Controlled trial of pelvic floor exercises in the treatment of urinary stress incontinence in general practice

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SUMMARY. The aim of this study was to assess the usefulness of pelvic floor exercises in the treatment of urinary incontinence in women and to analyse the factors which determine a successful outcome. The study involved 66 women who had reported 'genuine stress incontinence' to their general practitioner. They were assigned at random to the treatment or control group. The treatment group received instructions in pelvic floor exercises from a general practitioner. The control group received no therapy. At the start of the trial the severity of the patients' incontinence was assessed objectively. This assessment was repeated after three months and patients were also asked for their own perception of whether their incontinence had improved. After the three months' evaluation the patients in the control group were also given instructions in pelvic floor exercises. After another three months they were assessed in the same way. About 60% of the patients in the treatment group were dry or mildly incontinent after three months compared with only one patient in the control group; the mean weekly frequency of incontinence episodes fell from 17 to five in the treatment group but remained virtually unchanged in the control group; and about 85% of the women in the treatment group felt that their incontinence had improved or was cured compared with no one in the control group. These results were later corroborated by those for the control group. The most important factor in the success of the treatment was the patients' motivation, as demonstrated by their adherence to the daily exercises. Thus, it may be concluded that the majority of patients with genuine stress incontinence can be treated successfully by carrying out pelvic floor exercises following instruction from their general practitioner.

Introduction

ESTIMATES of the prevalence of urinary incontinence in women range from 15% to 25%.[1-4] The commonest form of incontinence in women is 'genuine stress incontinence'.[4] This occurs when, after a sudden rise in intra-abdominal pressure as a result of physical activities such as coughing, sneezing or lifting, the corresponding rise in bladder pressure temporarily exceeds maximal urethral pressure. The factor which is most commonly found to contribute to such incontinence is a weakness of the pelvic floor muscle resulting from perinatal damage. In 1956, Kegel[5] introduced the idea of treating stress incontinence by pelvic floor exercises. He emphasized that the first step in muscle re-education was to establish awareness of the muscle function. He, and many after him, reported successful results with this treatment.[6-11] Few such studies, however, included control groups and only one study has reported results from general practice.[11]

Owing to the high prevalence of urinary incontinence and its impact on the quality of life of the sufferer, this condition should ideally be treated in the primary care setting rather than require referral for specialist care. It is important, therefore, to have available in general practice a simple, cheap and conservative treatment.

The aim of this study was to evaluate the effectiveness of pelvic floor exercises among general practice patients with genuine stress incontinence and to analyse the factors which contribute to the success or failure of this treatment.

Method

Between 1 July 1987 and 1 January 1990 13 general practitioners in the eastern Netherlands selected women patients aged 20–65 years, presenting with urinary incontinence, for the study. Incontinence was defined as the involuntary loss of urine twice or more per month. Patients were excluded if they had previously undergone an operation for incontinence; if they suffered from underlying neurological causes for incontinence, from diabetes mellitus or from urinary tract infection; or if there was a temporary cause for their incontinence (for example, pregnancy or bed rest). Microscopy, followed in some cases by a urine culture, was performed to rule out the possibility of a urinary tract infection. Those with such an infection were included in the study later if incontinence persisted after therapy.

The general practitioners recorded the following information for all the women whether they agreed to participate or not: sociodemographic data, other diseases, medication and severity and type of incontinence.

All patients selected who agreed to take part in the study were examined by one general practitioner researcher (T L-J). The examination included a standard history and an abdominal and pelvic examination, with special attention to cystoceles and vaginal prolapses. All the patients underwent a complete urodynamic evaluation (including static and dynamic urethral pressure profiles and cystometer and uroflowmeter measurements) and were diagnosed according to the standard criteria of the International Continence Society.[12] Those with 'genuine stress incontinence' were entered into the trial.

