The conservative management of patients with symptoms of stress incontinence: A randomized, prospective study comparing weighted vaginal cones and interferential therapy

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Sixty-nine female patients with symptoms of stress urinary incontinence were randomized to treatment with either interferential therapy or weighted vaginal cones. Fifty-four patients completed treatment (interferential therapy, 30 patients; weighted vaginal cones, 24 patients). Patients were assessed by subjective response, pad testing, continence charts, and the maximum weight of cone that could be held actively and passively. Forty-seven patients were reassessed at 6 months (19 cones; 28 interferential), five patients (9.26%) required surgery, and two patients (3.7%) could not be reassessed. Subjective response to treatment was good, with 80% to 90% of patients cured or improved after treatment. After 6 months, 41.67% in the cone group and 40% in the interferential group were subjectively cured, with improvement in 50% and 30%, respectively. Of those patients initially referred for treatment, >30% in each group were cured of symptoms. There was an objective improvement in both groups. In the cone group 50% had improved after treatment and >60% had improved at 6 months as assessed by pad testing, while in the interferential group 76% had improved after treatment and 73% had improved at 6 months. There was no significant difference in improvement between the two groups in any of the methods of assessment. However, the cones require less supervision by trained staff and can be used at home by the patient. Their use results in a savings in time for the physiotherapy department. The use of the cones is recommended as a cost-effective method of treatment that can be added to the present therapy options available to the physiotherapist. (Am J Obstet Gynecol 1990;162:87-92.)

Key words: Stress incontinence, interferential therapy, cones

An adequate urethral closure pressure is necessary for the maintenance of urinary continence. One method of improving urethral closure pressure and urinary control is by active exercise of the pelvic floor muscles. As early as 1948, A. H. Kegel[1,2] advocated this approach and reported good results. Since these early reports, different success rates for the treatment of stress urinary incontinence by pelvic floor exercises have appeared in the literature. However, success with this form of treatment often depends on the instructor's enthusiasm and knowledge and on the patient's cooperation and motivation.

Electrostimulation of the pelvic floor as an adjunct to pelvic floor exercises is also widely used by physiotherapists in the management of female urinary incontinence. The feeling of contracting the muscles of the pelvic floor is a useful reminder to the patient of the sensation that should be perceived, and they are encouraged to try to contract the pelvic floor muscles during treatment. The most popular and successful form of such treatment is interferential therapy, where two slightly different, medium-frequency alternating currents interact at the level of the pelvic floor to produce a low-frequency therapeutic current. The results from this treatment are less dependent on patient cooperation and motivation than pelvic floor exercises alone, but the treatment is potentially more time-consuming for the physiotherapist.

Assessing a patient's ability to use the pelvic floor muscles is often difficult. In many centers a digital examination by the attending physiotherapist is used to ascertain whether the correct response has been taught; patients are asked to squeeze the vaginal muscles around the examiner's fingers. Others use a perineometer of a type developed by Kegel, which consists of a vaginal chamber attached to a manometer that measures the rise in pressure in the vagina as a result of perineal muscle contractions to provide a more objective assessment of pelvic floor activity. This has the added advantage of providing visual feedback to patients, to encourage them to improve the strength and

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Table I. Profile of patients in both treatment groups entered into study

Variable	*Cones (n = 24)*	*Interferential (n = 30)*
Age (yr)		
Range	26-57	24-73
Mean ± SD	43.2 ± 8.9	47.9 ± 13.0
Weight (kg)		
Range	48-80	44-98
Mean ± SD	64.7 ± 8.8	67.9 ± 14.1
Within 20% of ideal weight (%)	47	52
Over ideal weight by >20% (%)	53	48
Parity		
Range	0-5	1-8
Mean ± SD	2.2 ± 1.2	3.1 ± 2.0
Previous incontinence surgery	3	6
Severity of incontinence		
<2 ml	9 (37.5%)	9 (30.0%)
2-10 ml	5 (16.7%)	3 (10.0%)
10-50 ml	4 (20.8%)	11 (36.7%)
>50 ml	6 (25.0%)	7 (23.3%)
Duration of symptoms		
0-6 mo	0 (0%)	4 (13.3)
6-12 mo	3 (12.5%)	2 (6.7%)
1-5 yr	11 (45.8%)	15 (50.0%)
>5 yr	10 (41.7%)	8 (26.7%)

selective control of the pelvic floor muscles by pelvic floor exercises.[3]

