Int Urogynecol J (1996) 7:339–343

International Urogynecology Journal

Original Article

Biofeedback and Physiotherapy Versus Physiotherapy Alone in the Treatment of Genuine Stress Urinary Incontinence

K. Glavind, S. B. Nøhr and S. Walter
Departments of Gynecology and Obstetrics and Urology, Aalborg Sygehus, Aalborg, Denmark

Abstract: Biofeedback is a method of pelvic floor rehabilitation using a surface electrode inserted into the vagina and a catheter in the rectum. Forty women with genuine urinary stress incontinence were randomized to compare the efficacy of physiotherapy and physiotherapy in combination with biofeedback. The effect of the treatment was determined by a standardized pad-weighing test. Long-term status was determined using a questionnaire after 2–3 years. Thirty-four women completed the treatment. The study showed a statistically significant better improvement in the biofeedback group. The long-term effect in the biofeedback group seemed better and the patients were more motivated for training afterwards.

Keywords: Biofeedback; Stress urinary incontinence; Vaginal surface electrode

Introduction

Urinary incontinence severely affects the quality of life for many women. Genuine stress incontinence (GSI) is the most common cause of urinary incontinence, and is associated with congenital weakness of the connective tissue, pregnancy, vaginal delivery, the menopause and exacerbation by previous surgery for stress incontinence.

The role of active exercise for the pelvic floor musculature has been known since 1948, when Kegel described such exercises using a perineometer to determine the strength of the contractions [1]. Pelvic floor exercises are accepted as first-line treatment for GSI: numerous studies have shown the effect of physiotherapy [2–5], but fully satisfactory results have never been achieved, perhaps because many women are not aware of how to contract the pelvic floor muscles or how to avoid a simultaneous rise in intra-abdominal pressure. Biofeedback is a method which teaches this [6]. We present a prospective randomized study comparing the efficacy of physiotherapy alone with physiotherapy in combination with biofeedback. Long-term status was measured after 2–3 years by a questionnaire.

Correspondence and offprint requests to: K. Glavind, Department of Gynecology and Obstetrics, Aalborg Sygehus, 9000 Aalborg, Denmark.

Materials and Methods

Forty women with GSI were entered into the study. All patients had a thorough history taken, stating incontinence when coughing, laughing, lifting and during physical exercise. A gynecological examination with a stress test was performed. The patients were assessed by digital palpation as to their ability to contract the pelvic floor musculature, but we did not distinguish between patients with a weak contraction or those with no contraction at all. Both groups were included in the study. Uroflowmetry and sitting medium-fill water cystometry was performed to exclude infravesical obstruction and detrusor instability. Cystometry was performed with the Dantec Etude (Skovlunde, Denmark), using coughing as the provocative maneuver to elicit detrusor instability. Patients with detrusor instability were excluded from the study. All patients included had normal cystometrograms. Urinary incontinence was verified by a positive 1-hour pad-weighing test (>2 g) with a bladder volume of three-quarters of the cystometric capacity [7]. All patients leaked urine while coughing and jumping. Patients with severe

incontinence were not excluded, but were excluded if previous surgery for urinary incontinence had been performed. All patients who fulfilled the criteria were asked to enter the study.

After giving informed consent the women were randomized using sealed envelopes to receive treatment with physiotherapy alone or in combination with biofeedback. The control group was treated according to our standard procedure, with physiotherapy 2–3 times with individual instruction. The biofeedback group received the same physiotherapy treatment plus biofeedback treatment four times.

Biofeedback was performed with a vaginal surface electrode (Dantec 21L20, Skovlunde, Denmark) inserted in the vagina approximately 3 cm from the introitus (Fig. 1) [8]. A rectal catheter was placed approximately 10 cm into the rectum. The patient was instructed in contraction of the pelvic floor and how to avoid intra-abdominal pressure rises as she continuously observed the recording of the vaginal EMG and the intra-abdominal pressure [6]. Each contraction was sustained for 5–10 seconds, the exercises were performed supine, sitting and standing up, 10 times in each position. Figure 2 shows the vaginal EMG and the rectal pressure in a patient during biofeedback exercise.

