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Neuromuscular Electrical Stimulation and the Treatment of Lower Urinary Tract Dysfunction in Multiple Sclerosis—A Double Blind, Placebo Controlled, Randomised Clinical Trial

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Aims: Lower urinary tract dysfunction affects up to 75% of the multiple sclerosis population. Results from our recent Pilot Study (McClurg et al., 2006) indicated that a combined programme of pelvic floor muscle training, electromyography biofeedback and neuromuscular electrical stimulation modalities may alleviate some of the distressing symptoms within this population. This clinical trial aimed to evaluate further the efficacy of these interventions and to establish the benefit of neuromuscular electrical stimulation above and beyond that of EMG biofeedback and pelvic floor muscle training. **Methods:** 74 multiple sclerosis patients who presented with lower urinary tract dysfunction were randomly allocated to one of two groups - Group 1 received Pelvic Floor Muscle Training, Electromyography Biofeedback and Placebo Neuromuscular Electrical Stimulation (n = 37), and Group 2 which received Pelvic Floor Muscle Training, Electromyography Biofeedback, and Active Neuromuscular Electrical Stimulation (n = 37). Treatment was for nine weeks with outcome measures recorded at weeks 0, 9, 16 and 24. The Primary Outcome Measure was the number of leakage episodes. Within group analysis was by Paired Samples t-test. Group differences were analysed using Repeated Measures Analysis of Variance and Post-hoc tests were used to determine the significance of differences between Groups at each time point. **Results:** The mean number of incontinence episodes were reduced in Group 2 by 85% ($p = 0.001$) whereas in Group 1 a lesser reduction of 47% ($p = 0.001$) was observed. However, there was a statistically superior benefit in Group 2 when compared to Group 1 ($p = 0.0028$). This superior benefit was evident in all other outcome measures. **Conclusions:** The addition of Active Neuromuscular Electrical Stimulation to a programme of Pelvic Floor Muscle Training and Electromyography Biofeedback should be considered as a first-line option in alleviating some of the symptoms of lower urinary tract dysfunction associated with multiple sclerosis. *Neurourol. Urodynam. 27:231–237, 2008.* © 2008 Wiley-Liss, Inc.

Key words: uroflowmetry; neurogenic; prospective; pad test; bladder diary; incontinence

INTRODUCTION

Lower urinary tract dysfunction (LUTD) affects approximately 75% of people with multiple sclerosis (MS) at some stage, and more than 50% within 3–5 years of diagnosis.[1,2] The most common urodynamic finding is neurogenic detrusor overactivity associated in many with detrusor sphincter dyssynergia and symptoms include urgency, urge incontinence, frequency, nocturia, hesitancy and a feeling of incomplete emptying.[3] The most common treatment comprises pharmacotherapy and/or intermittent self-catheterisation.[4] However, in some patients anticholinergics have troublesome side effects[5] and intermittent self-catheterisation requires motivation and is not always possible for physical or psychological reasons.[6] More recently intravesical injection of botulinum toxin has been shown to be beneficial.[7] Much literature exists on the use of pelvic floor muscle training (PFMT), electromyography (EMG) biofeedback and neuromuscular electrical stimulation (NMES) in a non-neurogenic population,[8] but in a systematic review of the literature only two randomised controlled studies were found that reported on the efficacy of these modalities within an MS population.[9,10] The results of our small randomised controlled pilot study,[10] reported that in combination these modalities were effective in alleviating some of the LUT symptoms within this population. These findings support those of Vahtera et al.[9] which concluded that although most of their results were based only on the patient's verbal reports these treatment modalities should be considered in MS patients.

The aim of this double blind, randomised controlled clinical trial was therefore to further establish the efficacy of these interventions, and to establish any additional benefits with NMES.

