Neurourology and Urodynamics 15:37–52 (1996)

Efficacy of Biofeedback, When Included With Pelvic Floor Muscle Exercise Treatment, for Genuine Stress Incontinence

L.C.M. Berghmans, C.M.A. Frederiks, R.A. de Bie, E.H.J. Weil, L.W.H. Smeets, E.S.C. van Waalwijk van Doorn, and R.A. Janknegt

Department of Urology, University Hospital Maastricht, Maastricht (L.C.M.B., E.J.H.W., L.W.H.S., E.S.C.v.W.v.D., R.A.J.), and Department of Epidemiology, University of Limburg, Maastricht, The Netherlands (C.M.A.F., R.A.d.B.)

We performed a randomized clinical trial on the efficacy of physical therapy on genuine stress incontinence. Study objective: "Is a physical therapeutical training program (pelvic floor muscle training) combined with biofeedback, more effective than the same program without biofeedback in patients with mild or moderate stress incontinence?"

Forty-four patients were referred by a general practitioner or a urologist. After informed consent, 40 patients were randomized in an exercises and biofeedback group (BF), or treated with exercises exclusively (pelvic floor muscle training = PFMT). After a diagnostic phase of 1 week every patient received twelve treatment sessions, three times weekly.

The primary measure of effect, the quantity of involuntary urine loss, was measured with the 48 hours PAD test (Inco-test Mölnlycke). Before every treatment session the Symptoms questionnaire was filled out by the patient and the Patient diary was controlled.

The data of the trial were analysed according to the principal of intention to treat. During the trial there was 100% compliance. There were no drop-outs. Both treatment modalities appeared to be effective. After twelve treatment sessions there was a mean improvement of ± 55% ($P = 0.00$) in both treatment groups, measured by the primary measure of effect. In the group with BF this improvement was already realized after six treatment sessions ($P = 0.01$). Yet, the difference between BF and PFMT faded to reach significance at six treatment sessions ($P = 0.08$).

Although differences in treatment effects between both groups were not significant, our findings suggest that adding biofeedback to pelvic floor muscle exercises might be more effective than pelvic floor muscle exercises alone after six treatments.

Key words: biofeedback, stress incontinence, physical therapy, physiotherapy, pelvic muscle, exercise

Received for publication June 15, 1995; accepted October 2, 1995.

Address reprint requests to L.C.M. Berghmans, Department of Urology, P.O. Box 616, 6200 MD Maastricht, The Netherlands.

INTRODUCTION

The International Continence Society (ICS) defines urinary incontinence as involuntary urine loss that is a social or hygienic problem and which is objectively demonstrable [Abrams et al., 1988]. The most prevalent form of urinary incontinence among women is stress incontinence (SI) [Lagro-Janssen et al., 1991a; Wall and Davidson, 1992]. Pelvic floor muscle training (PFMT) and pelvic floor muscle training with biofeedback (BF) seem to be promising interventions [Kegel, 1951; Chiarelli and O'Keefe, 1981; Harrison, 1983; Laycock, 1983; Burns et al., 1990]. The PFMT program in this study is a special physical therapeutical program, consisting of information, pelvic floor re-education, homework exercises, and toilet regime [de Bruin, 1990]. Pelvic floor re-education may act in three ways: to increase the reflex action of the pelvic floor muscles through fast-twitch recruitment, to increase the awareness of these muscles, or to increase muscular strength and endurance [Norton, 1994].

Biofeedback is the technique whereby information regarding "hidden" physiological processes is displayed in a form understandable to the patient, to permit self-regulation of these events [Krebs, 1990]. An incontinence patient can be taught, with the aid of biofeedback, to be selective in the use of the pelvic floor muscles. Biofeedback is based on the principle of operant conditioning. Bo et al. [1988] and Bump et al. [1991] have found that approximately 30% of women are unable to perform an isolated pelvic floor contraction following written or verbal instruction. Once pelvic floor muscle contractions can be isolated, the patient gains improved awareness of this muscle action [Knight and Laycock, 1994]. It is hypothesised that in pelvic floor re-education, biofeedback will enhance the effect of the exercise programme and improve motor unit recruitment [Bo, 1994] and functional activity [Knight and Laycock, 1994]. At the beginning of the therapy the support of biofeedback is of vital importance [Burgio et al., 1986].

Excerpts show that much research has been done on the efficacy of physical therapy with and without biofeedback [Berghmans, 1993; Schüssler, 1994]. But only few randomized clinical trials have been conducted to prove the efficacy of exercise combined with biofeedback as opposed to exercise alone [Knight and Laycock, 1994]. Bo [1992] reviewed 5 studies [Shepherd et al., 1983; Castleden et al., 1984; Burgio et al., 1986; Dougherty et al., 1987; Ferguson et al., 1990] which compared the effect of additional biofeedback with pelvic floor muscle exercises to regular exercise. According to Bo, the sample sizes in these studies are small and the reliability and validity of the methods applied to measure outcome can be questioned. Burns et al. [1993] reviewed studies, using various combinations of biofeedback and pelvic muscle exercise, with symptom reduction rates of 78 to 90%, but these studies lacked the rigor of a "phase three" or randomized clinical trial. In 1992 the U.S. government created a special panel of experts on incontinence who recommended guidelines for clinical practice in urinary incontinence. These experts recognized that the literature on management of pelvic floor disorders includes many small studies lacking objective outcome criteria and correct methodology [Schüssler, 1994]. In many reports on clinical efficacy, the studies are uncontrolled and involve small numbers of patients. There are problems defining the most important parameter to be measured. Is it to be maximum strength, duration of contraction, or speed of recruitment?

