery. Symptoms followed primiparous delivery in 24 patients and multiparous delivery in 16 patients. There were no significant differences in age, parity, or duration of symptoms between the two treatment groups.

Twenty-eight (70 percent) patients reported combined daily fecal staining and poor control of flatus, eight (20 percent) reported fecal staining, and four (10 percent) reported poor control of flatus alone. Thirty (75 percent) patients had debilitating fecal urgency of less than five minutes, and 12 (30 percent) had episodic frank fecal continence. The median fecal continence score before treatment for the sensory biofeedback group was 8 (range, 2–20) and for the augmented biofeedback group 11 (range, 1–20; $P = 0.09$; Wilcoxon's rank sum test).

Anorectal Physiology Pretreatment

Of 39 patients who completed the study, all had evidence of anatomic injury on transanal endosonography. Thirty-seven patients (95 percent) had a defect in the external anal sphincter (EAS), and the remaining 2 patients (5 percent) had EAS scarring only. Eighteen patients (46 percent) had a full-thickness defect in the EAS that extended over more than one quadrant. Thirty-one patients (79 percent) had a full-thickness defect in the internal anal sphincter (IAS), and the remaining 8 patients (21 percent) had IAS thinning only. Thirty-two patients (82 percent) had defects involving both the EAS and IAS. There were no differences in the distribution of anal sphincter injury between the two treatment groups.

Anal manometry measurements and PTMNL before treatment were similar in the two treatment groups. Twelve (31 percent) patients had evidence of a pudendal neuropathy (>2.4 msec). There was no significant difference in distribution of pudendal nerve injury between the two groups. Mean duration of symptoms for those patients with a pudendal neuropathy (n = 12) was 5 (range, 3–24) months, and for those patients without a neuropathy (n = 18) it was 3 (range, 3–28) months.

Outcome After Therapy

Significant improvement in fecal continence scores was found in both groups after treatment. Median fecal score in the augmented biofeedback group after completion of therapy was 0 (range, 0–12; $P < 0.0001$), and in the sensory biofeedback group it was 4.2 (range, 0–19; $P < 0.0001$; Wilcoxon's rank sum test), with a median change in continence score of 10 in the augmented biofeedback group compared with 3 (range, 0–15) in the sensory group ($P < 0.001$; Wilcoxon's rank sum test; Fig. 2). In the augmented biofeedback group 15 patients became asymptomatic, and 5 noted improvement in fecal continence, whereas in the sensory biofeedback group only 7 became asymptomatic, 4 noted some improvement in symptoms, and the remaining 8 patients were unchanged.

After treatment mean maximum resting pressure, mean maximum squeeze pressure, and mean squeeze increment anal canal pressures all increased in the augmented biofeedback therapy group, but no significant changes were found in the sensory biofeedback therapy group (Table 1). No change was observed in vector symmetry index after treatment in either treatment group (Table 1).

Although there was no difference in the distribution of EAS defects between the two treatment groups, patients with a full-thickness EAS defect extending over more than one quadrant (n = 18) had a smaller improvement in continence (median 3; interquartile range, 0–6) compared with patients with smaller EAS defects (median 10; interquartile range, 4–16; P = 0.01; Wilcoxon's rank sum test).

DISCUSSION

This is the first prospective, randomized, controlled trial that compared the effect of augmented biofeedback therapy on postpartum fecal incontinence and anorectal physiology with that of conventional sensory biofeedback therapy. Results show that augmented biofeedback, combining audiovisual feedback with electrical stimulation, is an effective

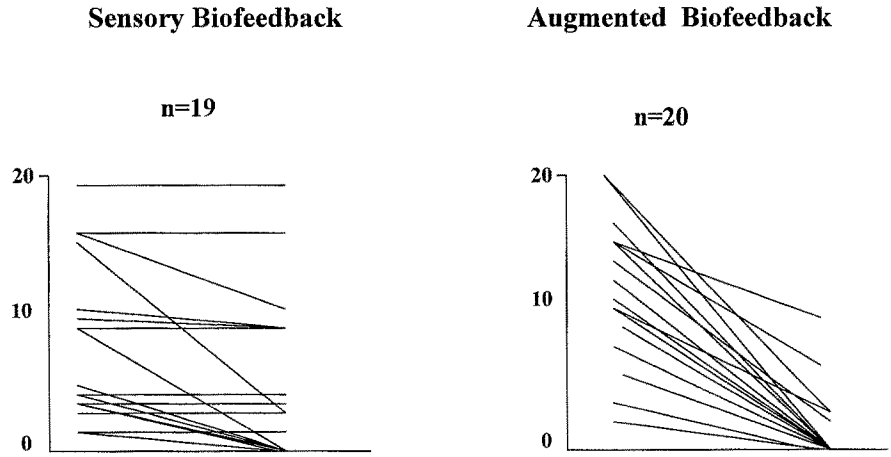

Figure 2. Change in fecal continence scores before and after biofeedback in the sensory training and augmented biofeedback groups.