METHODS

Participants

From July 2004 to July 2005, 95 patients with MS were screened for eligibility. Initial screening included a comprehensive medical history and a physical examination. Level of disability was determined by the Kurtzke Expanded Disability Status Scale and Functional Systems (Pyramidal, Bowel and Bladder Functions) assessment.[11] Urinalysis, (Multistix® Reagent Strips 8 SG, Bayer Diagnostics Mfg., Ltd, Bridgend, UK) was performed and, if indicated, urine culture was undertaken. Uroflowmetry (Urodyn 5000, Dantec Corporation,

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Abbreviations used: LUTD, lower urinary tract dysfunction; EDSS, Expanded Disability Status Scale; EMG, electromyography; MS, multiple sclerosis; NMES, neuromuscular electrical stimulation; PFMT, pelvic floor muscle training; VAS, visual analogue scale.
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Skovlunde, Denmark) with natural bladder filling was performed. Schäfer et al.[37] followed by measurement of post-void residual using an ultrasonic scanner (Mediwatch PLC, Rugby, UK). Digital vaginal (female) and anal (male) examination was carried out to assess musculature and screen for clinical signs of disease. EMG biofeedback assessment using a Neurotrac™ ETS unit (Verity Medical Ltd, Hampshire, UK) and a Periform or Anuform electrode (Neen Health Care, Oldham, UK), a 3-day bladder diary[15] and a 24-hr pad test,[12] were also carried out. To be eligible the patient had to be diagnosed with clinically definite or laboratory supported diagnosis of MS with disease stabilised for the previous 3 months, over 18 years of age, an EDSS $\leq$ 7.5, and sufficient dexterity enabling completion of assessments and treatment protocol. LUTD was confirmed after a clinical assessment as outlined by StÖhrer et al.[13] Participants were included if they presented with at least one of the following; any involuntary leakage of urine, voiding frequency >8 per 24 hr[14] nocturia, and/or reported voiding dysfunction such as hesitancy, straining, poor stream and incomplete emptying demonstrated during uroflowmetry with measurement of post-void residual.[15] Participants were excluded if they had a MS relapse necessitating hospitalisation 3 months prior to or during the study. Other exclusions were symptomatic prolapse, previous or current treatment for prostatic hyperplasia, presence of a urinary tract infection, current or recent diagnosis of a serious medical condition (other than MS), severe cognitive impairment, and any contraindications, such as pregnancy, to NMES.[16]

Recruitment was by self-referral in response to advertising via MS charities and hospital outpatient departments. Treatment was conducted in 12 health care facilities throughout Northern Ireland. Ethical approval was granted by the University of Ulster's Research Ethical Committee. All participants were given written and verbal information about the trial and provided written informed consent.

Ninety-five individuals were screened for eligibility, 81 were eligible, 7 of whom withdrew before completion of assessments. Thus 74 were recruited.

Procedures

Participants were stratified according to severity of leakage, 0-leaks, 1–2 leaks, >3 leaks, and were randomly allocated using the sealed envelope method to one of two groups: Group 1—PFMT, EMG biofeedback and placebo NMES (n = 37); and Group 2—PFMT, EMG biofeedback active NMES (n = 37).

The intervention period was for nine weeks and to counteract any diurnal variations participants attended the same clinic each week. A Neurotrac™ ETS (Verity Medical Ltd) and a Periform/Anuform intravaginal/intranal probe (Neen Health Care) were used to provide EMG biofeedback and active and placebo NMES.

At week 1 all participants were taught skills and strategies for preventing incontinence and suppressing urge and were provided with an information booklet. Additionally, participants were instructed to perform daily pelvic floor muscle exercises according to the initial vaginal assessment using the PERFECT scheme and the modified Oxford Scale.[17] Integration of the exercises into activities of daily living was encouraged and the regimen was reviewed weekly. EMG biofeedback was also performed for 15 min at each clinic visit. A Periform (females) or an Anuform (males) electrode (Neen Health Care) using Aquagel lubricating couplant (Adams, Leeds, UK) was inserted by the participants and connected to the Neurotrac™ ETS (Verity Medical Ltd) hand held unit and a monitor. Patient position, accuracy of placing the electrode, exact warm-up period and the time of day were all recorded. The exercise regimen included a warm-up of five contractions and five relaxations followed by a contraction/relaxation assessment. Participants were encouraged to selectively contract and relax their pelvic floor muscles with the assistance of visual and auditory feedback. Endurance exercises were performed, with emphasis on submaximal contraction and effective relaxation.

In addition participants in Group 1 were provided with Placebo NMES at parameters shown to have no physiological effect.[18,19] The same electrode and hand held unit as described for the EMG biofeedback was used in clinic and for home application. Parameters, which were pre-set, included a frequency of 2 Hz, a pulse width of 50 μsec, with 2 sec of stimulation and 60 sec of no stimulation, with a ramp of 8 sec. This was introduced at clinic and then used at home with a gradual increase to a daily maximum of 30 min.