Standardization of these measurements is another problem. Many studies report only on subjective outcome. What is the best method of teaching pelvic floor re-education? Which patients are most likely to benefit from pelvic floor re-education [Schüssler, 1994]? This article describes the results of a randomized clinical trial, in which the research question is whether PFMT and BF are more effective than PFMT alone in patients with mild or moderate genuine stress incontinence.

MATERIAL AND METHODS

Introduction

With the aid of a single blind, randomized clinical trial tests were performed to check the efficacy of biofeedback as an addition to a pelvic floor muscle training program for women with mild or moderate[1] stress incontinence. The study took place in an extramural practice for physiotherapy in coordination with the Department of Urology of the University Hospital Maastricht (UHM), The Netherlands, and the Department of Epidemiology of The University of Limburg (RL), The Netherlands.

Patient Recruitment

Forty-four patients were referred by a urologist or a general practitioner. The diagnosis genuine stress incontinence by the urologist was based on history taking, cystometry, uroflowmetry, urethral profilometry with determination of urethral closure pressure during rest and stress (cough), pad test with standardized bladder volume, and ambulatory urodynamics. The diagnosis genuine stress incontinence by the general practitioner was based on history taking and physical examination, according to the guidelines applied by Lagro-Janssen et al. [1991b]. All patients received from their doctor a patient information form. Approval to participate in the program was obtained through inclusion and exclusion criteria and history taking. During history taking these criteria were checked by the observer, to insure the homogenity of the research population in relation to the prognosis and the presumed sensitivity for the intervention [Tijssen et al., 1988]. In Table I the inclusion and exclusion criteria are presented. Only patients with mild or moderate levels of stress incontinence were allowed to participate in the experiment because more severe cases of stress incontinence are treated primarily surgically [Maksimovic et al., 1985]. When proven suitable the patient was extensively briefed about the intent and manoeuvre of the trial. After the informed consent form was obtained, the patient entered the trial.

Diagnostic Phase

A diagnostic phase of 1 week preceeded treatment. During the diagnostic phase the patient was required to fill out a symptoms questionnaire three times with an interval of 2 days. The patient also kept a patient's diary. The results of the PAD test (Incotest) classified the patient on the seriousness of the incontinence. These effect measurements formed the baseline values.

[1]*Mild* = grade 1: < 20 g/48 hours; moderate = grade 2:20–100 g/48 hours [Mulder and Vierhout, 1990].

TABLE I. Inclusion and Exclusion Criteria

Inclusion criteria
Sex: Female
Age: 18–70 years
Mild or moderate form of stress incontinence: grade 1 and 2
Able to fill out forms
Willingness to participate
Exclusion criteria
Use of medicine to counteract functional disabilities of the lower urinary tract
Pronounced lesions of the pudendus nerve during clinical neurophysiological examination
Positive sediment of urine culture
Non-compliance in the diagnostic phase
Neurogenic bladder function disability caused by pathology such as spina bifida, spinal cord lesion, etc.
Surgery of urological and/or gynecological nature
Period of 6 weeks after a delivery
Other forms of treatment to cure stress incontinence
Stress incontinence grade 3 or 4
Psychological disorders
Irritable vagina
Pacemaker, hip prosthesis
Not able to speak Dutch

Stratification and Randomisation

Stratification was done by seriousness of incontinence (grade 1 and 2) and by referral (general practitioner or urologist) because of differences in diagnostic possibilities and therefore prognostic incomparability. Next, randomization was done in blocks of four within the strata, using sealed envelopes, containing a note with PFMT or BF. The observer was blinded for allocation of treatment. Physiotherapist and patient were not blinded for the treatment. Forty patients were randomized in a PFMT or a BF group (Table II), after giving informed consent.

Interventions

After the diagnostic phase, each patient received twelve treatments, three times a week. Approximately 25–35 minutes per visit were spent. A choice was made for a frequent and intensive program. Bo et al. [1990a,b] showed that intensive and enthusiastic management strongly influences the progress in the positive direction of patients who participate in pelvic exercises. The physiotherapist gave the treatments in such a way that no difference was noticable in the approach of the two interventions. Each patient received an explanation about the pelvic anatomy, the function of the pelvic floor and the bladder, and the use of pelvic exercises. Every week during the treatment period, vaginal palpation was performed with the patients in the supine position with the legs straight and slightly abducted. The physiotherapist used the "PERFECT" Assessment Scheme [Laycock, 1992] for evaluation of the pelvic floor: power (P), endurance (E), number of repetitions (R), and number of fast (F) contractions; furthermore, every (E) contraction (C) is timed (T). This mnemonic pro-

TABLE II. Stratification Sketch

N = 40	PFMT (N = 20)	BF (N = 20)
Stratum 1 (general practitioner, grade 1)	10	9
Stratum 2 (general practitioner, grade 2)	5	6
Stratum 3 (urologist, grade 1)	1	2
Stratum 4 (urologist, grade 2)	4	3

vided a simple reminder of pelvic floor muscle assessment and also provided data regarding the fast- and slow-twitch muscle fibers, which provided information for the planning of the exercise program [Laycock, 1994]. All patients received an identical homework exercise program and were instructed to practice 3 times every day.

Description of PFMT

The exercise program started with exercises in the supine position, followed by exercises in the side position, standing position, and crawling position. In these positions the duration of contractions of the pelvic floor muscles varied from 3 to 30 seconds. The frequency of contractions varied from 10 to 30 times. All patients began with 4 sets of 10 (5 quick and 5 sustained) and increased by 10 per set until 30 times per set were realized. A more functional training (pelvic floor exercise combined with coughing, climbing stairs, lifting, and jumping) completed the exercise program.