Biofeedback was performed weekly, with a total of four lessons per patient. Physiotherapy was performed with 2–3 lessons per patient. The patients received individual tuition, with verbal instruction in the exercises and presentation of anatomical charts of the pelvic floor muscles, and instructed to perform the same exercises at home at least three times a day, and as often as possible.

Study outcome was measured by performing a new standardized pad-weighing test 1 and 3 months after the treatment and comparing the values to baseline values. The patient was considered cured when the pad test showed a result of 0 or 1 g.

After a median $2\frac{1}{2}$ years a questionnaire was sent to each patient concerning the current degree of incontinence and the amount of pelvic floor exercises being presently performed.

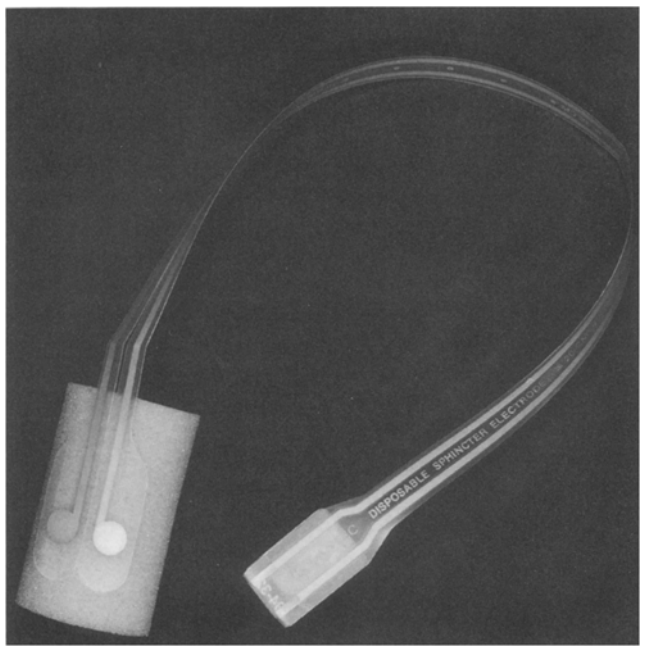

Fig. 1. A vaginal surface electrode (Dantec 21L20).

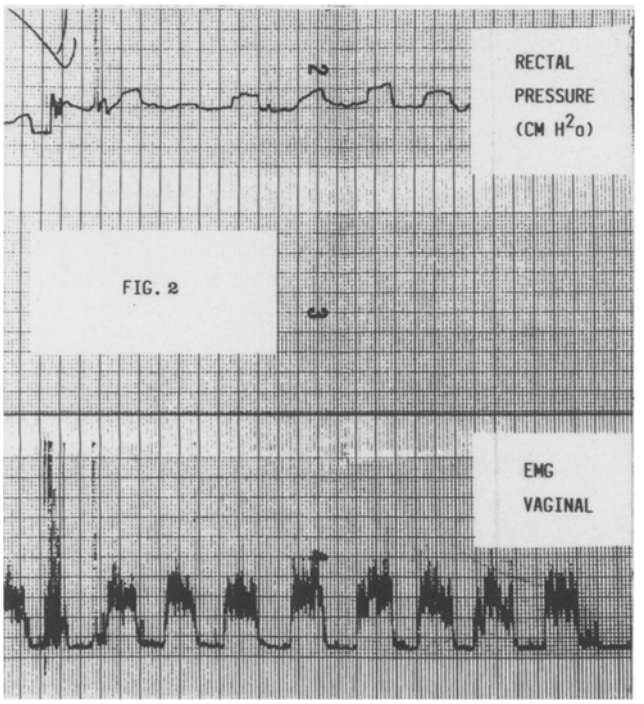

Fig. 2. Vaginal EMG and rectal pressure in a patient during biofeedback exercise.