The women were interviewed by the general practitioner researcher and an objective assessment of the severity of their incontinence was made using four indices (Appendix 1). Incontinence was divided into three categories — mild, moderate and severe — on the basis of the total scores patients attained. The patients had also recorded the frequency of episodes of incontinence on a seven day chart given to them when they first presented.[13] In order to determine the patients' psychological characteristics patients were asked to complete the following

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Submitted: 25 January 1991; accepted: 24 April 1991.

questionnaires: the health locus of control,[14] which measures the extent to which people perceive responsibility for their own health; a general health questionnaire (VOEG),[15] which measures functional complaints resulting from stress; and a scale for measuring anxiety.[16]

The patients were then assigned consecutively to the treatment or control groups which were stratified on the basis of the severity of their incontinence. Thus, if a patient with mild incontinence was assigned to the treatment group, the next patient with mild incontinence was assigned to the control group, and similarly for cases of moderate and severe incontinence.

At the start of the trial both groups received advice and instructions from a practice assistant about protective aids such as incontinence pads but the control group did not receive any further treatment. The treatment group was given a simple description of the pelvic floor muscle and the aim of the training. The general practitioner researcher taught the patients how to use and contract the correct muscle, achieved by placing two gloved fingers into the vagina and asking the patient to imagine that she was attempting to hold back the flow of urine. If the contraction was performed correctly, the doctor gave the instruction to squeeze the pelvic muscle as tightly as possible for six seconds. Special attention was paid to avoid contracting the abdominal, gluteal or adductor muscles incorrectly. The patients received written instructions for home practice in which they were to perform five to 10 sessions of 10 pelvic muscle contractions each day. They were encouraged to integrate these exercises into their daily activities.

All the patients were interviewed after three months by a research assistant who was unaware of the patients' treatment. In a subjective assessment patients were asked whether, compared with three months before, the problem had been cured, had improved, remained unchanged or deteriorated in three respects: the level of incontinence, the psychological impact of incontinence, and restrictions in activities owing to incontinence. The objective measure of severity and the seven day chart recording frequency of episodes of incontinence were repeated. At the end of the interview the interviewer determined which patients were in the treatment group. These patients were asked how many exercises they performed per day and how well they complied with the exercise programme (excellently, well, reasonably, poorly, not at all).

After the three months' evaluation the patients in the control group were instructed in pelvic floor exercises in the same way as the treatment group. After a further three months the outcome was evaluated using the same protocol. The effects of the intervention in this group were compared with the patient's condition in the period before the intervention, that is each patient acted as her own control.

Statistical tests

A Student's *t*-test was used to compare the effects between the treatment and control groups and a paired Student's *t*-test to compare the effects before and after treatment. Chi square tests were used to test across the groups, while a Pearson correlation analysis was used to determine whether covariates of age, the severity and duration of the incontinence, the presence of cystoceles or vaginal prolapses, psychological features or compliance had influenced the results.

For the purposes of the Pearson correlation analysis the patients were divided into three age categories: 20–34, 35–49 and 50–65 years. Similarly, the duration of incontinence was divided into three categories: less than two years, two to five years and more than five years.

Ethical approval

The study was approved by the medical ethics committee of the University of Nijmegen. The patients were informed about the study design and agreed on the terms of the study.

Results

A total of 146 women presenting to their general practitioner with urinary incontinence were selected for the study. Thirty six women refused to participate — the main reason given for not taking part (23 women) was that they did not consider their incontinence serious enough to warrant further investigation — leaving 110 women (response rate of 75%). There were no differences between participants and non-participants in the study in terms of sociodemographic data or the type of urinary incontinence. However, mild incontinence was more frequent among the non-participants (56%) than among the participants (7%).

Following urodynamic evaluation it was found that 66 of the 110 women had 'genuine stress incontinence'. Following random assignment into the treatment and control groups differences were sought between the two groups for the most important variables using the *t*-test or chi square test as appropriate (Table 1). No significant differences were found.

All the women in both the treatment and the control groups completed the first three months of the trial. None of the women received treatment for incontinence other than that described in the study design. The women in the treatment group judged their compliance with the therapy to be 'excellent' or 'good' in 61% of cases, 'reasonable' or 'poor' in 27%, while in the remaining 12% the exercises were not carried out at all.

The results of the subjective assessment after three months are shown in Table 2. The majority of women in the treatment group reported great improvement with regard to the three

Table 1. Characteristics of treatment and control groups.

