Use of a vaginal spheres device in the conservative treatment of stress urinary incontinence: a randomized controlled trial

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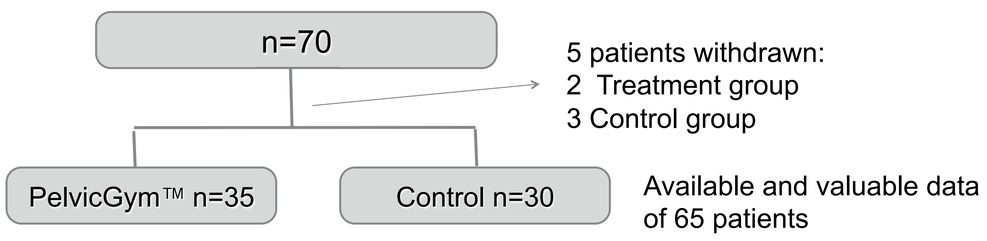
AIM OF THE STUDY

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 and safety 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.

INCLUSION CRITERA

- Women aged between 35 and 60.
- Mild or moderate stress UI or mixed IU (ICIQ-UI-SF ≤ 12).
- Parity ≥ 1.
- No previous PFMT treatment.



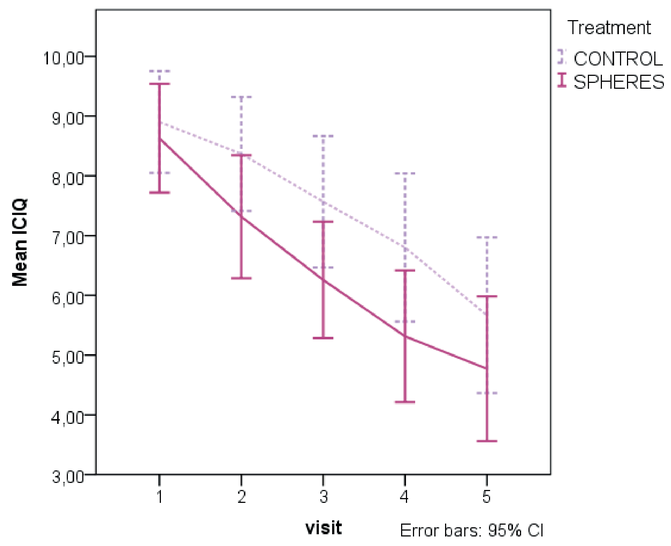
MATERIALS AND METHODS

- Multicentre, prospective, randomized, controlled and phase IV trial.
- Two groups:
  - Group 1 (Treatment): vaginal spheres (PelvicGym™, Pharmadiet S.L.U., Barcelona, Spain) + Kegel exercises.
  - Group 2 (control): Kegel exercises

  - Kegel exercises guideline:
  - 15 minutes, twice daily, minimum 5 days/week, 6 months.
  - In semirecumbent or lying position.
  - 15 slow contractions, followed by 5 consecutive series of 10 quick contractions, 2 minute resting time between series.
  - 30 minute physical-therapy session at day-0 visit for training + information leaflet.
  - Supervision session at day-7.
- Follow-up visits: days 0 (inclusion), 7, 30, 90 and 180.
- Outcome measures:
  - ICIQ-UI-SF questionnaire
  - 1-hour Pad-test
  - King's Health Questionnaire (KHQ) (physical/social limitation, personal relationships and emotions domains)
  - Adherence to treatment (adapted version of Morinsky-Green test)
  - Both patient and investigator subjective evaluation of efficacy and tolerance to treatment and physiotherapy
  - Adverse events monitoring

RESULTS

ICIQ-UI-SF questionnaire



Treatment	visit	N	Mean	SD
CONTROL	1	30	8,900	2,279
	2	30	8,367	2,553
	3	30	7,567	2,944
	4	30	6,800	3,316
	5	30	5,667**	3,487
SPHERES	1	35	8,629	2,647
	2	35	7,314	2,998
	3	35	6,257**	2,832
	4	35	5,314**	3,206
	5	35	4,771**	3,524

- ✓ Statistically significant improvement in the treated group from the third visit (**1 month**) on. In the control group, significant difference only in the last visit (6 months) (**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).