The participants in Group 2 were provided with active NMES. In this group two different parameters were used, one which has been demonstrated to encourage correct use of the pelvic floor muscles and the second which has been shown to inhibit detrusor overactivity.[16] The first, applied at clinic only, was a bi-phasic constant current at a frequency of 40 Hz, a pulse width 250 μsec, a stimulation time of 5 sec with 10 sec of no stimulation, and a ramp of 1 sec; this was at maximum tolerated intensity with active assisted exercises. The second parameter settings included a frequency of 10 Hz, a pulse width of 450 μsec, a stimulation time of 10 sec and a rest time of 3 sec, with a ramp of 2 sec, at maximum tolerated intensity. This was introduced at clinic and then used at home with a gradual increase to a daily maximum of 30 min.

Participants in both groups were warned that they may or may not feel stimulation throughout the treatment period and were provided with written instructions into the use and care of the Periform or Anuform and the Neurotrac™ stimulation unit.

The compliance of all participants was monitored by a concealed button on the Neurotrac™ ETS unit, and the unit was reprogrammed weekly. Treatment was conducted by the same chartered physiotherapist in both groups.

Valid and reliable outcome measures were recorded at week 0 (base-line), weeks 9, 16 and 24 and are listed in Table I.

SAMPLE SIZE

On the basis of our recently completed Pilot Study,[10] power analysis performed on the number of incontinent episodes demonstrated that for 80% power in a two group study, 37 participants per group were required for a 50% reduction in the number of incontinent episodes.

DATA ANALYSIS

Data were analysed using SPSS Version 11 statistical package (SPSS, Inc., Chicago, IL, USA). Data analysis was by intention to treat and was undertaken before unblinding. In this study (a randomised trial with equal group sizes), parametric statistics (ANOVA) were used throughout because these tests are known to be criterion robust (i.e. it preserves the approximate significance level) and approximates the permutation test. A *P*-value of 0.05 was considered significant. Week 0 data were compared using a One-Way ANOVA. All within group data were analysed using paired sample *t*-test. The primary analysis was conducted on week 9

TABLE I. Outcome Measures

Outcome measure	Variable
Bladder diary[13,15]	Leakage episodes
	Frequency
	Nocturia
	Maximum and minimum volumes
	Intermittent self catheterisation (number and quantity)
	Fluid intake
24-hr pad test[12,36]	Change in pad weight after use
Portable uroflowmetry[37,38]	Maximum flow rate (Q_{max})
Portable bladder scanner[39]	Voided volume
	Post-void residual
Pelvic floor muscle assessment	
Digital assessment[40]	Strength and endurance
EMG biofeedback[40,41]	Strength, endurance and relaxation
Incontinence Impact Questionnaire[42]	Thirty item questionnaire
	Four subscales: physical activity, travel, social and relationships and emotional health
	Total score
Urinary distress inventory[42]	Nineteen item questionnaire
	Three subscales: irritative symptoms, obstructive/discomfort and stress symptoms
	Total score
The International Prostate Symptom Score[43,44]	Seven questions in relation to symptom severity, and one concerning impact on quality of life, with a range in score from 0 to 5
Visual analogue scale[45]	Ten centimetre line with zero representing no bothersomeness and 10 representing the worst possible bothersomeness
Multiple Sclerosis Impact Scale 29[46]	29-point questionnaire
	Two subscores measuring physical (20 items) and psychological (9 items)
The Barthel index[47]	10-point index that includes: Feeding; Moving from wheelchair to bed; personal toilet; getting on and off toilet; bathing; walking; stairs; dressing; controlling bowels; and controlling bladder with each scoring 0, 5 or 10

data. To allow for baseline imbalances, differences/percentage changes from baseline were analysed, as appropriate. Group differences were analysed using repeated measures analysis of variance, and *post*-hoc tests were used to determine the significance of differences between groups at each time point. The Greenhouse-Geisser approximate correction was used for Time X Group interactions.

RESULTS

Ninety-five patients with MS were screened (Fig. 1). Fourteen failed to meet the inclusion/exclusion criteria and a further 7 were unwilling to take part.

There were no statistically significant differences detected in the demographic data between the two groups (Table II) and there was no statistically significant differences demonstrated between the groups in any outcome measure at week 0 ($P > 0.05$).