Description of BF

Biofeedback treatment was accomplished through the use of a vaginal probe (Verimed Inc., Coral Springs, FL) attached to a portable electromyograph (Myaction 12 of Uniphy BV, Son, The Netherlands). The EMG activity was sampled 10 times per second. The rectified averaged EMG was displayed as a line graph both on the EMG unit as on a computer screen, for which software was specifically designed (Uniphy BV). A contract/relax session type was used for which the contract/relax period (seconds) and, number of exercise cycles and treatment time (minutes: seconds) varied for the treatments 1–12. The sensitivity (μV) and treshold (μV) were set dependent on the muscle activity of the patient. All patients received visual and acoustical signals and were stimulated to exceed the treshold during contraction. The Myaction 12 scores very well on reproducibility and validity [Smidt and te Giffel, 1994].

Parameters Used

The PAD test objectively measures the quantity of involuntary urine loss. Evaluation has been performed on reliability and applicability [Mulder and Vierhout, 1989, 1990]. This test is also advantageous because urine incontinence is measured by the patient during normal daily activities [Hellström et al., 1986; Victor et al., 1984]. Patients were instructed to wear a standard-weighed pad (25 g) day and night during a 48-hour period and to change pads when required. The pads were weighed by the patients on a standardized balance after use; the weights were noted in a log-book. The patients were instructed to store the pads in airtight plastic bags and hand them in for weight control. The pads are weighed again by the observer within 24 hours. In the present study a good correlation existed between the weights mea-

sured by the patients as well as the observer (Pearson's r = 0.97). The Incotest is measured before the start of therapy, after six treatments and at the end of therapy.

Before each treatment the Symptoms questionnaire is filled out by the patient and the Patient's diary is controlled by the therapist.

The Symptoms questionnaire, a modification of the standardisized PRAFAB-score [Mulder and Vierhout, 1990], is a questionnaire that bundles a number of important objective and subjective elements of the experienced seriousness of involuntary urine loss.

The list consists of five elements:

1. At what level of bladder pressure involuntary loss of urine starts
2. Degree of wet caused by involuntary loss of urine
3. Frequency of involuntary loss of urine
4. Level of limitation of social activities because of incontinence
5. Emotional state related to involuntary loss of urine

The score is expressed at a 10-point interval scale, adding up to a minimum of 5 and a maximum of 50 points. The higher the score, the more serious is the problem.

The Patient's diary logs quantity, frequency and time of drinking, number of times and exact time of involuntary urine loss, activity level by involuntary urine loss, frequency of urinating and pad changes.

The three parameters together reflect a total change of improvement. Therefore a combined measure of effect is created. Every parameter has been assigned an equal weight. The results were expressed in percentages of improvement after six and after twelve treatments.

Data Analysis

Analysis of the research data took place according to the intention to treat principle. The primary measure of effect, the PAD test, and the secondary measures of effect, the Symptoms questionnaire, the Patient's dairy and the combined measure of effect, were measured on percentage changes in parametric Student *t*-tests and paired *t*-tests. The combined measure of effect is analysed by way of linear regression.

RESULTS

Compliance was 100%. There were no drop-outs. The comparison between the research groups was based on the information gathered during the diagnostic phase. Comparing both groups on anamnestical data and baseline characteristics, no significant differences ($P < 0.05$) were found, except for mean quantity of liquid intake ($P = 0.02$) (Table IIIa) and mean drink of the Patient's diary ($P = 0.01$) (Table IIIb).

Figure 1 shows the mean amount of urine loss per stratum. The mean (sd) urine loss in stratum 2 and stratum 4 was, respectively, 32.5 (22.8) and 70.9 g (31.2) per 48 hours. The difference amounted to 38.4 g per 48 hours. Grade 2 patients, who were referred by the urologist, appeared to be in a more serious category than the grade 2 patients referred by the general practitioner.

A treatment effect between patients with grade 1 and grade 2 was measured with

TABLE IIIa. Group Comparison Through Anamnestical Data*

	Pelvic floor muscle training (N = 20) (100%)	Biofeedback (N = 20) (100%)
Mean age (sd)	50,35 (10,50)	46,40 (12,12)
Grades		
Grade 1 N (%)	11 (55%)	11 (55%)
Grade 2 N (%)	9 (45%)	9 (45%)
Referred by		
General practitioner N (%)	15 (75%)	15 (75%)
Urologist N (%)	5 (25%)	5 (25%)
Previous treatment for stress incontinence		
Medication and physical therapy N (%)	0 (0%)	3 (15%)
Physical therapy N (%)	0 (0%)	1 (5%)
Duration since onset of urine loss		
1–12 months N (%)	3 (15%)	3 (15%)
12–24 months N (%)	2 (10%)	2 (10%)
24 months N (%)	15 (75%)	15 (75%)
Urine loss started after		
Delivery N (%)	7 (35%)	5 (25%)
Menopause N (%)	14 (70%)	11 (55%)
Mean number of pads or other recepticles per day (sd)	2,74 (1,92)	1,93 (2,16)
Mean number of wet days per week (sd)	4,85 (2,38)	4,50 (2,42)
Mean number of urination periods per night (sd)	1,6 (1,53)	1,2 (1,16)
Mean number of urination periods in daytime (sd)	7,65 (2,82)	6,15 (3,06)
Mean quantity of liquid intake (ml) (sd)**	2,180 (648)	1,690 (662)
Urine loss while walking N (%)		
Not	9 (45%)	11 (55%)
Seldom	7 (35%)	5 (25%)
Often	4 (20%)	4 (20%)
Urine loss while shifting body position, dancing, sports, climbing stairs N (%)		
Not	5 (25%)	6 (30%)
Seldom	2 (10%)	2 (10%)
Often	13 (65%)	12 (60%)
Urine loss while coughing, sneezing, pushing, lifting, bending over, jumping N (%)		
Not	1 (5%)	1 (5%)
Seldom	0 (0%)	2 (10%)
Often	19 (95%)	17 (85%)
Doing team sports N (%)	9 (45%)	8 (40%)
Incontinence, assessment list		
Daily activities: altered N (%)	12 (60%)	12 (60%)
Social consequences: altered N (%)	11 (55%)	9 (45%)
Self-worth: altered N (%)	11 (55%)	14 (70%)

*No significant differences ($P < 0,05$) between groups on anamnestical data.
**$P = 0,02$.

the PAD test. For grade 1 patients the mean of involuntary urine loss was at the start of the therapy 10.7 g/48 hours, after six treatments 10.2, and after twelve treatments 8.7. For grade 2 patients these numbers were, respectively, 51.7, 22.0, and 20.1 g/48 hours.