More recently, Plevnik[4] introduced the concept of weighted vaginal cones as a method of stimulating the pelvic floor. He first showed that women could be trained to contract the pelvic floor muscles to retain cones of increasing weight in the vagina. The feeling of "losing the cone" from the vagina is thought to initiate a powerful sensory biofeedback response, causing the pelvic floor muscles to contract around the cone to retain it. A clinical success rate of 60% to 70% has been reported with the use of the cones.[5]

The aim of the current study was to compare the use of the weighted vaginal cones with interferential therapy in a group of unselected female patients with urinary incontinence referred to an outpatient department of physiotherapy for pelvic floor "re-education." The patients were referred from departments of gynecology and urology on the basis that clinical assessment indicated a predominant sphincter weakness. It was not policy at this stage to perform routine urodynamic assessment but to reserve this for patients with failed empiric treatment or those requiring surgery.

Material and methods

Sixty-nine patients with symptoms of urinary incontinence (predominantly stress incontinence) were entered into the trial and randomly allocated either to interferential therapy (36 patients) or to treatment with the cones (33 patients). Patients who had been treated with pelvic floor physiotherapy within 6 months before referral were excluded, and informed consent was obtained from all those patients entered into the study. The two treatment groups were well matched for age, weight, parity, previous incontinence surgery, and duration of symptoms (see Table I).

All patients were assessed before treatment as follows: (1) All patients were asked to keep a continence-frequency chart starting a week before treatment and continuing throughout the course of therapy. (2) The cones were used to assess pelvic floor strength. Two measurements were obtained during this assessment: (a) passive cone weight, i.e., the weight of the heaviest cone that could be retained in the vagina for 1 minute while ambulatory without voluntary holding; (b) active cone weight, i.e., the weight of the heaviest cone that the patient could voluntarily retain. (3) Pad testing was done by a standard 1-hour pad test (internal report of the International Continence Society, Jan. 5, 1987).[6]

Nine patients were excluded from the trial at this stage because of a failure to tolerate the cones during pretreatment assessment (five in the cone group; four in the interferential group). In seven patients (four in the cone group; three in the interferential group) the vagina was too narrow and the cones "wedged." In one patient (cone group) irregular uterine bleeding prevented their use, and in one patient (interferential group) discomfort was experienced during use because of excessive scar tissue in the vagina.

Patients treated with the weighted vaginal cones attended the physiotherapy department for supervision of treatment once a week for 4 weeks. In each set there are nine cones of equal shape and volume but of increasing weight from 20 to 100 gm (Fig. 1). The patients were asked to try to train the pelvic floor muscles by actively retaining the heaviest cone possible while contracting the pelvic floor muscles. They were instructed to do this twice a day for up to 15 minutes, and when they were successful on two consecutive occasions they moved to the next heaviest cone.

Patients treated with interferential therapy attended the physiotherapy department three times a week for 4 weeks. Treatment was given with the patient in a semirecumbent position with the hips and knees flexed. Four large vacuum electrodes were used, two placed on the abdomen and two placed on the inside of the thighs. An interferential current of between 0 and 100 Hz was used, the intensity depending on the maximum that the patient could comfortably tolerate. Each treatment was given for 15 minutes.