	Treatment group (*n* = 33)	Control group (*n* = 33)
Mean age in years (SD)	46.1 (10.1)	44.6 (8.2)
Mean parity (SD)	2.5 (1.3)	2.1 (1.4)
No. (%) with other diseases	18 (*55*)	14 (*42*)
No. (%) using medication	6 (*18*)	10 (*30*)
No. (%) with cystocele or vaginal prolapse	11 (*33*)	12 (*36*)
Mean score (SD) on:		
Anxiety scale	2.0 (0.6)	2.1 (0.4)
VOEG scale	6.4 (4.8)	7.0 (4.1)
Health locus of control (internal)	2.8 (0.7)	3.0 (0.5)
Health locus of control (external)	2.8 (0.9)	3.0 (0.7)
Severity of incontinence[a] (no. (%))		
Mild	4 (*12*)	2 (*6*)
Moderate	17 (*52*)	20 (*61*)
Severe	12 (*36*)	11 (*33*)
Mean number of incontinence episodes (CI)[b]	17.3 (12.5–22.1)	23.1 (18.0–28.4)
Duration of incontinence (no. (%))		
<2 years	7 (*21*)	11 (*33*)
2–5 years	8 (*24*)	11 (*33*)
>5 years	18 (*55*)	11 (*33*)

n = total number of patients in group. SD = standard deviation. CI = confidence interval. [a]Objective assessment. [b]Recorded on seven day chart.

Table 2. Results of the subjective assessment of incontinence for the treatment and control groups after three months, and for the control group at six months.

	% of women (confidence interval)								
	Level of incontinence			Psychological impact			Restrictions in activities		
	Treatment group after 3 mths (*n* = 33)	Control group		Treatment group after 3 mths (*n* = 33)	Control group		Treatment group after 3 mths (*n* = 33)	Control group	
		After 3 mths (*n* = 33)	After 6 mths (*n* = 30)		After 3 mths (*n* = 33)	After 6 mths (*n* = 30)		After 3 mths (*n* = 33)	After 6 mths (*n* = 30)
Improved/cured	*85 (83–97)*	*0*	*90 (79–100)*	*70 (54–86)*	*0*	*73 (57–89)*	*73 (58–88)*	*6 (0–14)*	*70 (54–86)*
Unchanged	*15 (3–27)*	*88 (77–99)*	*10 (0–21)*	*30 (14–46)*	*97 (91–100)*	*27 (11–43)*	*27 (12–42)*	*88 (77–99)*	*30 (14–46)*
Deteriorated	*0*	*12 (1–23)*	*0*	*0*	*3 (0–9)*	*0*	*0*	*6 (0–14)*	*0*

n = number of patients in group.

aspects of incontinence. Although nearly a third of the women in the treatment group reported that there had been no change in psychological impact or in restriction of activities, 30% of women mentioned no such impact or restrictions before the treatment. In terms of the severity of incontinence, 20 patients (61%) in the treatment group were dry or only mildly incontinent after three months compared with only one in the control group (Figure 1). There was a significant difference between the treatment and control groups in terms of the weekly frequency of episodes of incontinence as reported in the charts at three months (Table 3).

After six months three women had dropped out from the control group — one had had a stroke, one had serious personal problems and one did not want to wait any longer for surgery. None of the women received treatment for their incontinence other than that described here. The compliance with the therapy given to the control group in the second three month period was judged by the women to be 'excellent' or 'good' for 53% of the women, 'reasonable' or 'poor' for 43%, while the remaining 13% did not carry out the exercises at all.

The results for the control group after treatment were very similar to those for the treatment group after the first three months. Ninety per cent of the women felt their condition had improved or was cured with respect to the level of incontinence (Table 2); 15 patients (50%) were dry or only mildly incontinent (Figure 1) and the weekly frequency of episodes of incon-