TABLE IIIb. Comparison of Baseline Characteristics (T = 0)*

	Pelvic floor muscle training (N = 20)	Biofeedback (N = 20)
PAD test (Incotest)		
Quantity of urine loss during 48 hour in ml mean (sd)	28,98 (31,66)	26,63 (24,47)
Symptom scores		
Number of points (5–50) mean (sd)	23,78 (6,89)	22,12 (4,64)
Patient's diary		
Drink, mean (sd)**	1,916 (677)	1,462 (466)
Daily urination frequency, mean (sd)	7,9 (2,3)	7,2 (2,7)
Number of daily pad changes, mean (sd)	2,6 (1,2)	2,4 (1,8)
Number of involuntary daily urine losses, mean (sd)	3,0 (3,4)	2,0 (2,1)

*(T = 0) = exact time of first treatment; SD = standard deviation; ml = milliliters; α = 0.05. No significant differences between groups on baseline characteristics.
**P = 0,01.

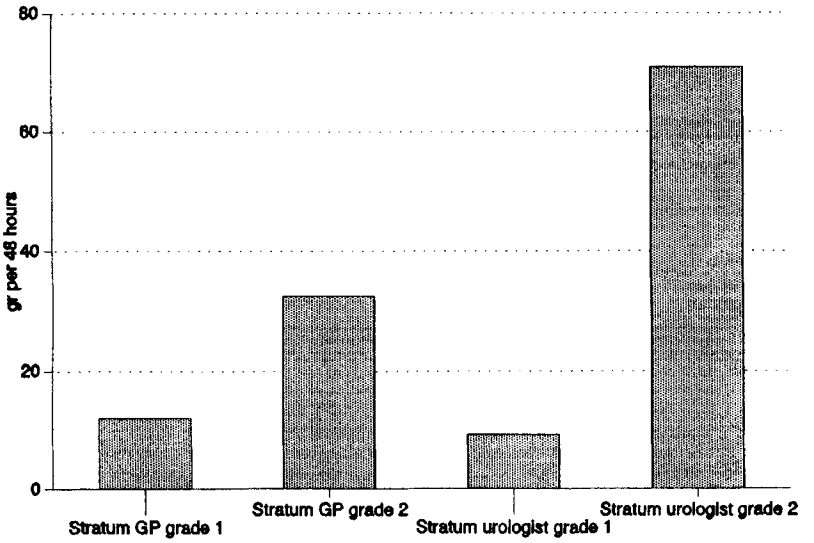

Fig. 1. Mean amount of involuntary urine loss per stratum.

Quantity of Involuntary Urine Loss per 48 Hours

Before the first treatment (Week 0) the mean (sd) quantity of involuntary urine loss in grams per 48 hours was 29.0 (31.7) for the PFMT group and 26.6 (24.5) for the BF group (see Fig. 2).

At the onset of the seventh treatment (start of week 3) the mean (sd) were, respectively, 17,4 (17.6) and 12.4 g (10.0). The difference in improvement between both groups is not significant (P = 0.36). After the last treatment, the mean quantity of involuntary urine loss was 12.5 g (12.0) for the PFMT and 12.2 g (15.4) for the BF. The difference in improvement between the groups is not significant (P = 0.40). The results of the PAD test for both the PFMT and BF showed a significant 55% (P

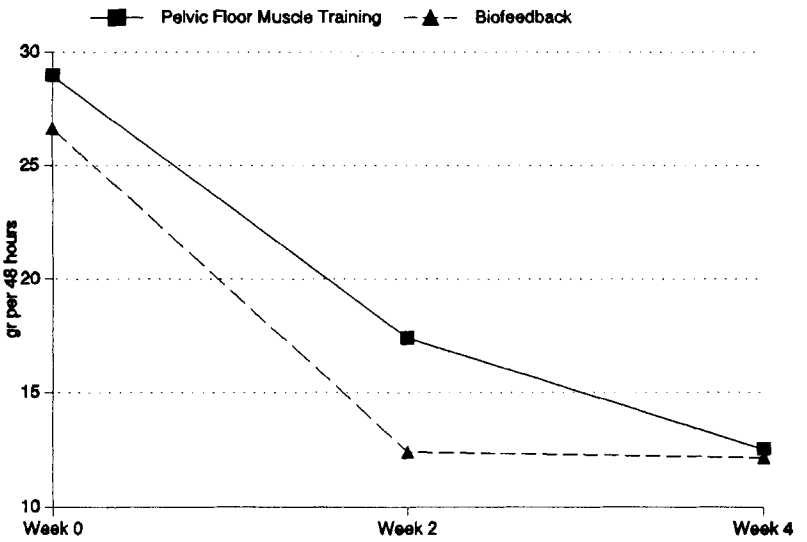

Fig. 2. Mean involuntary urine loss in grams per 48 hours.

= 0.00) improvement after twelve treatments, however for BF alone, the same results already reached significance after six treatments ($P = 0.005$). PFMT showed no significant improvement after six treatments ($P = 0.06$).

After twelve treatment sessions in the PFMT group 3 patients were cured, 14 patients improved, and 3 patients were worse. In the BF group 5 patients were cured, 14 improved, and only 1 patient was worse. After six treatment sessions 16 patients improved, 2 patients were unchanged, and 2 were worse.