All patients were taught pelvic floor exercises. All assessments were repeated after treatment and at 6 months, each assessment being performed by a single physiotherapist with a special interest in urinary incon-

Table II. Subjective response to treatment in the cone treatment group

	After treatment			*After 6 mo*		
	No.	*Referred (n = 33) (%)*	*Treated (n = 24) (%)*	*No.*	*Referred (n = 33) (%)*	*Treated (n = 24) (%)*
Cured	4	12.12	16.67	10	30.30	41.67
Improved	15	45.45	62.50	7	21.20	29.17
Unchanged	4	12.12	16.67	1	3.03	4.17
Worse	1	3.03	4.16	1	3.03	4.17
Not assessed	9	27.27	—	2 (11*)	33.34	8.34
Surgery	—	—	—	3	9.09	12.50

*Number of patients referred who were not assessed at 6 months.

Table III. Subjective response to treatment in the interferential treatment group

	After treatment			*After 6 mo*		
	No.	*Referred (n = 36) (%)*	*Treated (n = 30) (%)*	*No.*	*Referred (n = 36) (%)*	*Treated (n = 30) (%)*
Cured	4	11.12	13.34	12	33.34	40.00
Improved	23	63.89	76.67	15	41.67	50.00
Unchanged	3	8.34	10.00	0	—	—
Worse	0	—	—	1	2.78	3.34
Not assessed	6	16.67	—	0 (6*)	16.67	0
Surgery	—	—	—	2	5.56	6.67

*Number of patients referred who were not assessed at 6 months.

tinence (N. B.). In addition, all patients were asked for their subjective responses to treatment (cured, improved, no change, or worse).

Nonparametric statistics were applied to the data (Wilcoxon's rank sum test), and, where appropriate, correlation coefficients are quoted with the appropriate level of significance.

Results

Of 60 patients that commenced treatment, 54 completed the course of therapy (24 in the cone group; 30 in the interferential group) and six failed to attend. A further seven patients failed to complete a 6-month follow-up. Five of the patients had not improved significantly with treatment and had stress leakage that was considered severe enough to warrant surgery (three in the cone group; two in the interferential group). In addition, one patient in the cone group developed a psychiatric disorder and was considered unfit for assessment, and another patient in the cone group died of an unrelated cause. Thus 47 patients were actually assessed at 6 months (19 in the cone group; 28 in the interferential group), although for the purpose of this trial all patients were included in the analysis of the percentage improvement between the groups.

The subjective response to treatment is outlined in Tables II and III. After treatment, 79.17% of the cone group (19 patients) and 90% of the interferential group (27 patients) that completed treatment felt that their symptoms had improved. After 6 months, further improvement in symptoms was reported by 41.7% in the cone group (10 patients) and 70% in the interferential group (21 patients), while 33.3% in the cone group (eight patients) and 20.9% in the interferential group (six patients) reported no change (these numbers include those patients who were symptomatically cured or improved and whose improvement was sustained). Overall, 70.83% (17 patients) in the cone group and 90% (27 patients) in the interferential group felt that they had improved. Thus approximately 40% of patients that completed treatment were cured of symptoms in each group at 6 months. However, of the patients initially referred for treatment and randomized for the study (69 patients), 30.30% of patients were subjectively cured in the cone group and 33.34% were similarly cured in the interferential group (see Tables II and III).

The pad test analysis results are similar to the subjective results and are outlined in Table IV. After treatment, 50% (12 patients) in the cone group and 76% (23 patients) in the interferential group showed an improvement on pad testing. At 6 months, of those pa-

Table IV. Pad test results

	Weight of urine lost (gm) (mean ± SD)	
	Cone group	*Interferential group*
Before treatment	27.7 ± 38.8	32.2 ± 49.1
After treatment	14.0 ± 36.7	10.5 ± 17.3
After 6 mo	2.8 ± 8.3	9.7 ± 28.4

Table V. Continence chart results

	Weekly leakage (gm) (mean ± SD)	
	Cone group	*Interferential group*
Before treatment	22.0 ± 31.4	19.3 ± 22.6
After treatment	8.2 ± 14.5	7.7 ± 11.7
After 6 mo	3.9 ± 9.4	5.3 ± 9.2