During the 9 weeks of treatment one participant in the placebo Group (Gp 1), withdrew completely because the protocol was found to be too demanding, and one participant in the active treatment Group (Gp 2), discontinued because of a severe urinary tract infection. Three participants in the placebo group (one male, two females), and two (one male, one female), in the active treatment group were unable to use the stimulator at home, but attended for treatment weekly at clinic, and fulfilled all other protocols and assessments.

It is recognised some bias may have been possible in the results of the pelvic floor muscle assessment as these were undertaken by the clinician and blinding was therefore not possible. All other outcome measures were completed blind by an independent assessor. An exit questionnaire undertaken at week 24 assessed the blinding of participants and demonstrated that this was successful.

PRIMARY OUTCOME MEASURE

At the end of the active treatment period (week 9), there was a significant difference in treatment effects between groups ($P = 0.028$), with Group 2 demonstrating the superior improvement. At weeks 16 and 24 this significant difference was not maintained ($P \geq 0.535$; Figs. 2 and 3).

SECONDARY OUTCOME MEASURES

24-hr pad test

At week 0 Group 1 demonstrated a marginally greater pad weight gain than Group 2 although this was not statistically significant ($P = 0.563$). Following the 9-week intervention period there was a statistically significant between group difference ($P = 0.001$), with Group 2 again demonstrating the superior benefit. At weeks 16 and 24 this statistically significant difference was maintained ($P \leq 0.012$).

Uroflowmetry

Group 2 demonstrated statistically superior improvement at week 9 for voided volume and post-void residual when compared to Group 1 ($P \leq 0.036$; Table III).

Digital Assessment of Pelvic Floor Muscles (Oxford Classification)

Both groups demonstrated similar levels of muscle function at week 0. By week 9 it was observed that both groups had increased power and endurance significantly ($P = 0.001$), however, there was no significant difference between groups demonstrated ($P = 0.214$). These improvements were maintained throughout the study period.

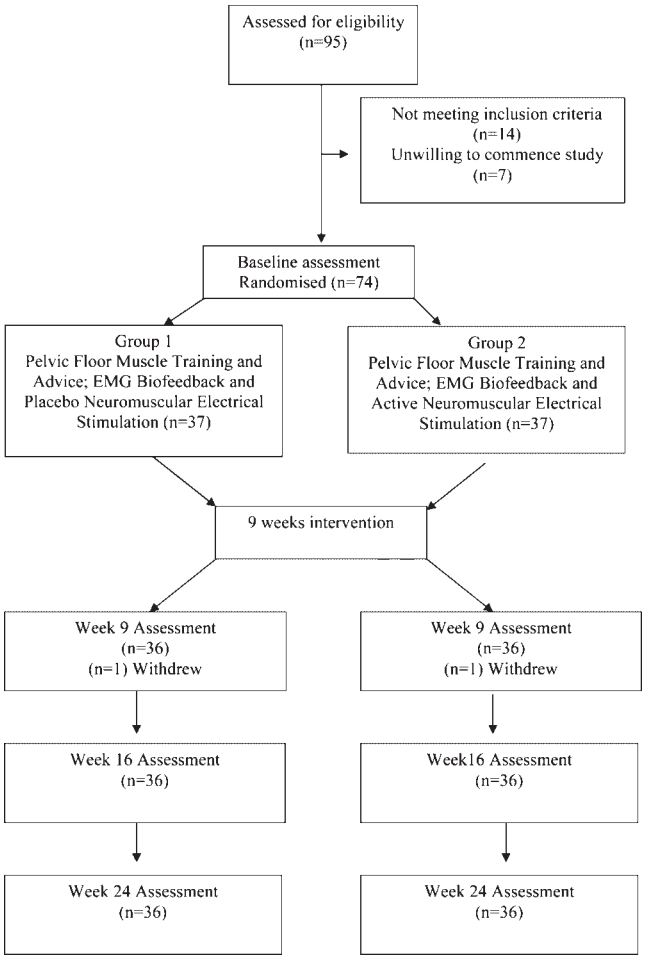

Fig. 1. Recruitment and progress of participants.

Electromyography Biofeedback Contraction (Work) Relaxation (Rest) and Endurance

There was no statistically significant difference demonstrated between groups in power, endurance or relaxation ($P \geq 0.341$).