Statistical Analysis

Descriptive statistics include the median, quantiles and confidence limits of the median. The results of the pad-weighing tests were analysed as an ANOVA with repeated measurements by means of PROC MIXED of SAS [9]. In order to approximate data to a normal distribution a logarithmic transformation with a correction factor of 0.25 ($y = 1n$) (pad-weighing test in g + 0.25 g) was used. Absolute changes in logarithmic transformed data correspond to relative changes in untransformed data. To compare outcome in relation to the ICS classification we used the Mann–Whitney rank sum test, and to compare outcome in terms of cured/not cured we applied Fisher's exact test.

The study was accepted by the local ethical committee.

Results

Forty women entered the study. Six women failed to complete the treatment period, 1 in the biofeedback plus physiotherapy group (biofeedback group) and 5 in

the group with physiotherapy alone (control group). There was no statistical difference in age or degree of incontinence between the patients who dropped out and those who completed the study. Thirty-four patients with a median age of 45 years (range 40–48) (95% confidence limits) completed the study, 19 patients in the biofeedback group and 15 in the control group. There was no statistically significant difference in age or first pad-weighing test between the two groups.

The results of the pre- and post-treatment pad-weighing tests in the two groups are shown in Table 1 and Figure 3.

Comparison of the pad-weighing tests in the biofeedback group and the control group shows a significant difference in the benefit of treatment over time: $P=0.0221$ (analysis of variance with repeated measurements (PROC MIXED)). In the biofeedback group the estimated relative change in the pad-weighing test after 3 months in relation to the baseline level is 88.4% (78%–94%, 95% confidence interval) and in the control group it is 53.9% (2.1%–78%) (Fig. 3).

Tables 2 and 3 shows the severity of the incontinence according to the ICS classification before and after treatment. There is a statistically significant difference

Table 1. Results of pad-weighing test before and after treatment

	Before treatment	After treatment	
		1 month	3 months
+ Biofeedback			
median (g)	9	2.5	0.8
95% confidence interval (g)	(5–22)	(1–10)	(0–4)
− Biofeedback			
median (g)	12.8	19.0	10.0
95% confidence interval (g)	(9–44)	(0–51)	(2–27)

Table 2. Incontinence according to ICS grouping before treatment

ICS group	+ Biofeedback	− Biofeedback
1 (<2 g)	0	0
2 (2–10 g)	10	5
3 (10–50 g)	8	7
4 (>50 g)	1	3
Total	19	15

No statistically significant difference. Mann–Whitney test $P=0.228$

Table 3. Incontinence according to ICS grouping after treatment

ICS group	+ Biofeedback	− Biofeedback
1 (<2 g)	11	3
2 (2–10 g)	5	2
3 (10–50 g)	3	9
4 (>50 g)	0	1
	19	15