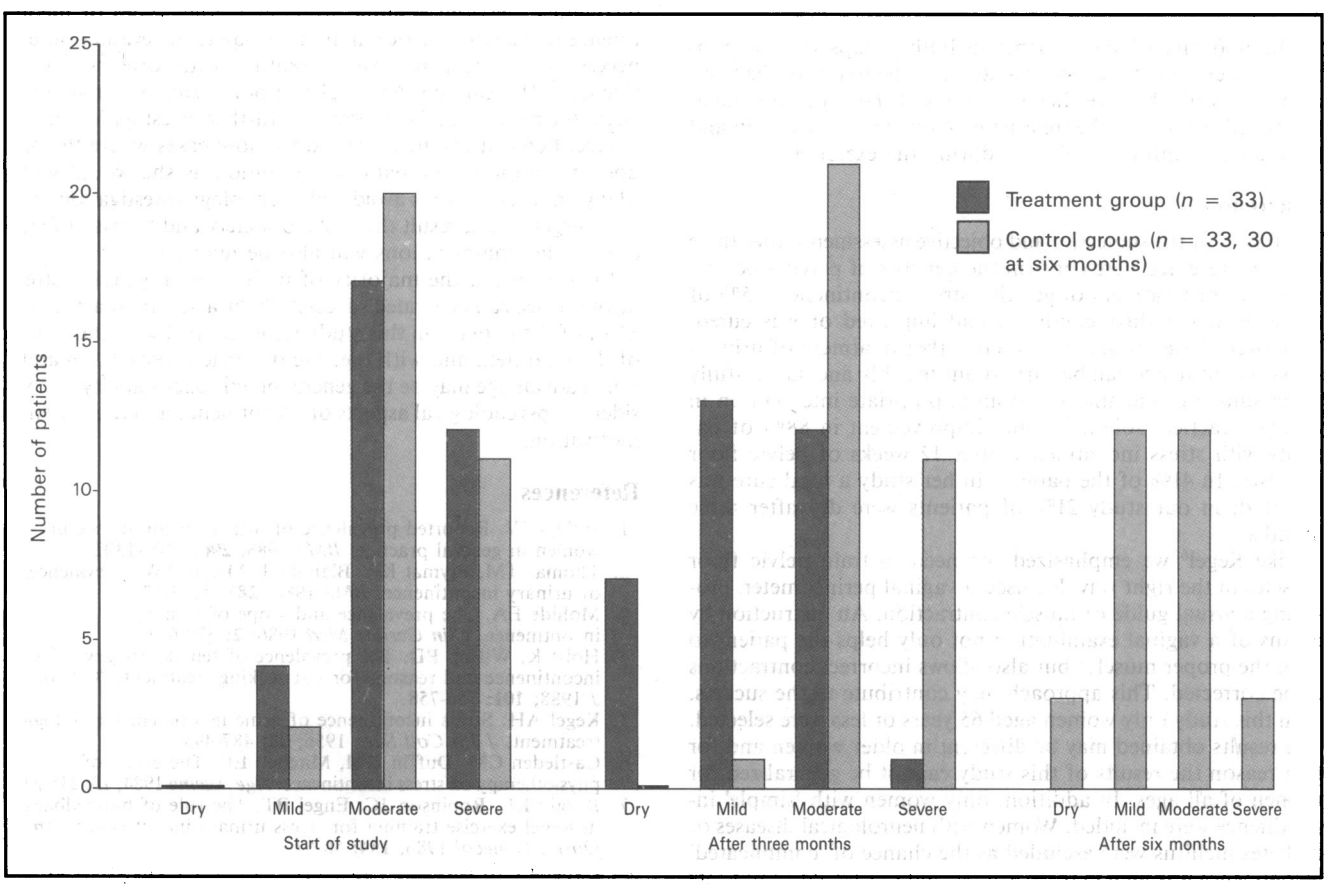

Figure 1. *Severity of incontinence at the start of the trial and at three months for the treatment and control groups, and additionally at six months for the control group (*n *= total number of patients in group).*

Table 3. Weekly frequency of episodes of incontinence for the treatment and control groups.

	Mean no. of episodes of incontinence over seven days (CI)		
	Start of trial	After 3 months	After 6 months
Treatment group ($n=33$)	17.3 (12.5–22.1)	4.8 (2.8–6.8)	–
Control group ($n=33$)[a]	23.1 (18.0–28.4)	25.3[b] (19.9–30.7)	9.7[c] (5.1–14.3)

CI = confidence interval. n = number of patients in group. [a]n = 30 at 6 months. [b]Treatment versus control group at 3 months, $P<0.01$. [c]Control group: 6 months versus 3 months, $P<0.01$.

tinence fell significantly (Table 3).