Visual Analogue Scale

Both groups demonstrated a significant improvement throughout the duration of the study ($P = 0.001$). However, Group 2 demonstrated a superior improvement throughout the study which was statistically significant at weeks 9 and 24 ($P \leq 0.013$) when compared to Group 1.

Incontinence Impact Questionnaire (IIQ) and Urogenital Distress Inventory (UDI)

There was a significant superior benefit in Group 2 in the irritative subscale of the UDI at weeks 16 and 24 ($P \leq 0.043$).

International Prostate Symptom Score (IPSS)

Throughout the study both groups demonstrated significant improvement ($P = 0.001$) at all time points which was superior in Group 2 but not significantly so ($P \geq 0.132$).

DISCUSSION

The aims of this double blind, placebo controlled, randomised clinical trial were to evaluate the effectiveness of the aforementioned interventions in a neurological population, and to establish the efficacy of NMES above and beyond that of EMG biofeedback and PFMT. The results of this trial have demonstrated that PFMT and EMG biofeedback significantly reduce the symptoms of LUTD within this population and moreover improves quality of life. The findings have also demonstrated that the addition of NMES significantly increases the benefits gained. Furthermore, the benefits appear to be relatively long lasting.

TABLE II. Demographic Details at Base-Line

	Group 1 (n = 37)	Group 2 (n = 37)	*P*-value
Stratification			
0 Leaks	13	12	0.961*
1–2 Leaks	12	12	
≥3 Leaks	12	13	
Females/males	26 Females 11 Males	31 Females 6 Males	0.269*
Age (mean years, SD) Range: (27–72 years)	52.0 (8.8)	48.3 (11.5)	0.138^{+}
Body mass index (mean, SD; kg/m) Range: 15–35	23.3 (8.9)	23.7 (4.0)	0.556^{+}
Expanded disability status score (mean, SD) Range: 2.0–7.5	4.9 (1.4)	4.7 (1.5)	0.473^{+}
Years since diagnosis (mean, SD) Range: 1–32 years	11.0 (7.6)	10.2 (8.6)	0.677^{+}
Type of MS (n)			
Relapsing remitting	13	20	0.873^{+}
Primary progressive	8	5	
Secondary progressive	16	12	
Smoker	28 Non-smokers 9 Smokers	33 Non-smokers 4 Smokers	0.131*
Intermittent self-catheterisation routinely used (n)	8	7	0.776*
Parity (n) Range: 0–6	P0 = 5	P0 = 9	0.668*

*Chi Square test; $^{+}$independent samples *t*-test

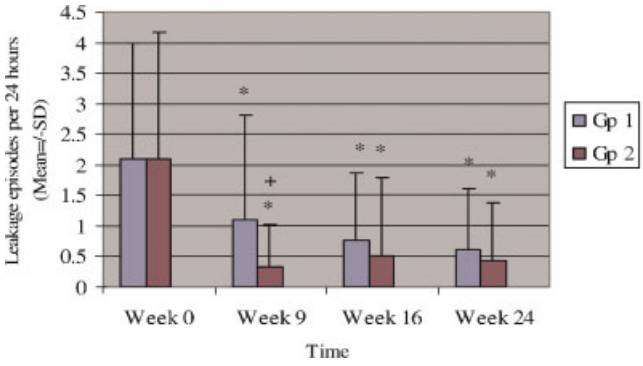

Fig. 2. Primary outcome measure—leakage episodes per 24 hr (mean ± SD). *Statistically significant difference compared to week 0 ($P \leq 0.001$). [+]Statistically significant difference between Group 1 and 2 ($P = 0.028$). [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

The effectiveness of these interventions within this population has not previously been established. Unlike the non-neurogenic population LUTD within a neurological population may be due to dysfunction of the detrusor/sphincter or a combination. The effectiveness of these treatment modalities within such a neurologically impaired population compared to a non-neurological population will depend on the extent of improvement possible in a non-optimally functioning pelvic floor with poor sensation, decreased strength and timing, and/or the effectiveness of neuromodulation in those with partial denervation at spinal or supraspinal level.