Table VI. Results of active cone testing

	Weight of cone held (gm) (mean ± SD)	
	Cone group	*Interferential group*
Before treatment	47.1 ± 20.7	40.7 ± 22.9
After treatment	65.0 ± 23.9	56.0 ± 27.1
After 6 mo	53.7 ± 32.7	51.7 ± 27.0

Table VII. Results of passive cone testing

	Weight of cone held (gm) (mean ± SD)	
	Cone group	*Interferential group*
Before treatment	37.5 ± 22.3	30.7 ± 22.1
After treatment	43.7 ± 22.8	44.0 ± 25.8
After 6 mo	36.3 ± 25.0	36.7 ± 25.4

tients completing treatment, 58% (14 patients) in the cone group and 73% (22 patients) in the interferential group had improved since the pretreatment assessment. There was no statistical difference between the two groups in the decrease in urine loss assessed by pad testing after treatment ($0.1 > p > 0.05$) or after 6 months ($0.2 > p > 0.1$). The pad test results correlated well with the continence chart results for both the cone group ($r = 0.4125$, $0.05 > p > 0.02$) and the interferential group ($r = 0.3916$, $0.05 > p > 0.02$).

The continence charts in each treatment group showed a significant improvement after treatment and at 6 months (see Table V). After treatment 83.3% of patients in the cone group and 60% of patients in the interferential group showed an improvement in weekly urinary leakage, and 41.67% of patients in the cone group and 33.34% in the interferential group had no leakage charted after treatment. There was no significant difference in improvement between the two groups ($0.5 > p > 0.2$). In those patients assessed at 6 months there was a further reduction in mean weekly leakage in each group, although the amount was not significant (cone group, $0.2 > p > 0.1$; interferential group, $0.5 > p > 0.2$). Thus 84% of patients in the cone group and 61% in the interferential group had a reduction in urinary leakage. Of those patients completing treatment, 50% of patients in the cone group and 40% in the interferential group had no leakage at 6 months.

There was a significant increase in the weight of cone that could be held passively and actively in the vagina after treatment in each group (Tables VI and VII). There was no significant difference in the overall improvement in weight of cone that could be held in each group on passive ($0.2 > p > 0.1$) and active ($0.5 > p > 0.2$) assessment.

In the patients treated with interferential therapy there was no correlation between the reduction in urine lost on pad testing and the improvement in the weight of cone that could be held in the vagina actively ($r = -0.0195$, $p > 0.5$) or passively ($r = 0.0876$, $p > 0.5$). However, in the cone group there was a significant correlation between the reduction in urine loss and the improvement in weight of cone that could be held passively ($r = 0.4091$, $0.02 < p < 0.05$). The correlation with the weight of cone that could be held actively was not significant ($r = 0.3553$, $0.1 > p > 0.05$).

By the nature of the method of treatment, patients treated with interferential therapy spent more time in the physiotherapy department than patients treated with the cones. In addition, more time was spent with each patient by the physiotherapist in the instruction and supervision of treatment (time spent with each patient, 184.9 ± 13.4 minutes (mean ± SD); range = 177 to 230 minutes). After the initial instruction and assessment, treatment with the cones is on an outpatient basis with patients using the cones at home and following specific guidelines. Thus the amount of time spent by the physiotherapist in treating each patient is significantly reduced (time spent with each patient, 36.3 ± 12.3 minutes (mean ± SD); range = 20 to 60 minutes; $p < 0.001$).

Comment

Pelvic floor physiotherapy plays an important part in the management of cases of stress incontinence. Pelvic floor exercises alone are a safe, simple treatment with