The outcome of the treatment was not influenced by the patient's parity, age or psychological features, the severity of the incontinence at the start of the study, the duration of incontinence, or the presence of cystoceles or vaginal prolapses. There was, however, a significant relationship between compliance and the objective assessment of the treatment. For both groups combined after treatment an improvement of at least 30% in the number of episodes of incontinence per week after three months of treatment was significantly correlated with carrying out more than 50 exercises each day (Pearson correlation coefficient 0.002) and with the subjective judgement that adherence to the therapy had been 'excellent' or 'good' (Pearson correlation coefficient 0.0004).

The majority of the patients in both groups (80%) spontaneously expressed their satisfaction with the results of the treatment and with the care they had received. Four patients mentioned side effects of the treatment — one mentioned pain and three an uncomfortable feeling during the exercises.

Discussion

The results of the subjective and objective assessments after three months presented here confirm the benefits of pelvic floor exercises in the treatment of genuine stress incontinence; 85% of the women felt their condition had improved or was cured. Moreover, these results make it clear that treatment of urinary stress incontinence can be carried out feasibly and successfully using simple explanations and an appropriate intervention in general practice. Jolleys[11] found improvement in 88% of patients with stress incontinence after 12 weeks of pelvic floor exercises. In 41% of the patients in her study a total cure was reported; in our study 21% of patients were dry after three months.

Like Kegel[6] we emphasized the need to train pelvic floor muscles in the right way. He used a vaginal perineometer, providing a visual guide of muscle contraction. An instruction by means of a vaginal examination not only helps the patient to train the proper muscles but also allows incorrect contractions to be corrected. This approach may contribute to the success.

In this study only women aged 65 years or less were selected. The results obtained may be different in older women and for that reason the results of this study cannot be generalized for women of all ages. In addition, only women with 'simple' incontinence were included. Women with neurological diseases or diabetes mellitus were excluded as the chance of 'complicated' incontinence was high in these women and this would complicate analysis of the results of the study. However, pelvic floor exercises can be recommended in all cases of urodynamically diagnosed genuine stress incontinence regardless of concurrent conditions.

Fifteen per cent of the women in this study failed to respond to the pelvic floor exercises. It is our impression that this may be considered to be patient rather than treatment failure. For nearly one third of the patients the psychological impact of their incontinence and the restrictions in activities which this incontinence imposed remained unchanged after treatment. However, 30% of the women mentioned no such impact or restrictions before the treatment. Quite a few patients found mild incontinence acceptable and the wishes of these individuals should be taken into account when assessing the failure or success of treatment.

The most important prognostic factor in the success of the treatment is the patient's motivation, as expressed by their compliance with the therapy. The more patients carry out the exercises, the more improvement can be expected. The success of the treatment was not influenced by the patient's age, parity, psychological features, nor by the duration or severity of the incontinence, and it is therefore not appropriate to select patients for treatment using these criteria. Clinicians usually recommend pelvic floor exercises only to selected patients and some do not regard such exercises as a real alternative to surgical treatment.[17,18] However, although surgical procedures are usually successful, there is always the risk of complications.[19] This study reveals that there is no barrier to successful pelvic floor exercises in general practice other than low motivation on the part of the patient. A long-term study is needed to assess the duration of the effect, but a prolonged benefit is likely to depend on the patient's continuation of the exercises.

It has been shown that a standard history can be used to distinguish between genuine stress and other types of incontinence in general practice, making urodynamic evaluation unnecessary in most women presenting with urinary incontinence.[20] If treatment with pelvic floor exercises is not sufficient, the patient can be referred for further investigation in due course. Referral can be restricted to those cases where therapy does not improve the patient's condition as she would wish. Many patients can thus avoid high-technology investigations and also surgery. As a result the costs to society and the risk of side effects and complications will also be reduced.

In conclusion, the majority of patients with genuine stress incontinence can be treated successfully by a general practitioner. Most of the patients in this study were satisfied with the results of the treatment and with the care they had received. An additional advantage may be the general practitioner's ability to consider the psychological aspects of incontinence and the patient's motivation.