Incontinence, as measured by the number of leakage episodes and pad test, was significantly reduced across all time points in both groups, ($P \leq 0.001$). However, Group 2 (active NMES) demonstrated a statistically significant improvement at week 9 in the number of leakage episodes ($P = 0.028$) and in the amount of leakage as determined by the pad test at all time points ($P \leq 0.012$) when compared to Group 1 (placebo NMES). The results from this trial would appear to confirm those previously published in our study[10] which reported that the group who received a combination of

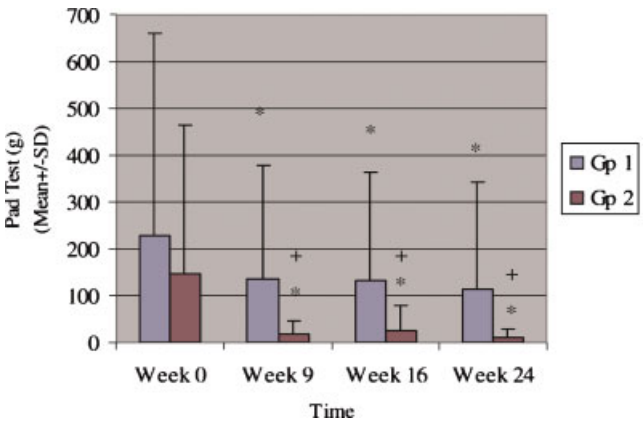

Fig. 3. Secondary outcome measure—pad test (mean ± SD). *Statistically significantly different from Week 0 ($P = 0.001$). [+]Statistically significantly between Group 1 and 2 ($P \leq 0.005$). Group 1: Pelvic Floor Muscle Training, EMG Biofeedback and Placebo Neuromuscular Electrical Stimulation. Group 2: Pelvic Floor Muscle Training, EMG Biofeedback and Active Neuromuscular Electrical Stimulation. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

TABLE III. Uroflowmetry Results

	Maximum flow rate (mean ± SD) ml/sec				Voided volume (mean ± SD) ml				Post-void residual (mean ± SD) ml			
	Week 0	Week 9	Week 16	Week 24	Week 0	Week 9	Week 16	Week 24	Week 0	Week 9	Week 16	Week 24
Group 1	15 ± 9	17 ± 12	17 ± 8.5	18 ± 11	107 ± 65	145 ± 75*	130 ± 57	156 ± 125*	69 ± 76	56 ± 55*	53 ± 36	49 ± 32
Group 2	13 ± 8	20 ± 11*	17 ± 7.6*	17 ± 7*	101 ± 67	192 ± 116**	153 ± 70*	162 ± 78*	74 ± 56	38 ± 18**	35 ± 16*	38 ± 23*

Group 1—pelvic floor muscle training, EMG biofeedback and placebo neuromuscular electrical stimulation.
Group 2—pelvic floor muscle training, EMG biofeedback and active neuromuscular electrical stimulation.
*Significant improvement from week 0 ($P < 0.005$) paired samples *t*-test.
**Significant difference between groups ($P < 0.005$) *post*-hoc tests.

TABLE IV. Frequency of EDSS

EDSS	Frequency
2.00	1
2.50	5
3.00	6
3.50	7
4.00	7
4.50	13
5.00	8
5.50	6
6.00	7
6.50	6
7.00	4
7.50	4
Total	74

PFMT, EMG biofeedback and NMES demonstrated a significant reduction in the number of incontinent episodes ($P \leq 0.014$) and amount of leakage compared to the group which received PFMT only ($P \leq 0.001$).

The results for both groups in the current trial demonstrated that following treatment, endurance of the pelvic floor muscle contraction was statistically significantly increased as measured by digital and EMG biofeedback assessment ($P = 0.001$). Fried et al.[20] also reported a statistically significant association between increased pelvic floor contraction duration and a reduction in incontinence episodes in a neurogenic population. It would appear from both studies that an improvement in pelvic floor muscle endurance improves the symptoms of LUTD in some people with MS, but similar to the non-neurogenic population, there appears to be no correlation between the extent of the improvement and the level of contraction or endurance required to achieve it. The addition of NMES does not however appear to aid improvement in pelvic floor muscle power or endurance over above those receiving PFMT and EMG biofeedback.

There were no serious side effects or adverse incidents encountered as a result of the interventions employed. In addition, compliance and motivation have been shown in several studies to have a strong statistical association with outcome.[20–22] Overall compliance in this trial was excellent and motivation among this disabled population was high. Indeed, although the vaginal or anal application of an electrode can sometimes be viewed as invasive[23] this was not evident in this trial. Only five participants were incapable of using the electrode at home and were treated weekly at clinic, and completed all other protocol demands and assessments. The reasons provided for not being able to use the electrode at home were lack of confidence or, because of physical disability, it was considered very difficult.