Table 1.
Change in Anorectal Physiologic Parameters After Physiotherapy

	Sensory Biofeedback (n = 19)			Augmented Biofeedback (n = 20)		
	Pre	Post	*P*	Pre	Post	*P*
Mean Max RP	33 (30–53)	32 (19–53)	0.9	38 (19–56)	54 (32–64)	0.01*
Mean Max SP	59 (25–87)	51 (43–88)	0.9	57 (35–81)	86 (46–101)	0.001*
SI	20 (12–38)	24 (17–33)	0.9	19 (5–31)	30 (18–45)	0.002*
VSI	0.4 (0.2–0.8)	0.5 (0.4–0.8)	0.3	0.5 (0.4–0.8)	0.5 (0.4–0.7)	0.7

Mean Max RP = mean maximum resting pressure; Mean Max SP = mean maximum squeeze pressure; SI = squeeze increment; VSI = vector symmetry index; Pre = pretreatment; Post = posttreatment.

Values expressed in mmHg as median (interquartile range). *P* values from Wilcoxon's rank-sum test.

* Statistically significant differences.

treatment in the management of impaired fecal continence after obstetric trauma and that results after augmented biofeedback are superior to those after conventional sensory biofeedback therapy using a perineometer and standard Kegel exercises. Although both treatments did improve continence, the change in continence scores after treatment was greater in those receiving augmented biofeedback. However, only augmented biofeedback therapy produced objective changes in anal canal pressures. This differential response highlights the subjectivity of continence scores as a measure of outcome and illustrates the complexity of the continence mechanism in which psychological factors play an important role in determining symptom severity. The ability to target damaged muscle and initiate a minimum voluntary contraction is a prerequisite for effective biofeedback training.[14] Patients with postpartum incontinence frequently have difficulty in initiating and coordinating voluntary contraction of the pelvic floor muscles.[4, 5] This may be secondary to a loss of cortical awareness after vaginal delivery in addition to neuromuscular injury.[4, 5, 15] The differential effect on anorectal manometry observed between the two study groups may be attributed to the electrical stimulation component of the augmented biofeedback training. The rationale for inclusion of electrical stimulation in this study was to facilitate the biofeedback response by enhancing both patient awareness of anal sphincter and puborectalis contraction and motor unit recruitment. In doing so augmented biofeedback combined the motor and sensory components of rehabilitation.[16] Resting anal canal pressure reflects both IAS activity and slow twitch EAS fiber activity, whereas squeeze pressure reflects fast twitch fiber activity.[17] The frequency parameters used in this study were specifically chosen to target both the static (20 Hz) and dynamic (50 Hz) components of pelvic floor musculature.[18] Normal neural activity is asynchronous, where separate motor neurons are excited at different times and rates. In contrast, electrical stimulation results in the same nerve fibers being stimulated repeatedly at the same frequency.[19] Generally, only a small part of the motor neuron pool can be activated by the external stimulus, because of the size and orientation of the fibers relative to the stimulating electrode. For this reason an internal electrode was chosen, because the closer the electrode to the anal sphincter muscles, the greater the selectivity.[20] With electrical stimulation, the number of motor units recruited is dependent on frequency and intensity of the external stimulus.[11, 13, 21] Increasing frequency and intensity of electrical stimulation causes rapid neuromuscular fatigue attributed to decreased neurotransmitter release at or before the synaptic junction.[22] This difficulty was overcome by using a 20 percent ramp modulation increment time to allow patients to develop sensory tolerance and by allowing a long rest period between stimulations to allow neuromuscular recovery.[22]

Biofeedback training has been criticized as being time consuming and labor intensive. We have shown that augmented biofeedback training over 12 weekly sessions, each lasting 35 minutes, is associated with significant improvements in both continence scores and anal manometry. However, improvement in fecal continence was significantly less in those patients with extensive full-thickness EAS defect such that surgical repair should not be withheld pending outcome of biofeedback in patients with such injury. Although prolonged follow-up is required to determine how long patients remain symptom free, recent work has suggested that there is substantial long-term benefit.

CONCLUSIONS

Augmented biofeedback, combining audiovisual feedback with electrical stimulation, is an effective treatment in the management of impaired fecal continence after obstetric trauma and is superior to conventional sensory biofeedback. Although surgical repair will remain the primary treatment for those patients with extensive anatomic injury,[23] augmented biofeedback training may be used as an adjunct to surgery or, in those less severely injured, to improve fecal continence and coordination of pelvic floor muscle activity. We commend augmented biofeedback as a first-line treatment for patients with symptoms of impaired fecal continence postpartum.

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Invited Editorial

To the Editor—The authors are certainly to be congratulated for having perpetuated one of the goals of our Journal: to encourage good scientific enquiry culminating in the publication of prospective, randomized studies. The purpose of the study is indeed interesting: to compare biofeedback alone with biofeedback combined with electrical stimulation. As we know from the stimulated graciloplasty literature, chronic low-voltage stimulation is indeed capable of enhancing muscular activity, as proven by documentable morphologic changes.[1–3]

However, several problems exist with this study, the first of which is that the groups were in no way equivalent. The "biofeedback alone" group had vaginal biofeedback probes inserted. Two hundred seventy degrees of the circumference of these probes