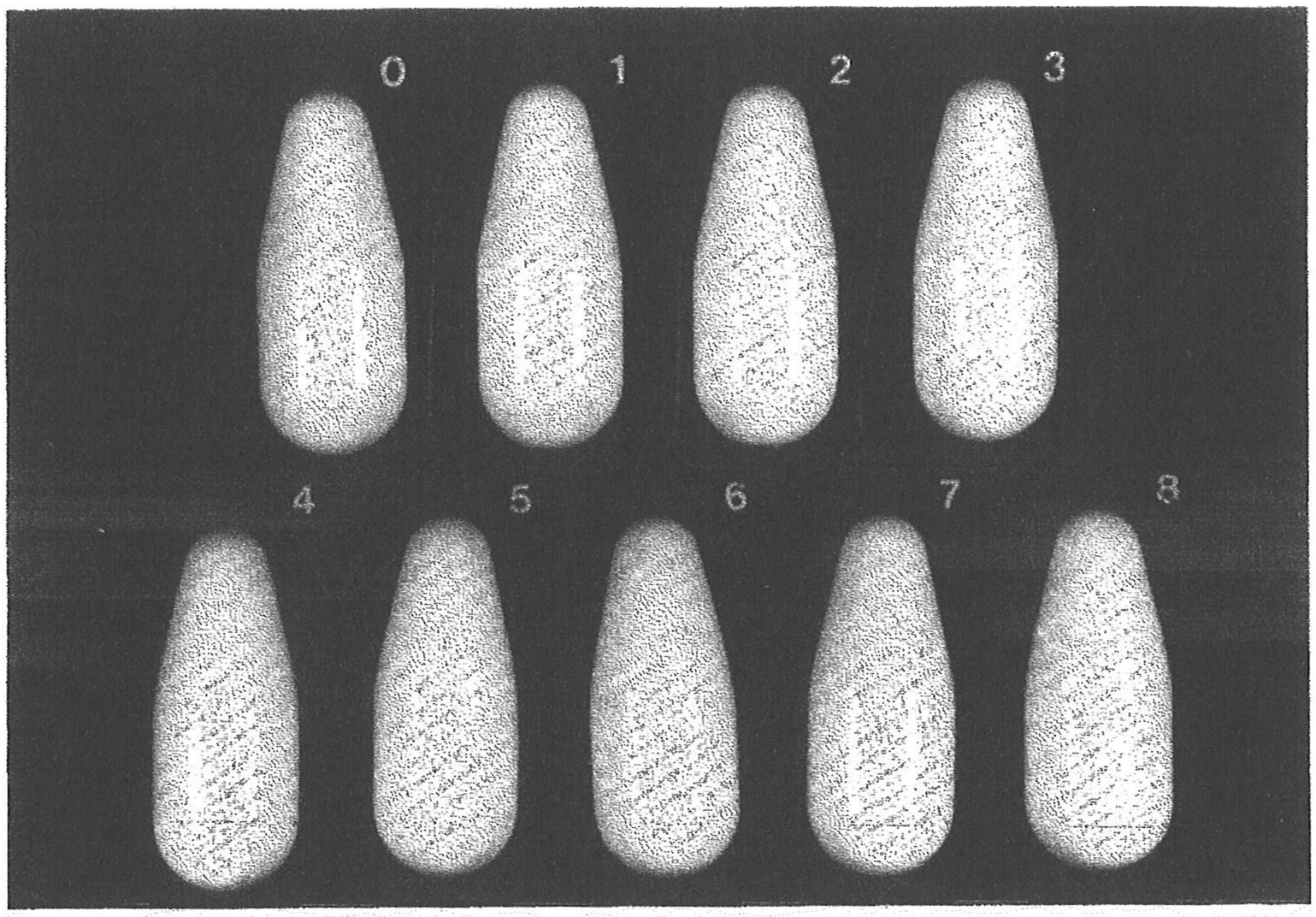

Fig. 1. A set of weighted vaginal cones. Each cone has an attached nylon thread at its apex to facilitate its removal.

a cure rate of around 25%.[7] Kegel first recognized the importance of biofeedback techniques in the "re-education" of the pelvic floor musculature, and it is accepted that the results of treatment can be improved with such assistance.[3,8] Kegel's original biofeedback device, the perineometer, has the disadvantage of measuring intra-abdominal pressure in addition to the pressure rise resulting from pelvic floor contractions. A recently developed biofeedback therapy, weighted vaginal cones, was first described by Plevnik[4] in 1985. Their use is reported to be associated with a 70% cure or improvement and a reduction in the number of patients requiring bladder neck surgery.[5,9]