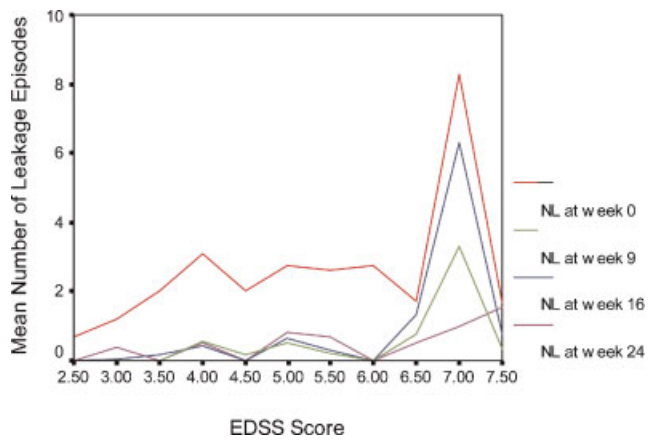

Fig. 4. Number of leaks and EDSS. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

Observed changes in the reduction in the number of incontinent episodes and bladder function, combined with a low incidence of side-effects within this study population, have been translated into patient benefit with a statistically significant improvement in quality of life in both groups at all time points.

The individuals within this study presented with a wide range of disability, EDSS 2.0–7.5, see Table IV and it would appear from the results that improvement in leakage severity could occur across all levels. At baseline there was a correlation between an increase in the severity of leakage (as measured by leakage episodes and pad test) with an increase in EDSS (i.e. more disabled) see Figure 4. This is in keeping with findings reported by Betts et al.[24] that severity of urinary symptoms are related to the extent of pyramidal dysfunction in the lower limbs. After 9 weeks of treatment a decrease in leakage severity across all disability levels was observed which was largely maintained by week 24. However further analysis did not demonstrate any correlation between post-void residual and EDSS, EMG biofeedback and EDSS, or EMG biofeedback and PVR and the only predictor of poor success was a high post-void residual (Pearson's correlation coefficient and analysis of covariance). Two studies however by De Ridder et al.[25,26] did demonstrate a correlation between the relaxation score, that is pelvic floor spasticity (measured at digital examination) and the presence of detrusor sphincter dyssynergia, EDSS and post-void residual to be highly significant and were predictors of poor prognosis with these interventions in people with MS. It was also evident from the results of the visual analogue scale (VAS) on bothersomeness, that at week 0 participants reported most bothersomeness around EDSS level 3.5, which appears to correlate with a known previously reported frustration with bladder symptoms such as urgency and leakage as mobility becomes increasingly difficult;[27] following treatment participants across all disability levels felt less bothered by their symptoms.

Incontinence has been shown to have a high personal cost (e.g. additional laundry), to be one of the main factors in relation to giving up work,[28,29] is a main precursor to institutionalisation, is associated with comorbid conditions such as pressure sores[30–32] and an increase risk in falls as people with urge incontinence hurry to get to the WC.[33,34] Cost analysis demonstrated a possible direct saving of £220.00 over 6 months if there was a 50% reduction in the use of containment and/or medication, but the benefits in terms of improved quality of life cannot be quantified in financial terms.

Findings would suggest that all patients with MS who present with LUTD should be provided with information on the likely causes of the dysfunction and advice on self-help techniques and pelvic floor muscle exercises. Those patients requiring further treatment should then be offered more specialist intervention (i.e. EMG biofeedback and/or NMES).

Further high quality research however is required to assess the overall longer-term benefits and address such issues as the long-term use of NMES if symptoms return. This study also failed to record the level of urgency; a symptom reported by many, and future studies should attempt to monitor this by using, for example, the Urgency Perception Scale.[35]

CONCLUSION

From the results of this trial it can be concluded that a programme of PFMT and advice with EMG biofeedback reduces the symptoms of LUTD and improves quality of life associated with MS. Furthermore, it has been established that the benefits of applying NMES are significantly superior above and beyond that of EMG biofeedback and/or PFMT. These reductions in lower urinary tract symptoms, the lack of side effects and the overall improvement in quality of life make these interventions an attractive treatment option within this population.

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