References

1. Jolleys JV. Reported prevalence of urinary incontinence in women in general practice. *BMJ* 1988; **296:** 1300-1302.
2. Thomas TM, Plymat KR, Blannin J, Meade TW. Prevalence of urinary incontinence. *BMJ* 1980; **281:** 1243-1245.
3. Mohide EA. The prevalence and scope of urinary incontinence. *Clin Geriatr Med* 1986; **2:** 639-655.
4. Holst K, Wilson PD. The prevalence of female urinary incontinence and reasons for not seeking treatment. *N Z Med J* 1988; **101:** 756-758.
5. Kegel AH. Stress incontinence of urine in women: physiologic treatment. *J Int Coll Surg* 1956; **25:** 487-499.
6. Castleden CM, Duffin HM, Mitchell EP. The effect of physiotherapy on stress incontinence. *Age Ageing* 1984; **13:** 235-237.
7. Burgio KL, Robinson JC, Engel BT. The role of biofeedback in Kegel exercise training for stress urinary incontinence. *Am J Obstet Gynecol* 1986; **154:** 58-64.
8. Henalla SM, Kirwan P, Castleden CM, *et al.* The effect of pelvic floor exercises in treatment of genuine urinary stress incontinence in women at two hospitals. *Br J Obstet Gynaecol* 1988. **95:** 602-606.

9. Wilson PD, Al Samarrai T, Deakin M, *et al.* An objective assessment of physiotherapy for female genuine stress incontinence. *Br J Obstet Gynaecol* 1987; **94:** 575-582.
10. Tchou DCH, Adams C, Varner RE, Denton B. Pelvic-floor musculature exercises in treatment of anatomical urinary stress incontinence. *Phys Ther* 1988; **68:** 652-655.
11. Jolleys JV. Diagnosis and management of female urinary incontinence in general practice. *J R Coll Gen Pract* 1989; **39:** 277-279.
12. Massey A, Abrams P. Urodynamics of the female lower urinary tract. *Urol Clin North Am* 1985; **12:** 231-246.
13. Wilson PD, Al Samarrai T, Brown ADG. Quantifying female incontinence with particular reference to the urilos system. *Urol Int* 1980; **35:** 298-302.
14. Wallston KA, Wallston BS. Health locus of control scales. In: Lefcourt HM (ed). *Research with the locus of control construct. Volume 1. Assessment methods.* New York: Academic Press, 1981.
15. Dirken JM. *Arbeid en stress* [*Work and stress*]. Groningen: Wolters, 1969.
16. van der Ploeg HM, Defares PB, Spielberger CD. *Zelfbeoordelingsvragenlijsten. Handleiding, formulieren en sleutels* [*Questionnaires for self-perception. Manual, forms and keys*]. Lisse, The Netherlands: Swets en Zeitlinger, 1980.
17. Cardozo LC, Stanton SL. Genuine stress incontinence and detrusor instability — a review of 200 patients. *Br J Obstet Gynaecol* 1980; **87:** 184-190.
18. Diokno AC, Brown MB, Brock BM, *et al.* Prevalence and outcome of surgery for female incontinence. *Urology* 1989; **33:** 285-290.
19. Klarskov P, Belving D, Bishoff N, *et al.* Pelvic floor exercise versus surgery for female urinary stress incontinence. *Urol Int* 1986; **41:** 129-132.
20. Lagro-Janssen ALM, Debruyne FMJ, van Weel C. Value of the patient's case history in diagnosing urinary incontinence in general practice. *Br J Urol* 1991; **67:** 569-572.

Appendix 1. Severity of incontinence.

	Score
Frequency of urine loss	
Three or four times a month	1
A few times a week	2
Daily	3
Amount of urine loss	
A few drops	1
A little	2
A lot	3
Use of protective pads or garments	
None	1
Only on occasion	2
Most of the time	3
Restrictions in daily activities owing to incontinence	
None	1
Some	2
Many	3
Category of incontinence (total score)	
Mild	4–6
Moderate	7–9
Severe	10–12

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