Symptoms Questionnaire and Patient's Dairy

Figure 3 shows a weekly overview of the mean (sd) symptoms score for both research groups. The difference in improvement between both groups in W2 and W4 compared to W0 is not significant (W0–W2: $P = 0.48$; WO-W4: $P = 0.45$). On the Symptoms questionnaire the biggest improvement in the BF vs. the PFMT was realized in the first six treatments; this corresponds with the findings of the PAD test.

In the Patient's diary among other things the pattern of the daily occurrence of involuntary urine loss (IU) was noted. In Figure 4 the mean numbers of IU per week are recorded. The difference in decrease between both groups between W0 and W2 and between W0 and W4 is not significant (W0–W2: $P = 0.40$; W0–W4: $P = 0.18$). Analysis in level of activity showed no difference. In Table 4 the mean daily liquid intake is shown. Between W0 and W4, the BF group increased with a mean daily liquid intake of 100 ml, and the PFMT group with 13 ml.

Combined Measure of Effect

The mean (sd) percentage improvement after six treatment sessions is for PFMT 15.1% (55.4) and for BF 34.7% (23.8) (see Fig. 5). After twelve treatment sessions the mean are 51.8% (34.6) for PFMT and 46.2% (26.2) for BF. The difference in improvement between both research groups after six treatments was 19.6% in favor

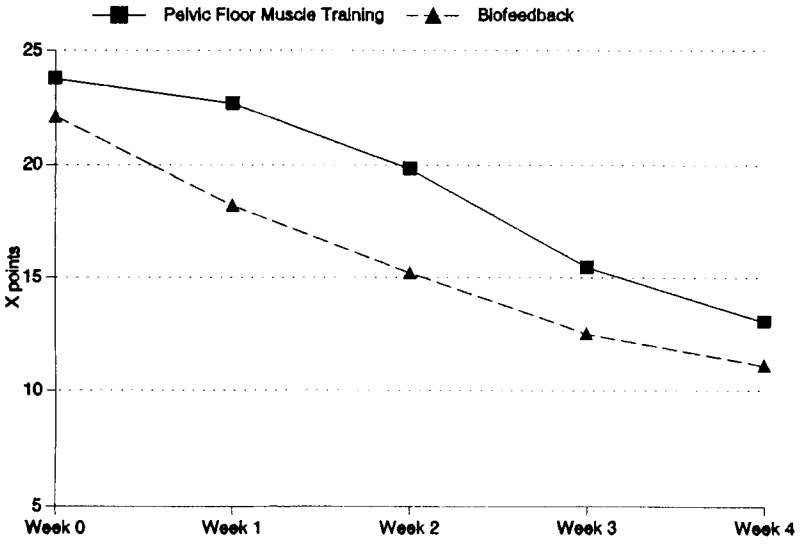

Fig. 3. Mean total score of the symptoms questionnaire per week.

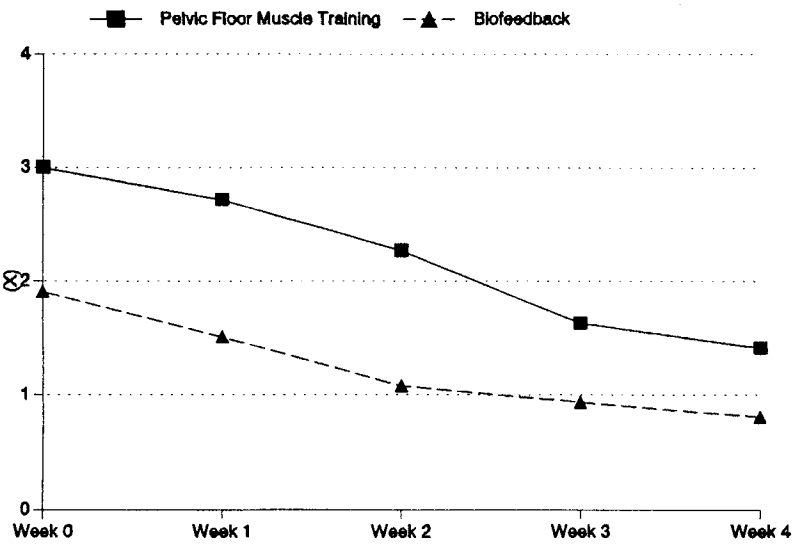

Fig. 4. Mean involuntary urine loss per week.

of BF. The difference is not significant ($P = 0.08$). Table 4 shows that there is a difference in the mean intake of daily liquid between both groups. This difference cannot be based on the difference in body weight. The mean body weight in the BF group is 76.2 kg, in the PFMT group 77.6 kg. After correction for liquid intake and body weight by means of linear regression, a significant improvement for BF compared to PFMT after six treatments was shown ($P = 0.04$). After twelve treatments however, these findings faded to reach significance ($P = 0.43$).

TABLE IV. Mean Daily Liquid Intake (ml)*

	W0	W1	W2	W3	W4
PFMT	1,915	1,804	1,858	1,874	1,928
BF	1,461	1,488	1,563	1,524	1,561

*PFMT = pelvic floor muscle training; BF = biofeedback; ml = milliliters; W0 = diagnostic phase; W1–W4 = treatment week 1–4.