Statistically significant difference. Mann–Whitney test $P=0.0064$

Table 4. Treatment outcome in the biofeedback group and the control group

Outcome	+ Biofeedback	− Biofeedback
Cured	11	3
Not cured	8	12
	19	15

Fisher's exact test, $P=0.0576$

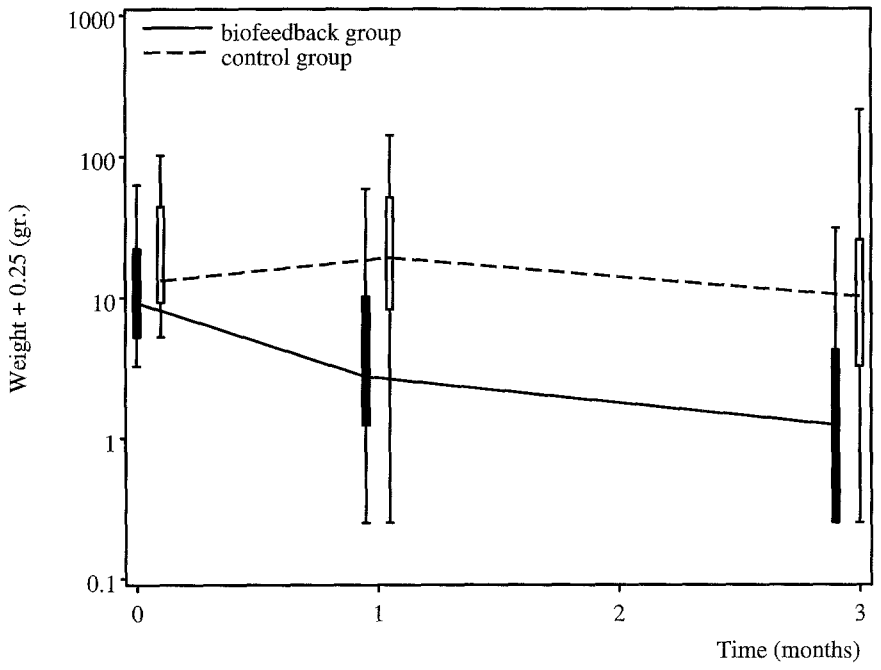

Fig. 3. Results of the pad-weighing tests in the two groups before treatment (time = 0), after 1 month and after 3 months. The lines illustrate the changes in median values. The boxes represent the inter-quartile ranges and the whiskers the total range.

between the groups after treatment at 3 months (Mann–Whitney test, $P=0.0064$). This simple analysis is in accordance with the more detailed analysis mentioned above.

In the biofeedback group 11/19 patients (58%) were cured. In the control group 3/15 patients (20%) were cured (Table 4). Fisher's exact test gives $P=0.0576$.

Thirty-three (97%) of the 34 patients completing the treatment answered the questionnaire. In the biofeedback 5/19 patients (26%) were still subjectively cured, and 8/19 (42%) were subjectively improved. None of the patients in the control group were still subjectively cured, but 4/14 (29%) were subjectively improved compared to before treatment. Almost 75% of the patients in the biofeedback group but only 50% in the control group found that they could accept their present degree of incontinence, if any. When asked about their training activity, more patients in the biofeedback group did pelvic floor exercises regularly: 89% (17/19) compared to 50% (7/14) in the control group.

Discussion and Conclusion

Awareness of the pelvic floor muscles is crucial for obtaining any effect from pelvic floor excercises. Many women are not able to perform Kegel exercises correctly. Bump et al., in 47 women, demonstrated that 25% of patients displayed a Kegel technique that could potentially promote incontinence. Only 49% had an ideal Kegel effort, that is, a significant increase in urethral pressure without a concurrent increase in vesical and abdominal pressure [10]. Bø and co-workers showed that 70% of the women studied had done incorrect exercises before instruction [11].

Several different techniques for obtaining awareness of pelvic floor function have been tried out. Kegel used the perineometer [1], but this has the disadvantage of measuring both intra-abdominal and intravaginal pressure at the same time. Vaginal cones of increasing weight are another method. The feeling of losing the cone initiates a contraction of the pelvic floor musculature [12]. The theoretical background for the use of cones, however, may be questioned as the vagina is not positioned vertically and analysis of the literature has shown a low correlation between the strength of the pelvic floor muscle and the ability to hold the cones [13]. Our method of combining biofeedback with recording of EMG signals from the pelvic floor musculature using a vaginal surface electrode and simultaneous monitoring of the intra-abdominal pressure overcomes both these problems.

Our results showing more improvement in the patients receiving both biofeedback and physiotherapy than with physiotherapy alone compares well to the work by Bø [11] stating the importance of learning how to perform pelvic floor exercises correctly. The patients in the biofeedback group received more instruction (four half-hour sessions) than the patients in the control group, but it could not have been this small amount of extra exercise that made the difference.

By chance, the initial pad-weighing test showed a somewhat greater loss in the control group, although is was not statistically significant. This might have had an influence on the chances of being cured, but not to the extent shown in our study.

