ELSEVIER

European Journal of Obstetrics & Gynecology
and Reproductive Biology 77 (1998) 89–93

OBSTETRICS & GYNECOLOGY

Pelvic floor exercises versus vaginal weight cones in genuine stress incontinence

Hendrik Cammu[a,*], Michelle Van Nylen[b]

[a]*Department of Urogynaecology, A.Z. V.U.B., Laarbeeklaan 101, 1090 Brussels, Belgium*
[b]*Department of Physiotherapy, Academic Hospital, V.U.B., Brussels, Belgium*

Received 6 June 1997; received in revised form 27 August 1997; accepted 6 October 1997

Abstract

Objective: To compare pelvic floor exercises and vaginal weight cones in the treatment of genuine stress incontinence. Study design: Randomised controlled trial. Methods: Sixty ambulatory and fit white women (mean age 56 years) with urinary stress incontinence, treated by a single physiotherapist as outpatients during twelve weeks. Thirty women were allocated to a weekly session of pelvic floor exercises. Thirty were allocated to using cones, they were seen every two weeks. Outcome measures: Objective: stress test, vaginal squeezing capacity. Subjective: urinary diary, visual analogue scales. Results: Characteristics of both study groups were comparable. Unfortunately, there was an early withdrawal of fourteen (47%) women in the group treated with cones, and none in the other group. Therefore the pelvic floor exercise group was compared not only with the group intended to be treated with cones, but also with the selected group that only received cone therapy. No statistically significantly differences in outcome measures were found between the groups: 53% in the group assigned to pelvic floor exercises and 57% into the group assigned to cones, of which 50% in the group actually treated with cones, considered themselves as cured or improved to a significant degree. Long-term follow-up was not possible as all cone users refused continued exercises with cones once the twelve weeks had ended. Conclusion: Pelvic floor exercises and cones are equally effective in the treatment of genuine stress incontinence. Cones are cost and time saving. However, the low patient compliance with the cones importantly limits its clinical applicability, especially in the long run. Therefore, we do not recommend the use of cones. © 1998 Elsevier Science Ireland Ltd.

Keywords: Pelvic floor exercises; Cones; Urinary incontinence

1. Introduction

Genuine stress incontinence is defined as the loss of urine from the urethra synchronous with physical exertion and in the absence of a detrusor contraction [1]. Strengthening the pelvic floor by means of pelvic floor muscle exercise (PFE) is an old [2] and presently well accepted therapy for stress incontinence [3]. However, intense training with a dedicated physiotherapist is mandatory to obtain good results [4,5].

Vaginal weight cones were designed and first used by S. Plevnik in 1985 (published as : New method for testing and strengthening the pelvic floor muscles. Proceedings of the 15th annual meeting of the ICS, London 3–6/9/1985: pp. 267–268). Plevnik used tampon-like weighted vaginal cones for the purpose of having the patient identify pelvic floor muscle contractions and exercise these muscles. This was achieved by using a set of cones of equal volume but increasing weights. Plevnik also wanted to lessen reliance on the physiotherapist: the cones act as a biofeedback for testing and exercising the muscles and allow self-treatment of incontinence in the patient's home [6].

If, by using cones, the number of visits to the physiotherapist can be reduced without altering the therapeutic results, then their use may be considered beneficial. We

*Corresponding author.

PII S0301-2115(97)00237-6

designed a randomised trial in order to verify this assumption.

2. Patients and methods

Sixty-four ambulatory, mentally and physically fit white women with a troublesome and urodynamically proven genuine stress incontinence agreed to follow a pelvic floor exercise program. All women had a vaginal capacity permitting the use of a vaginal probe-EMG biofeedback-or cones. The women included were not in the post-partum period, and had neither a genital prolapse nor any other associated pathology that warranted surgery. Furthermore, these women had no detrusor instability, no outflow obstruction and no intrinsic urethral sphincter deficiency [7]. Women were asked to keep a self-monitoring urinary diary recording the frequency of micturition, the episodes of urinary leakage and the changes of protective garment during one week before treatment and after completion of therapy. Women were also asked to rate their degree of incontinence and psychological distress on a visual analogue symptom scale, before and after therapy. All prior clinical assessment was carried out by the physician (HC).

During the first visit to the physiotherapist, the patient was told about pelvic anatomy, the purpose of pelvic floor re-education and the possible use of vaginal cones. The women were then asked to take part in our randomised trial. Four refused and were excluded from the study. A list of random numbers was generated using a computer. A numbered opaque sealed envelope containing the method-indicator card was opened by the secretary of the department. Women were randomly allocated to either pelvic floor exercises (PFE) or to vaginal cones.