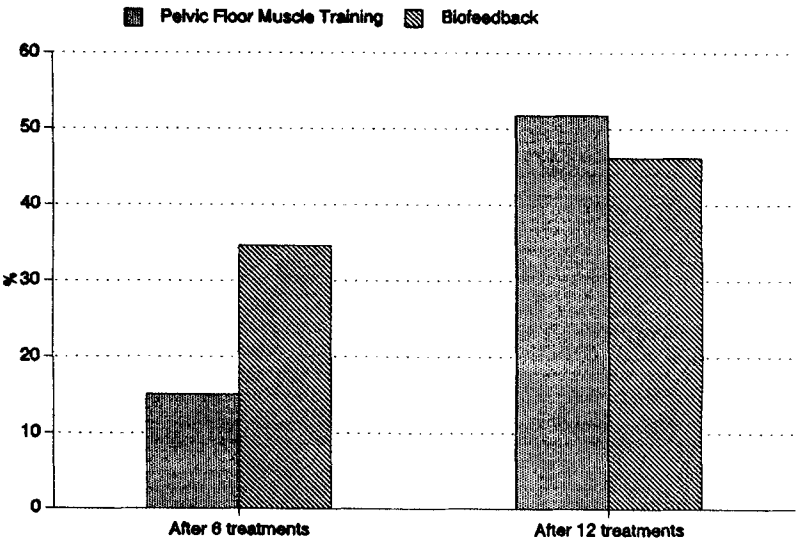

Fig. 5. Mean percentages of improvement measured by the combined measure of effect.

DISCUSSION

Lagro-Janssen [1991] concluded that patients with mild or moderate urinary incontinence, who apply to their general practitioner for help, don't need to be referred to the urologist. Diagnostics and treatment should take place in general practice, before exposing patients to more complicated interventions [Lagro-Janssen, 1991]. In order to conduct a study under circumstances as close as possible to daily practice, patients could directly be referred by a general practitioner to physiotherapy.

Stratification by referral (general practitioner or urologist) was done because of differences in diagnostic possibilities, and therefore prognostic differences. The diagnosis genuine stress incontinence implies urodynamic assessment [Bo, 1992]. However, urodynamic investigations are not readily available to general practitioners and often not effective in the setting of general practice [Lagro-Janssen et al., 1991b]. Lagro-Janssen assessed the diagnostic value of the patient's medical history in distinguishing between genuine stress incontinence, detrusor instability, and mixed incontinence. A total of 103 women with urinary incontinence presented to their general practitioner and underwent a standard history taking, physical examination, and urodynamic testing. The urodynamic diagnoses were analysed against symptoms and symptom complexes. Symptoms of stress incontinence in the absence of symptoms of urge incontinence had a sensitivity of 78%, a specificity of 84%, and a predictive

value of 87%. Symptoms of urge incontinence in the absence of symptoms of stress incontinence excluded genuine stress incontinence. It was concluded that a standard history is valuable in general practice to distinguish between genuine stress and other types of incontinence. Urodynamic evaluation can be restricted to patients whose history reveals symptoms of both stress and urge incontinence [Lagro-Janssen et al., 1991b]. Because the guidelines of Lagro-Janssen were applied in the present study, it is possible that 1 in 5 patients, referred by a general practitioner, was inappropriately diagnosed as having genuine stress incontinence.

The randomization was reasonably successful. The relevant prognostic variables appeared to be equally divided between the groups (Table IIIa and IIIb). The only significant difference between both groups was mean quantity of liquid intake (Table IIIa) and mean drink of the Patient's diary (Table IIIb).

No known research exists on the influence of liquid intake vs. the results of the treatment (decrease of involuntary urine loss). According to Brink [1990], influencing the liquid intake pattern is an important strategy in the decrease and elimination of incontinence, because of the relationship between liquid intake and urination. Because of these reasons it was decided to report the liquid intake pattern and thus possible differences in liquid intake became part of the analysis. However, the biological plausibility and the (causal) link between liquid intake and the measure and frequency of involuntary urine loss need to be further researched and proven.

A possible explanation for the high compliance is the very high motivation among the patients and a very enthusiastic supervision during the treatments [Bo et al., 1990a; Susset et al., 1990; Wall and Davidson, 1992]. Protocol deviation was almost nonexistent. No harmful effects were reported either by patients or by therapists.

Blinding was not possible at all levels. BF was given as a support to exercise therapy. Because of an intravaginal electrode during biofeedback no blinding of patient and therapist was possible. Double blind research is often unrealistic in physiotherapy [Deyo et al., 1990]. However, effect measurements and data analysis were blinded.

This study was based on three effect measurements to measure subjectively and objectively the involuntary urine loss. Pad tests are a relatively crude way to estimate urine loss, they are limited and are problematic in reproducibility and interrater reliability [Kromann-Andersen et al., 1989]. Pad tests without standardized bladder volume are known to be less reproducible than those with standardized bladder volume. As found by Victor et al. [1984] and Jacobsen et al. [1987], a 48-hour test, performed by the patient at home while performing ordinary daily activities, has shown good reproducibility and patient compliance [Kromann-Andersen et al., 1989; Mouritsen et al., 1989]. The Inco-test is tested on reliability and acceptability [Mulder and Vierhout, 1989, 1990]. The coefficient of correlation between patient's and examiner's measurement was 0.98 [Mulder and Vierhout, 1990]. This is in accordance with the findings in the present study. The Inco-test can be easily handled and is suitable for evaluation purposes [Lagro-Janssen, 1991]. However, lack of standardization restricts the use of home pad tests for scientific purposes [Jacobsen et al., 1987]. It is preferable to use standardized, reliable, and valid tests. It is not known whether any pad test for objective urine-loss measurement will ever have these qualities [Kromann-Andersen et al., 1989].

The patient's diary is an important test instrument (Bates et al., 1973). It shows a daily pattern of, among other things, the frequency of the numbers of involuntary urine loss. A disadvantage is that patients might get sloppy during routine reporting. During the diagnostic phase emphasis was put on the exact and accurate record keeping, and during the treatment phase, compliance was checked by the therapist. The results of the PAD test showed that in chronic complaint pattern such as stress incontinence the treatment realized an improvement of ± 55% ($P = 0.001$) in both groups. The BF group realized this big progress after only six treatments ($P = 0.005$). Remarkably, the BF group showed only little improvement between six and twelve treatments. It is possible that the optimal physiological improvement, as a result of the treatment, was already realized in the first 2 weeks.

