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USE OF A VAGINAL SPHERES DEVICE IN THE CONSERVATIVE TREATMENT OF STRESS URINARY INCONTINENCE: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

There is strong evidence so as to recommend pelvic floor muscle training (PFMT) as the first line treatment for stress urinary incontinence (SUI), especially in mild to moderate symptomatic women. However, despite vaginal medical devices such as vaginal spheres (also known as vaginal Kegel balls) are becoming increasingly popular, little is known regarding its efficacy as adjuvant therapies to PFMT.

We hypothesised if the use of vaginal spheres with PFMT compared to the same PFMT scheme without any device was effective and safe in the treatment of stress UI. Secondarily, we studied adherence to this physiotherapy.

Study design, materials and methods

Multicentre, prospective, randomized, controlled and phase IV trial. Inclusion criteria was mild or moderate SUI or stress predominant mixed incontinence (ICIQ-UI-SF≤12), in women aged between 35 and 60, parity ≥1 that had not received any PFMT treatment prior to their inclusion in the study. Women accepting to participate were randomly assigned to two groups. Group 1 (treatment) used vaginal spheres (PelvicGym®, Pharmadiet S.L.U., Barcelona, Spain) while performing Kegel exercises during 15 minutes, twice daily, a minimum of 5 days per week during 6 months. Group 2 (control) performed the same Kegel exercises regime, without any vaginal medical device. In both groups Kegel exercises were performed in semirecumbent or lying position. A total of 15 slow contractions were followed by 5 consecutive series of 10 quick contractions with a 2 minute resting time between series. A 30 minute physical-therapy session was planned at day-0 visit for training and supervision purposes. A supervision session was performed at day-7 to ensure a good understanding of the exercises. After this supervision session, a leaflet containing information on Kegel exercises regime was given to all participants.

Five follow-up visits were planned at days 0 (inclusion), 7, 30, 90 and 180.

Evaluation of results was made by means of ICIQ-UI-SF questionnaire, 1-hour Pad-test and King's Health Questionnaire (KHQ) (physical/social limitation, personal relationships and emotions domains). Adherence to treatment in both groups was evaluated with an adapted version of Morinsky-Green test. Both patient and investigator subjective evaluation of efficacy and tolerance to treatment and physiotherapy were measured and registered. Adverse events were carefully monitored and registered.

Statistical analysis was carried out in IBM SPSS version 19.0. All outcome measures were summarised by descriptive statistics. Analysis of the variance for repeated measures (linear mixed model) was used to compare the initial and days 7, 30, 90 and 180 values for ICIQ data within group; and analysis of the variance for independent measures (linear mixed model) was used for comparison between groups. Mann-Whitney U test and Friedman and Wilcoxon tests were use to compare values between or within groups, respectively, for Pad-test, KHQ and efficacy data. Intention-to-treat (ITT) analysis was used and latest values were carried forward for the five women who dropped out in both groups. The confidence interval (1-α) was set at 95%, with a significance level of 0.05 and a power of 90%. Taking this into account, the sample size was estimated based on bibliographic data from similar studies and based on the variance of the quantitative variable ICIQ-IU-SF, adjusting to 20% of potential dropouts and to the risk assumed.

Results

70 patients were included. 4 patients (3 in control group, 1 in treatment group) did not attend follow-up visits, and one patient broke study regime protocol. Those 5 patients were considered not suitable for evaluation. Data were obtained from the remaining 65 patients, distributed in two groups: PelvicGym® (n=35) and control (n=30) group. Both groups were homogeneous.

Regarding ICIQ-UI-SF results, a statistically significant improvement was observed in the treated group from the third visit (1 month) on. In the control group, this significant difference was only observed in the last visit ($p<0.01$). Comparisons between groups showed significant differences at visit 4 (3 months), where the treated group improved with respect to control ($p<0.05$) (Figure 1).

With regard to Pad-test results, significant differences were observed in the treated group from third visit on, until the end of the study when compared to baseline ($p<0.01$). These differences were not observed in the control group. Comparisons amongst groups showed no significant differences.

Quality of life and personal relationships domains (KHQ) showed no significant differences throughout the study or between groups. A trend towards lower scoring was observed in the treatment group although statistical significance was not achieved.

Investigator and patient subjective assessment of efficacy by means of a 5-point Likert scale showed an improvement in both groups.

Adherence to treatment as measured with the Morinsky-Green test was higher in the vaginal device group than in controls (65.7% vs 60% at day 30; 42.9% vs 33.3% at day 180), though nonsignificant (table1).

Tolerance to treatment was good or excellent in 91.4% (PelvicGym®) and 90% (control). Mild adverse events (AE) were reported at visit 2 either in treatment group (n=4) and in control group (n=1). No AE were reported in the following visits in any group.

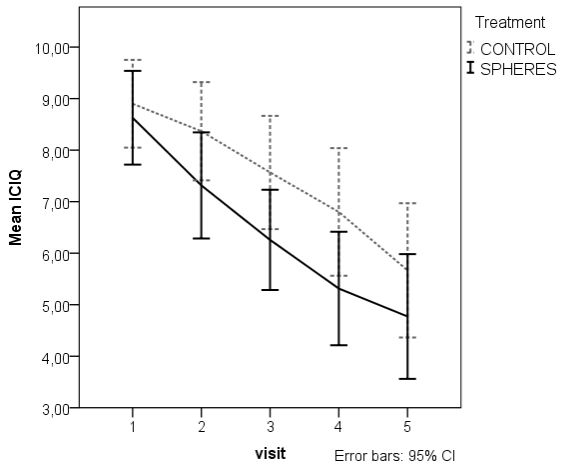

Figure 1. Evolution of the mean value of the ICIQ-UI-SF for both treatment groups: Kegel exercises + spheres (continuous black line) and Kegel exercises alone (dashed grey line).

Table1. Percentage of adherence to treatment, in both groups, in each visit.

		Adherence		No adherence		
treatment	visit	N	%	N	%	N total
CONTROL	2	18	60	12	40,0	30
	3	15	50	15	50,0	30
	4	15	50	15	50,0	30
	5	10	33,3	20	66,7	30
SPHERES	2	23	65,7	12	34,3	35
	3	17	48,6	18	51,4	35
	4	20	57,1	15	42,9	35
	5	15	42,9	20	57,1	35

Interpretation of results

According to the results of this study, performing Kegel exercises during 6 months either with or without vaginal spheres is effective in the treatment of mild to moderate SUI. However, significant improvements in objective outcome measures (ICIQ-UI-SF and Pad-test) were observed after 1 month in the treatment group whereas those results in the control group were only achieved after 6 months. Thus, the concomitant use of Kegel exercises with vaginal spheres allows obtaining positive results earlier. A positive impact on quality of life outcome measures has been observed in both groups. In addition to that, this medical device has proven to be safe as adverse events have been mild and transitory, probably linked to inexperience at the beginning of its use.

Both the promptitude in the achievement of good results and the excellent tolerance to the device seem to play a role in the trend showed towards a better adherence to treatment at 6 months in the spheres group.

Concluding message

The use of PelvicGym® vaginal device together with Kegel exercises is effective and safe in the treatment of mild to moderate SUI. Its use allows for more prompt positive results to be obtained and seems to help keep adherence to long-term treatment.

Disclosures

Funding: The corporate funding source of this study is Pharmadiet S.L.U., an OPKO Health company. **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Ethics Committee of Hospital de la Santa Creu i Sant Pau, Barcelona; Hospital Universitario Virgen de las Nieves, Granada; and Hospital Universitario 12 de Octubre, Madrid (Spain). **Helsinki:** Yes **Informed Consent:** Yes