

Jesse Ron Swire T¹, Teng Aik O¹, Su Yen K², Razack A H¹, Ning Yi Y¹, Kamal N³, Ken Lim N¹, Md Latar I L²
 1. Department Of Surgery, University Of Malaya, 2. Department Of Obstetrics & Gynaecology, University Of Malaya,
 3. Department Of Physiotherapy, University Of Malaya Medical Centre

A RANDOMIZED CONTROLLED TRIAL ON THE USE OF A NOVEL PHYSICAL CONTACT BIOFEEDBACK DEVICE FOR FEMALE STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

Pelvic floor training (PFE) has been established as a proven, effective first line treatment for stress urinary incontinence (SUI). PFE can also be enhanced by using biofeedback devices as reported by previous studies. Vibrance Kegel Device (VKD) is a new biofeedback device which will aid patients in identifying the appropriate group of muscles to contract when performing PFE. The purpose of this study is to evaluate the efficacy of pelvic floor exercises performed with Vibrance Kegel Device as compared to normal pelvic floor exercise for the treatment of stress urinary incontinence.

Study design, materials and methods

This was a prospective randomized controlled trial of women with SUI who underwent pelvic floor exercise at University Malaya Medical Center from October 2011 to October 2013. A total of 40 patients were randomly divided into two groups: 19 patients in control group (PFE alone) and 21 patients in VKD group (PFE with VKD biofeedback). Patients underwent 4 months of pelvic floor training and assessed by validated pelvic floor questionnaires (validated by Baessler K) & Modified Oxford Scales. Total sample size of 40 patients was considered sufficient for this study because this is a pilot study. Taking a 15% possibility of dropout into account, 46 patients are enrolled.

Results

3 out of 19 patients in control group drop out at 4th month training while the VKD group reported 100% compliance. VKD group reported significantly earlier improvement in stress urinary incontinence symptoms ($p=0.038$). Pelvic floor muscle strength was significantly better in VKD group at 1st ($p=0.025$) and 4th month ($p=0.001$). Subjective cure rate after 4 months were reported at 62.5% in control group and 61.9% in VKD group. All patient who had pelvic floor training reported significant improvement after 4 months however there was no statistically different difference between the groups post treatment.

Table 1: Descriptive statistics of stress urinary incontinence score improvement in both group studied.

SUI score improvement	Month 1		p value	Month 4		p value
	CONTROL	VKD		CONTROL	VKD	
No	8 (42.1%)	2 (9.5%)	0.038	3 (18.8%)	4 (19.0%)	0.998
Yes	11 (57.9%)	19(0.5%)		13 (81.2%)	17 (81.0%)	

Table 2: Improvement in Modified Oxford Scale in groups studied.

MOS	Improvement in MOS					
	Control			VKD		
	No	Yes	p-value	No	Yes	p-value
1 month	12	0	1.000	9	5	0.025
4 months	8	4	0.059	2	14	0.001

Table 3: Subjective assessment of improvement in stress urinary incontinence after 4 months.

Outcome	CONTROL	VKD	p value
Continent	5	7	0.998
Almost Continent	5	6	
Improved	3	4	
Unchanged	3	4	

Interpretation of results

In this study, after 4 months of treatment, women treated with VKD showed significantly earlier improvement in urinary leakage symptoms. The significant decrease in stress urinary incontinence score and improvement in pelvic floor muscle strength are evidence of early improvement. The positive effect of VKD was not statistically significant after 4 months although the VKD group still have better SUI score and significantly better pelvic muscle strength at the end of study. There was significant improvement in urinary symptoms in both groups after 4 months of training. The total urinary score was not significant between the two groups because it also measures urge incontinence and overactive bladder symptoms. Our study showed similar subjective cure rates compared to previous studies with 61.9% patients in biofeedback and 62.5% patients in control group reported cure. All our patients are compliant to VKD training as compared to control group, indicating that usage of VKD is fairly acceptable to patients. There are no adverse events reported regarding the usage of VKD in this trial. This is comparatively better than vaginal cones training which have lower tolerance.

Concluding message

Pelvic floor training is effective in reducing stress urinary incontinence with high cure rate. VKD group has significantly earlier improvement in pelvic floor training and pelvic muscle strength was also significantly improved at end of study. VKD is a viable and safe adjunct to pelvic floor training that allows patient to identify the proper pelvic muscle during training with acceptably good patient compliance.

Disclosures

Funding: The corporate funding source of this study is from Bioinfinity (M) Sdn Bhd **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Committee for clinical studies of University of Malaya Medical Centre (UMMC), K.Lumpur, MALAYSIA. **Helsinki:** Yes **Informed Consent:** Yes