Women in the PFE group received a weekly, thirty minutes duration private session during twelve weeks.

First, vaginal palpation was performed to elicit awareness of position of levator ani muscles. Then, a vaginal perineometer,- a vaginal probe with surface electromyography electrodes which generates a reading of muscular squeezing in microvolts as a lighted scale on a screen- was used. A surface electrode was placed on the anterior abdominal wall to help detect counterproductive Valsalva-type efforts. Fast and slow twitch fibers [8] were trained by alternating fast and firm with long-sustained and slow contractions: one series consisted of ten brief, forceful contractions followed by ten slow maximal contractions lasting ten seconds each.

We considered the squeezing capacity as the mean (in μV) of ten consecutive contractions. The patients were also instructed to voluntary contract the pelvic floor prior to a sudden intra-abdominal pressure rise. The private physiotherapy sessions aimed at gradually increasing the number of series according to the patient's capacity. Home exercises consisted of trying to increase the number of series. No vaginal device was used at home.

Women using cones were seen every two weeks during twelve weeks. The first visit was on the whole similar to that in the other group: it aimed at making the patient aware of the pelvic floor muscles and measuring the squeezing capacity (μV). Then, the women were instructed as to the use of the cones. A set of five cones of identical shape but of increasing weight (20, 32, 45, 57 and 70 g) was used (®Femina). Starting with the lightest weight, the women were taught to place the cone into the vagina whilst standing. The heaviest weight that could be retained in place for one minute without voluntarily contracting the pelvic floor was called the passive cone. Then, the patient would use the heavier weight that required a voluntary contraction of the pelvic floor to prevent the cone from slipping out of the vagina. The heaviest weight that could be retained with a muscular contraction was the active cone. Women were instructed to exercise fifteen minutes, twice daily (except during menstruation). These home exercises were aimed at trying to increase the passive and the active cone weight. The physiotherapy sessions served mainly to assess whether the cones were correctly used. No biofeedback perineometer was used.

After twelve weeks, or earlier for those women who wanted to end therapy before the twelve weeks were completed, the squeezing capacity (μV) in both study groups was again determined and the woman was seen by the physician for final assessment (see above).

The comparison of the continuous variables in the study group was carried out using the Mann–Whitney *U* test. Pearson and Mantel–Haenszel chi-square tests were used to evaluate the association between discrete variables. The level of statistical significance was set at $P=0.05$.

3. Results

Women in both groups were comparable (Table 1). However, at the first control visit in the group using cones, fourteen women withdrew. Alleged reasons mentioned for not using cones were: unpleasant feeling (five×), time consuming (three×), inability to introduce the cone when too nervous or when in a hurry (two×), interference with the menstrual cycle (two×), a certain cone held in the morning could not be held any longer in the evening (muscle fatigue) (two×).

The body mass index was the only objective patient characteristic that significantly determined the non-compliance with the cone therapy (logistic regression, $P=0.0228$; odds ratio 1.54 (1.06–2.22). Menopause, oestrogen status, age, parity, duration of symptoms, degree of incontinence, severity of symptoms and vaginal squeezing capacity were of no importance in the non-compliance with the cones.

Thus, nearly half the number of women assigned to cones interrupted this kind of therapy. These withdrawals

Table 1
Patients' characteristics at randomisation

Variable: mean±SD	A *N*=30	B *N*=30	C *N*=16
Age (year)	55.9 (9.5)	56.3 (11.4)	56.4 (9.2)
Parity (*N*)	2.2 (1)	2.2 (1.2)	2.0 (1)
Duration symptoms (year)	6.7 (7.2)	5.3 (5.2)	5 (5.9)
BMI	27.3 (4.3)	26.4 (2.3)	25.8 (2.2)
MUP (cm H_2O)	78 (30)	77 (26)	76 (31)
Urinary frequency/week	53 (18)	53 (15)	51 (15)
N leakages/week	14.4 (10)	13.6 (12)	13.9 (18)
N pads/week	13.4 (8)	15.8 (14)	15.1 (16)
Squeezing capacity-fast (μV)	7.2 (4.4)	6.1 (3.5)	7.8 (4.3)
Squeezing capacity-slow (μV)	7.1 (4.1)	6.4 (3.6)	8.2 (4.5)
Visual analogue scale (0–10)			
Severity of incontinence	4.7 (1.7)	5.2 (1.7)	4.0 (1.7)
Psychological distress of incontinence	5.4 (2.4)	6 (2.1)	5.3 (2.5)

A=women treated with pelvic floor exercises; B=women intended to treat with cones; C=women really treated with cones; N=number; BMI: weight/height^2=kg/m^2; MUP: maximal urethral pressure.
A versus B and A versus C are not statistically significantly different.

received PFE but stayed in the cone group. Therefore we compared the entire cone group ''intention to treat'' as well as the selected group of women that actually received cone therapy with the group that received PFE (Table 1). Pelvic floor exercises and cone therapy are equally successful in treating urinary stress incontinence (Table 2). The women who used cones showed a 39% improvement in the passive (from a mean of 36 g to 50 g) and a 29% improvement in the active cone weight (from a mean of 48 g to 62 g).