Interferential therapy used alone has been shown to be an effective treatment in patients with genuine stress incontinence[10] and is a useful adjunct to pelvic floor exercises. A 36% cure rate has been reported with its use.[11]

In this study patients with symptoms of stress incontinence were treated with pelvic floor exercises and either weighted vaginal cones or interferential therapy. The aim of the trial was to compare two methods of treatment in unselected patients referred to the department of physiotherapy, and those patients entering the study were not urodynamically assessed. In general it is desirable that all female patients who are suspected to have incontinence as a secondary result of sphincter weakness be investigated dynamically, but in practice the numbers of patients preclude this and many patients are cured by simple, nonsurgical techniques.

Patient compliance was good, with only six patients failing to complete their treatment (four in the cone group; two in the interferential group). In addition, however, five patients in the cone group and four in the interferential group could not use the cones. Therefore 22% (15 patients) originally randomized to the study did not undergo a full course of treatment (27% in the cone group and 16% in the interferential group). Thus, although 41.67% of patients in the cone group and 40% of patients in the interferential group that completed treatment were cured of symptoms after 6 months, only 30.3% and 33.34%, respectively, of those originally referred for treatment were cured of symptoms. However, the proportion of patients cured is greater than that previously reported for treatment with pelvic floor exercises alone. The results are consistent with those previously reported for interferential therapy[13] and indicate that the use of the cones gives very similar results. This was borne out by objective assessment of the two methods of treatment.

It is interesting to note that the improvement in weight of cone held passively in the cone group correlates with the reduction in urine lost on pad testing while the improvement in the weight of cone held actively does not. A similar result has been reported previously[5] and indicates that the resting pelvic floor

tone may be more important for the maintenance of urinary continence than strength on active contraction. Active and passive pelvic floor strength measured with the cones does not correlate with improvement on pad testing in the interferential treatment group. This may be because those patients treated with the cones have been trained to respond to the presence of the cone in the vagina. In those patients treated with interferential therapy the biofeedback response is not developed, and the sensation of "losing the cone" does not initiate the pelvic floor contraction. Thus, despite an improvement in continence, the assessment of pelvic floor strength with the cones is of little value in the interferential group. In both treatment groups there was an increase in the weight of cone that could be held actively and passively after treatment, with a slight reduction after 6 months. However, improvement in continence in the majority of patients was sustained. This may be a consequence of the use of the cones, and thus their use in pelvic floor assessment is part of a learned response or reflex. The assessments after 6 months were undertaken after no other treatment except continuing pelvic floor exercises, and thus the assessment with the cones bore little relation to the change in continence.

Patients treated with the cones required much less supervision by the physiotherapist and spent much less time at the hospital department than those patients treated by interferential therapy. This represents a saving in time by the physiotherapy department, and treatment is thus very cost-effective. Treatment is effectively performed at home, with initial supervision by a physiotherapist in the hospital department. The treatment, having evolved from the principles of biofeedback techniques such as perineometry, combines the effectiveness of such methods with a practical method of application. The cost of treatment could be reduced further if individual cones could be purchased. This is because the average "operating range" of the cones is 20 to 60 gm.

Although a useful form of treatment, the cones are not suitable for all patients. There was a group of patients ($n = 9$) in whom the cones could not be used either because the cones were too large or too small in relation to the vagina or in one case irregular uterine bleeding precluded their use. In addition, this form of treatment may not be acceptable to all patients, and this may be reflected in those patients who fail to complete treatment. However, the general response to the cones was good, with the majority of patients finding them acceptable.

Pelvic floor physiotherapy is an effective form of treatment for patients with stress incontinence. Its use, properly conducted and supervised, results in a reduction in the number of patients requiring surgery for stress incontinence. For this purpose, the use of the cones is recommended as a cost-effective method of treatment that can be added to the present therapy options available to the physiotherapist.

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