In the first weeks of training, success of pelvic re-education, with and without the aid of biofeedback, can be explained as due to an increased reflex action of the pelvic floor through fast-twitch recruitment, to an increased awareness of these muscles [Norton, 1994], and to strength development caused by a more effective recruitment of motor units and increased frequency of excitation. Further increase in strength because of hypertrophy is a much slower process [DiNubile, 1991]. The support of the exercise therapy with the aid of biofeedback could increase the coordination in muscle strength and better control of the pelvic muscles vs. exercise therapy by itself [Burns et al., 1990]. Burgio et al. [1986] concluded that biofeedback is of vital importance at the beginning of the therapy.

The American College of Sports Medicine [1990] recommended a duration of treatment of at least 5 months in order to reveal the real potential of pelvic floor muscle strength training. In the present study a short treatment period was chosen in order to reveal the short-term effects of exercises and biofeedback vs. exercises alone after 2 and 4 weeks. Benvenuti et al. [1987] found in a study of 26 women undergoing supervised pelvic floor exercises and behavioral modification, that most of the improvement was seen within 2 weeks of initiating therapy. Examining study patients for improvement after 2 weeks of treatment might demonstrate whether the benefit is simply an increased awareness of the pelvic floor muscles, but most studies do not measure improvement until after a treatment period of 4–6 weeks [Norton, 1994].

Because of the choice for a short treatment period, the real potential of pelvic floor muscle strength could not be revealed in this study. Therefore, no emphasis was put on pelvic muscle strength as a measure of effect.

In five studies BF (vaginal devices demonstrating the results while exercising) was compared to PFMT. In the studies of Burgio et al. [1986] and Shepherd et al. [1983] adding biofeedback improved the results compared to exercises without such systems. In contrast to these studies, Castleden et al. [1984], Dougherty et al. [1987], and Ferguson et al. [1990] could not demonstrate such improved effect. The effect of adding biofeedback is controversional [Bo, 1992]. Extrapolation of the results of the present study to other research is not easy due to the use of other research populations, interventions, equipment, and effect measures.

It is necessary to perform follow-up tests, including measurements of pelvic floor muscle strength, in view of the effects during a longer period of time [Burns et al., 1993; Elia and Bergman, 1993; Bo, 1994]. The long-term effects are currently being researched.

CONCLUSIONS

Pelvic floor muscle training with biofeedback and pelvic floor muscle training alone are effective treatment modalities for involuntary urine loss in patients with mild or moderate stress incontinence. It is clear from the analysis that BF as a support to therapy is most important in the first 2 weeks, during the first six treatments. Although differences in treatment effects between both groups were not significant, our findings suggest that adding biofeedback to pelvic floor muscle exercises might be more effective than pelvic floor muscle exercises alone after six treatments. Research of these results during a longer period of time is momentarily in progress.

ACKNOWLEDGMENTS

We express our sincere gratitude to Loe M.A. van Veggel, M.Sc., and Alfons G.H. Kessels, M.Sc., for their assistance with the production of this article.

REFERENCES

Abrams P, Blaivas JG, Stanton SLR, et al. (1988): Standardization of terminology of lower urinary tract function. Neurourol Urodyn 7:403.

American College of Sports Medicine (ACSM) (1990): The recommended quantity and quality of exercise for developing and maintaining cardiorespiratory and muscular fitness in healthy adults. Med Sci Sports Ex 22:265–274.

Bates CP, Loose H, Stanton SLR (1973): The objective study of incontinence after repair operations. Surg Gynecol Obstet 136:17.

Benvenuti F, Caputo GM, Bandinelli S, Mayer F, Biagini C, Sommavilla A (1987): Re-educative treatment of female genuine stress incontinence. Am J Med 66:155–168.

Berghmans LCM (1993): Stress-incontinentie en fysiotherapie, een literatuurover-zicht (Jaarwerkstuk). Maastricht: Rijksuniversiteit Limburg.

Bo K (1992): Stress urinary incontinence, physical activity and pelvic floor muscle strength training. Scand J Med Sci Sports 2:197–206.

Bo K (1994): Isolated muscle exercises. In Schüssler B, Laycock J, Norton P, Stanton S (eds): "Pelvic Floor Re-Education." London: Springer-Verlag.

Bo K, Larsen S, Oseid S, Kvarstein B, Hagen R, Jorgensen J (1988): Knowledge about the ability to perform correct pelvic muscle exercises in women with urinary stress incontinence. Neurourol Urodyn 7:261–262.

Bo K, Hagen RR, Kvarstein B, et al. (1990a): Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. Validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction. Neurol Urodyn 9:479.

Bo K, Hagen RR, Kvarstein B, et al. (1990b): Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. Effects of two different degrees of pelvic floor muscle exercises. Neurourol Urodyn 9:489.

Brink CA (1990): Absorbent pads, garments, and management strategies. JAGS 38:368–373.

Bump RC, Glenn Hurt W, Fantl JA, Wymann JF (1991): Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction. Am J Obstet Gynecol 165:322–329.

Burgio KL, Robinson JC, Engel BT (1986): The role of biofeedback in Kegel exercise training for stress urinary incontinence. Am J Obstet Gynecol 154:58–64.

Burns PA, Pranikoff K, Nochajski TH, Desotelle P, Harwood MK (1990): Treatment of stress incontinence with pelvic floor exercises and biofeedback. JAGS 38:341–344.

Burns PA, Pranikoff K, Nochajski TH, Hadley EL, Levy KJ, Ory MG (1993): A comparison of effectiveness of biofeedback and pelvic muscle exercise treatment of stress incontinence in older community-dwelling women. J Gerontol Med Sci 48:167–174.