Sixteen women (53%) in the PFE group and seventeen (57%) women in the group assigned to cones of which eight (50%) in the group were actually treated with cones, considered themselves as cured or improved to a significant degree. Five women (17%) in the PFE group and nine (30%) in the group allocated to cones of which four (25%) in the group actually treated with cones underwent anti-incontinence surgery post-physiotherapy. Long-term results were not available as none of the patients wanted to use the cones after the completion of the study period of twelve weeks.

Reasons for this were similar to those mentioned before: the unpleasant feeling (four×), time-consuming (four×), muscle fatigue (three×). Five women were actually positive about the use of cones but none of them bought a set of cones for continuous long-term home practice.

Table 2
Patients' changes after twelve weeks therapy

Variable: mean±SD	A *N*=30	B *N*=30	C *N* =16	Significance A vs B	Significance A vs C
N leakages/week	5.6 (5.5)	8.7 (13)	8.3 (15)	*P*=0.23	*P*=0.42
Improvement (%)	61	36	40	*P*=0.13	*P*=0.37
N pads/week	6 (5.6)	8.8 (13)	8.6 (15)	*P*=0.29	*P*=0.44
Improvement (%)	55	44	43	*P*=0.95	*P*=0.88
squeezing capacity-fast (μV)	10.7 (5.9)	9 (4.1)	10.3 (4.1)	*P*=0.22	*P*=0.83
Improvement (%)	49	48	32	*P*=0.63	*P*=0.33
squeezing capacity-slow (μV)	11.4 (6.2)	9.7 (5.4)	10.9 (4.6)	*P*=0.29	*P*=0.81
Improvement (%)	61	52	33	*P*=0.62	*P*=0.19
Visual analogue scale (0–10)					
Severity of incontinence	2.6 (2.1)	2.9 (2.4)	2.3 (2)	*P*=0.57	*P*=0.69
Improvement (%)	45	44	42	*P*=0.33	*P*=0.44
Psychological distress	2.1 (2.1)	3.4 (3.3)	2.6 (2.8)	*P*=0.18	*P*=0.43
Improvement (%)	61	43	57	*P*=0.16	*P*=0.41
N of women with a negative stress test (%)	12 (40)	12 (40)	7 (44)	*P*=1.00	*P*=0.69

A=women treated with pelvic floor exercises; B=women intended to treat with cones; C=women treated with cones.
N=number.

4. Discussion

PFE and the use of cones give a forty to sixty percent decrease in the frequency of urinary leakage and pad-changes. This is comparable with our earlier findings in a cohort group of stress incontinent women treated with physiotherapy [9].

When women are properly instructed and regularly followed, PFE and cones are of a comparable efficacy. This corroborates the finding of a randomised trial published in abstract form where PFE and cones alone were compared (published as : Haken J, Benness C, Cardozo L, Cutner A. A randomised trial of vaginal cones and pelvic floor exercises in management of genuine stress incontinence. Neurourol Urodyn 1991; 10: 393–4 Abstract). Other studies also report a significant improvement in incontinence when cones are applied [10–12]. PFE combined with cones showed a comparable improvement as PFE combined with interferential therapy [13]. However, Pieber et al. [14] found no additional benefit of vaginal cones in women with mild to moderate stress urinary incontinence treated with PFE. Kondo et al. [15] reported a low success rate with cones alone as only seven out of fifty women were cured or had a reduction of $>50\%$ of the original severity. Patients in this latter study [15] were treated in groups of ten and no mention is made of digital muscular control. Both these features were found to adversely affect outcome [4,5].

Women in the group treated with cones were seen less frequently. We concur with other authors [6,10–13] that this is time and cost saving. However, the low patient compliance rate is a very important drawback: only five women (17%) of the group allocated to treatment with cones were positive but none to the extent of using cones for a long period. Obese women especially were prone to refuse cone therapy. Most of the patients who continued the training with cones did so because of the prior commitment to take part in the study.