It is well known that not all patients benefit from pelvic floor exercises, but too little is known about the characteristics of the patients who are not cured. It seems that the best results are obtained in younger patients with milder grades of incontinence; and in patients who have not undergone surgery [5]. One of the most important factors seems to be motivation [14]. Our study seems to indicate that patients who have received biofeedback treatment are more motivated for training afterwards.

Contrary to surgery, biofeedback treatment has no adverse affects. We propose that before any surgery is performed all patients should have biofeedback treatment.

References

1. Kegel AH. Progressive resistance exercises in the functional restoration of the perineal muscles. *Am J Obtet Gynecol* 1948;56:238–248
2. Henella SM, Kirwan P, Castleden CM, Hutchins CJ, Breeson AJ. The effect of pelvic floor exercises in the treatment of genuine urinary stress incontinence in women at two hospitals. *Br J Obstet Gynaecol* 1988;95:602–606
3. Kujansuu E. The effect of pelvic floor exercises on urethral function in female stress urinary incontinence: a urodynamic study. *Ann Chir Gynaecol* 1983;72:28–32
4. Wilson PD, Alsamararai T, Deakin M, Kolbe E, Brown ADG. An objective assessment of physiotherapy for female genuine stress incontinence. *Br J Obstet Gynecol* 1987;94:575–582
5. Mouritsen L. Pelvic floor exercises for female stress urinary incontinence. *Int Urogynecol J* 1994;5:44–51
6. Glavind K, Nøhr SB, Walter S. Pelvic floor training using biofeedback for muscle awareness in the treatment of stress urinary incontinence: preliminary results. *Int Urogynecol J* 1992;3:288–291
7. Jacobsen H, Vedel P, Andersen JT. Objective assessment of urinary incontinence; an evaluation of three different pad-weighing tests. *Neurourol Urodyn* 1987;6:325–330
8. Lose G, Andersen JT, Kristensen JK. Disposable vaginal surface electrode for urethral sphincter electromyography. *Br J Urol* 1987;59:408–413
9. SAS Technical Report P-229. SAS/STAT Software: Changes and Enhancements, Release 6.07. Chapter 16, The MIXED Procedure Cary, NC: SAS Institute 1992
10. Bump R, Hurt WG, Fantl JA, Wyman JF. Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction. *Am J Obstet Gynecol* 1991;165:322–328
11. Bø K, Larsen S, Oseid S, Kvarstein B, Hagen R, Jorgensen J. Knowledge about the ability to correct pelvic floor muscle exercise in women with urinary stress incontinence. *Neurourol Urodyn* 1988;7:261–262
12. Peattie AB, Plevnik S, Stanton SL. Vaginal cones: a conservative method of treating genuine stress incontinence. *Br J Obstet Gynaecol* 1988;95:1049–1053
13. Bø K. Vaginal weight cones. Theoretical framework, effect on pelvic floor muscle strength and female stress urinary incontinence. *Acta Obstet Gynecol Scand* 1995;74:87–92
14. Sheperd AM, Conservative management. In Drife JO, Hilton P, Stanton SL (eds) Micturition. Springer-Verlag, 1990:209–219

EDITORIAL COMMENT: These authors have enhanced our knowledge of physiotherapy and biofeedback in this well done study. Its design is prospective and randomized, with objective measurements of urine loss using a standardized format at 1 and 3 months. Further subjective follow-up provided the information that those trained with biofeedback were better off and that a greater proportion continued to do Kegel exercises at the mean of 2.5 years later. We need further information regarding how to predict which patients are going to respond to this type of therapy. In the non-responder group a great deal of time and effort is being wasted, owing to the personnel-intensive nature of this type of therapy. Although we are not told of the parity of these patients, presumably many are multiparous, as evidenced by some who could not contract their pelvic floor at all prior to therapy. Are these the non-responders whose pelvic floors were permanently damaged during childbirth? Should all patients have pudendal motor terminal latency studies to rule out pelvic floor neuropathy, as it is unlikely that these patients will respond? These are unanswered questions and this editor would like to encourage investigators to carry this type of study further, to define who is likely to benefit from this therapy.