1-hour Pad-test

Treatment	visit	N	Mean	SD
CONTROL	1	30	1,498	3,028
	2	30	2,831	5,133
	3	30	1,151	2,000
	4	30	1,565	3,170
	5	30	1,891	3,344
SPHERES	1	35	3,275	4,776
	2	35	3,012	4,194
	3	35	2,134**	3,687
	4	35	2,152**	3,863
	5	35	1,862**	3,718

- ✓ Significant differences in the treated group from third visit on, until the end of the study compared to baseline (**p<0.01).
- ✓ No differences in the control group.
- ✓ Comparisons between groups showed no significant differences.

Adherence to treatment

Treatment	visit	Adherence N	Adherence %	No adherence N	No adherence %	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

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

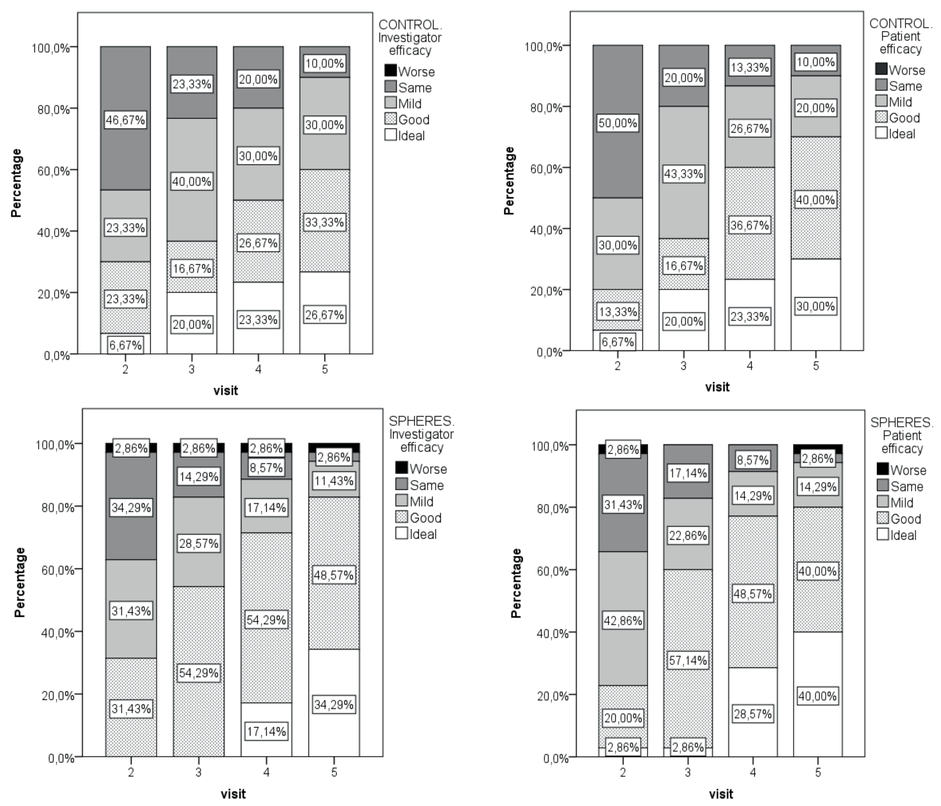
Adherence to treatment was higher in the vaginal device group than in controls (65.7% vs 60% at day 30; 42.9% vs 33.3% at day 180), though nonsignificant.

King's Health Questionnaire

Quality of life and personal relationships domains 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.

Efficacy, investigator and patient

Results of efficacy, as subjectively evaluated by both investigator and patient, show a trend to better scoring in the treatment group.



Tolerance and Safety

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

CONCLUSIONS

1. The use of PelvicGym™ with PFMT is **more effective** in the treatment of UI than performing PFTM alone.
2. The degree of UI and the amount of urine loss significantly improve **from the first month** of treatment in the PelvicGym™ group, while in the control group these parameters improve after 6 months or do not improve, respectively.
3. The spheres group shows a better evolution over time of all efficacy parameters studied.
4. The use of spheres seems to **help keep adherence** to long-term treatment.
5. The use of vaginal spheres presents a very **good tolerance and safety**.