Tolerance with cone therapy may be overestimated: Peattie et al. [11] had an initial drop out rate of 23% in 39 pre-menopausal women but cones were used for only one month and merely to elicit pelvic floor muscle awareness.

However, none of the patients disliked the technique. Wilson and Borland [12] showed that once women had learned to identify pelvic floor contractility with cones, the majority continued with PFE alone essentially on the grounds of convenience. Olah et al. [13] found an initial drop out rate of 27% that further increased to 42% after six months. Kondo et al. [15] had an initial drop out rate of only 12% but three years later none of their patients was still using cones while 36% had taken part in some form of pelvic rehabilitation. We therefore think that cones have only a role to play for a short term.

Cones increase the pelvic floor muscle strength: cone weight and vaginal squeezing capacity increase. This increase may be the result of a better muscular co-ordination-a learning effect-rather than that of muscular hypertrophy [16]. However, Deindl et al. [17] found that the repetitive intermittent pelvic floor contraction, generated to prevent the cone from slipping down the vagina, strengthened the pelvic floor.

To conclude, we have insufficient ground to reject the null-hypothesis that PFE and cones are equally effective in the treatment of genuine stress incontinence. Unfortunately, the low patient compliance with the cones limits its clinical applicability and therefore cones have only a very limited place in the treatment armamentarium.

Acknowledgements

We are grateful to J.J. Amy for his critical review of the manuscript and to P. Meyvisch for his statistical advice.

References

[1] Abrams P, Blaivas JG, Stanton SL, Andersen JT. The standardisation of terminology of lower urinary tract function recommended by the International Continence Society. Int Urogynecol J 1990;1:45–58.
[2] Kegel AH. Progressive resistance exercise in the functional restoration of the pelvic muscles. Am J Obstet Gynecol 1948;56:238–48.
[3] Wall LL, Davidson TG. The role of muscular re-education by physical therapy in the treatment of genuine stress urinary incontinence. Obstet Gynecol Surv 1992;47:322–31.
[4] Bø K, Hagen RH, Kvarstein B, Jorgensen J, Larsen S. Pelvic floor muscle exercise for the treatment of female stress incontinence: III. Effects of two different degrees of pelvic floor muscle exercises. Neurourol Urodyn 1990;9:489–502.
[5] Bump RC, Hurt WG, Fantl A, Wyman JF. Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction. Am J Obstet Gynecol 1991;165:322–9.
[6] Plevnik S. Vaginal cones. In: Schüssler B, Laycock J, Norton P, Stanton S, editors. Pelvic floor re-education. Springer-Verlag, 1994:139–42.
[7] McGuire EJ, Lytton B, Pepe V, Kohorn EI. Stress urinary incontinence. Obstet Gynecol 1976;47:255–64.
[8] Gosling JA, Dixon JS, Critchley HOD, Thompson SA. A comparative study of the human external sphincter and periurethral levator ani muscles. Br J Urol 1981;53:35–41.
[9] Cammu H, Van Nylen M, Derde MP, De Bruyne R, Amy JJ. Pelvic physiotherapy in genuine stress incontinence. Urology 1991;38:332–7.
[10] 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.
[11] Peattie AB, Plevnik S, Stanton SL. Vaginal cones: a conservative method of treating genuine stress incontinence. Br J Obstet Gynaecol 1988;95:1049–53.
[12] Wilson PD, Borland M. Vaginal cones for the treatment of genuine stress incontinence. Aust NZ J Obstet Gynaecol 1990;30:157–60.
[13] Olah KS, Bridges N, Denning J, Farrar DJ. The conservative management of patients with symptoms of stress incontinence: a randomized, prospective study comparing weighted vaginal cones and interferential therapy. Am J Obstet Gynecol 1990;162:87–92.
[14] Pieber D, Zivkovic F, Tamussino K, Ralph G, Lippitt G, Fauland B. Pelvic floor exercises alone or with vaginal cones for the treatment

of mild to moderate stress urinary incontinence in pre menopausal women. Int Urogynecol J 1995;6:14–7.
[15] Kondo A, Yamada Y, Niijima R. Treatment of stress incontinence by vaginal cones: short- and long-term results and predictive parameters. Br J Urol 1995;76:464–6.
[16] Wrigley T. The effect of training with vaginal weighted cones and pelvic floor exercises on the strength of the pelvic floor muscles: a pilot study. Int Urogynecol J 1995;6:4–9.
[17] Deindl FM, Schüssler B, Vodusek DB, Hesse U. Neurophysiologic effect of vaginal cone application in continent and urinary stress incontinent women. Int Urogynecol J 1995;6:204–8.