Castleden CM, Duffin HM, Mitchell EP (1984): The effect of physiotherapy on stress incontinence. Age Ageing 13:235–237.

Chiarelli PE, O'Keefe DR (1981): Physiotherapy for the pelvic floor. Aust J Physiother 27:103–108.

de Bruin AJJ, Haage-de Bruin MJJC (1990): Hulpverlening en speciële fysiotherapie. In Bruin AJJ de (ed): "Incontinentie en hulpverlening." Houten/Antwerpen: Bohn Stafleu Van Loghum.

Deyo RA, Walsh NE, Schoenfeld LS, Rama-Murthy S (1990): Can trials of physical therapy be blinded? The example of transcutaneous electrical nerve stimulation for chronic pain. Am J Phys Med Rehabil 6g:1:6–10.

DiNubile NA (1991): Strength training. Clin Sports Med 10:33–62.

Dougherty MC, Abrams RM, Battisch CD, Bishop KR, Gimptty P (1987): Effect of exercise on the circumvaginal muscles (CVM). Neurourol Urodyn 6:189–190.

Elia G, Bergman A (1993): Pelvic muscle exercises: When do they work? Obstet Gynecol 81:283–286.

Ferguson KL, McKey PL, Bishop KR, Kloen P, Verheul JB, Dougherty MC (1990): Stress urinary incontinence: Effect of pelvic muscle exercise. Obstet Gynecol 75:671–675.

Harrison SM (1983): Stress incontinence and the physiotherapist. Physiotherapy 69:144–147.

Hellström AL, Andersson R, Hjälmäs K, Jodal K (1986): Pad tests in children with incontinence. Scand J Urol Nephrol 20:47–50.

Jacobsen H, Vedel P, Andersen JT (1987): Objective assessment of urinary incontinence: An evaluation of three different pad-weighing tests. Neurourol Urodyn 6:325–330.

Kegel AH (1951): Physiologic therapy for urinary stress incontinence. J Am Med Assoc 14:915–917.

Knight SJ, Laycock J (1994): The role of biofeedback in pelvic floor re-education. Physiotherapy 80:145–148.

Krebs DE (1990): Biofeedback in therapeutic exercise. In Basmajian JV, Wolf SL (eds): "Therapeutic Exercise." Baltimore: Williams and Wilkins.

Kromann-Andersen B, Jacobsen H, Anderson JT (1989): Pad weighing tests: A literature survey on test accuracy and reproducibility. Neurol Urodyn 8:237–242.

Lagro-Janssen ALM (1991): Urine-incontinentie bij vrouwen in de huisartspraktijk (dissertatie). Lelystad: Meditekst.

Lagro-Janssen ALM, Debruyne FMJ, Smits AJA, van Weel C (1991a): Controlled trial of pelvic floor exercises in the treatment of urinary stress incontinence in general practice. Br J Gen Pract 41:445–449.

Lagro-Janssen ALM, Debruyne FMJ, van Weel C (1991b): Value of the patient's case history in diagnosing urinary incontinence in general practice. Br J Urol 67:569–572.

Laycock J (1983): Graded exercises for the pelvic floor muscles in the treatment of urinary incontinence. Physiotherapy 73:371–373.

Laycock J (1992): Assessment and treatment of pelvic floor dysfunction. PhD thesis, University of Bradford, West Yorkshire, UK.

Laycock J (1994): Clinical evaluation of the pelvic floor. In Schüssler B, Laycock J, Norton P, Stanton S (eds): "Pelvic Floor Re-Education." London: Springer-Verlag.

Maksimovic P, Schröder FH, Kurth KH (1985): Stress-incontinentie bij de vrouw; resultaten van de operatieve behandeling volgens Stamey Pereyra. NTvG 129:951–954.

Mouritsen L, Berild G, Hertz J (1989): Comparison of different methods for quantification of urinary leakage in incontinent women. Neurourol Urodyn 8:579–587.

Mulder AFP, Vierhout ME (1989): The Incotest: A 48-hour home pad weighing test for objective quantification of urinary incontinence. Papers to be read by title. 19th annual meeting ICS, Ljubljana, Yugoslavia 109–110.

Mulder AFP, Vierhout ME (1990): De Inco-test. Medicus 2:64.

Norton P (1994): Treatment of stress urinary incontinence. In Schüssler B, Laycock J, Norton P, Stanton S (eds): "Pelvic Floor Re-Education." London: Springer-Verlag.

Schüssler B (1994): Schüssler B, Laycock J, Norton P, Stanton S (eds): "Pelvic Floor Re-Education." London: Springer-Verlag.

Shepherd A, Montgomery I, Anderson RS (1983): A pilot study of a pelvic exercise in women with stress urinary incontinence. J Obstet Gynecol 3:201–202.

Smidt N, te Giffel MAB (1994): Valideringsonderzoek Myaction-12. Onderzoek naar de validiteit, reproduceerbaarheid en hanteerbaarheid van de Myaction-12 (Jaarwerkstuk). Maastricht: Rijksuniversiteit Limburg.

Susset JG, Galea G, Read L (1990): Biofeedback therapy for female incontinence due to low urethral resistance. J Urol 143:1205–1208.

Tijssen JPG, Lubsen J, Roelandt JRTC (1988): Grondslagen van interventieonderzoek. NTvG 132:2006–2010.

Victor A, Larsson G, Asbrink AS (1984): A simple patient administered test for objective quantification of the symptom of urinary incontinence. Scand J Urol Nephrol 21:277–279.

Wall LL, Davidson GD (1992): The role of muscular re-education by physical therapy in the treatment of genuine stress urinary incontinence. Obstet Gynecol Surv 47:326–327.