Using the Vibrance Kegel Device With Pelvic Floor Muscle Exercise for Stress Urinary Incontinence: A Randomized Controlled Pilot Study

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OBJECTIVE To evaluate the effectiveness of pelvic floor muscle exercises (PFMEs) performed with the new biofeedback Vibrance Kegel Device (VKD), compared to PFMEs alone, in treating stress urinary incontinence (SUI).

MATERIALS AND METHODS This was a pilot prospective, randomized trial of women aged ≥18 years with SUI symptoms who underwent PFMEs at University Malaya Medical Centre from October 2011 to October 2013. The patients were randomly divided into two groups: control (PFMEs alone) and VKD (PFMEs with VKD biofeedback). The patients underwent 16 weeks of pelvic floor training, during which they were assessed using Australian pelvic floor questionnaires and modified Oxford scales for pelvic floor muscle strength at week 0, 4, and 16.

RESULTS Forty patients were recruited (control 19, VKD 21). Three patients in the control group dropped out during week 16 training, whereas the VKD group had no dropouts. The VKD group reported significantly earlier improvement in SUI scores, as assessed by the Australian pelvic floor questionnaires ($P = .035$) at week 4. However, there was no significant difference between the groups' SUI scores at week 16. Pelvic floor muscle strength was significantly better in the VKD group at week 4 ($P = .025$) and week 16 ($P = 0.001$). The subjective cure rate was similar in both groups at week 16 (62.5% for control and 61.9% for VKD) ($P = 0.742$).

CONCLUSION Using the VKD resulted in significant early improvement in SUI scores, and pelvic muscle strength had improved significantly by the end of the study. The VKD proved useful as an adjunct for pelvic floor training. UROLOGY 86: 487–491, 2015. © 2015 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Urinary incontinence is a common and debilitating condition affecting 15% of adult population in America and more than one-third of women above the age of 60.[1] Pelvic floor muscle exercises (PFMEs) have been the first-line treatment for urinary incontinence since Arnold Kegel introduced them half a century ago.[2] However, studies have shown that approximately 30% of women are unable to perform an isolated pelvic floor contraction following written or verbal instruction.[3,4] Biofeedback was subsequently introduced into clinical practice with the aim of enhancing the effects of PFMEs and improving muscle function.[5]

The biofeedback devices used, compared with PFMEs alone, have produced variable results in the treatment of stress or mixed urinary incontinence[6-11] (Supplemental Table S1). Out of 6 studies, only Burgio et al[11] and Burns et al[9] reported statistically significant results using biofeedback devices with PFMEs. Burgio et al noted a statistically significant difference between treatment groups in favor of a biofeedback device for the average reduction of incontinence and improvement in the contractional force of the pelvic floor.[11] Burns et al showed statistically significant improvement in the contractional force of the pelvic floor, but not in the average reduction of incontinence.[9]

The Vibrance Kegel Device (VKD) is a new biofeedback tool designed by Bioinfinity Pte Ltd (Fig. 1A). As a T-shaped device with a pressure-sensitive body (to detect vaginal squeeze pressure), sheath, and outer body, the VKD uses vibrational pulses as active biofeedback on pelvic muscle

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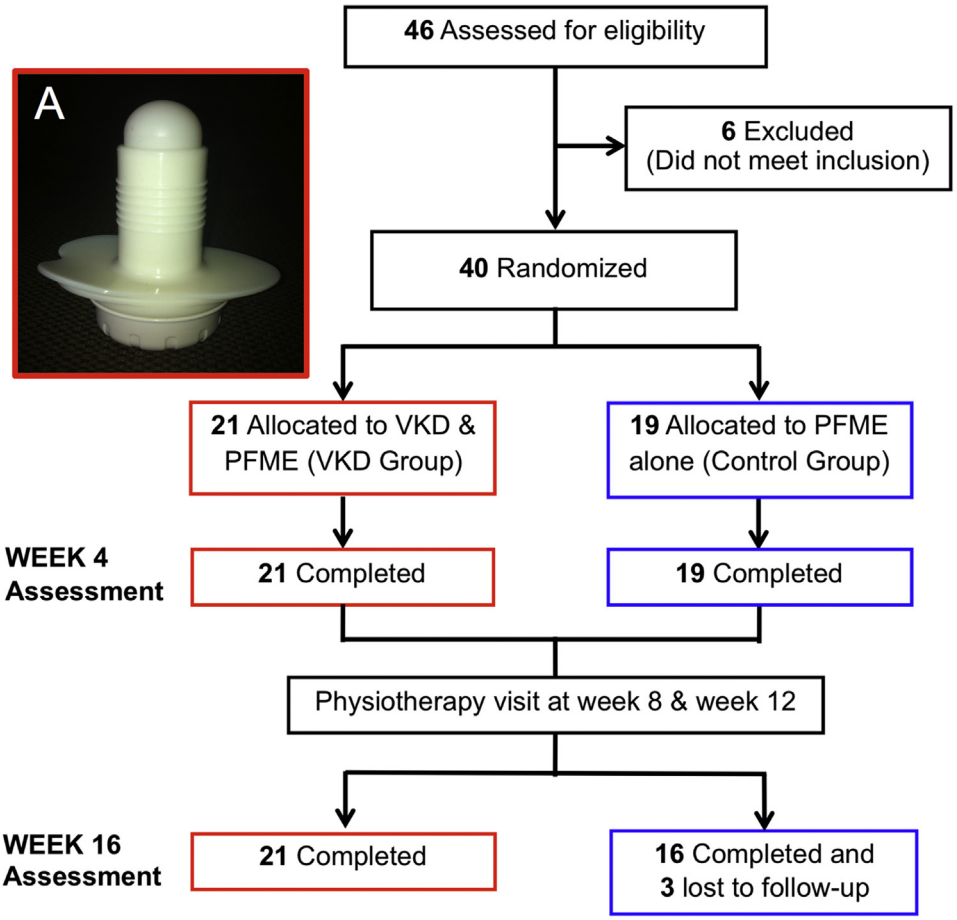

Figure 1. CONSORT (Consolidated Standards for Reporting Trials) flow diagram for patient recruitment and analysis. Box A shows the VKD. The red boxes indicate the VKD group whereas the blue boxes indicate the control group.

contractions. The outer sheath has varying degrees of resistance for different training intensities. Proper pelvic muscle contractions are detected by the device, which provides the user with vibrational feedback. The VKD is user-friendly, mobile, and approved for use by the FDA (K141893), providing patients with flexibility in their training schedules.

In the current study, we assessed the VKD's effectiveness when used in conjunction with PFMEs, compared with PFMEs alone, for treating female stress urinary incontinence (SUI).

MATERIALS AND METHODS

Study Design

The study was a nonblinded, randomized controlled pilot study performed from October 2011 to October 2013 at University Malaya Medical Centre (UMMC). Ethical approval was obtained from the UMMC ethics committee (Report 877.7).

Female patients with SUI were recruited from urological, gynecological, and primary care clinics. Two standard questions about stress ("Do you leak urine with activities such as coughing, sneezing, or running?") and urge urinary incontinence ("Does urine leak when you rush/hurry to the toilet?") were used to determine the patient eligibility. Only women predominantly suffering from SUI were recruited. The exclusion criteria included previous incontinence surgery, concomitant medical treatment for urinary incontinence, urinary tract infection, and neurologic or psychiatric disease. All of the participants provided written informed consent. Simple randomization was used for this study. The participants were randomized by casting lots with a box containing equal numbers of lots for the control and VKD groups. The lots, which were replenished before each cast, decided the participants' allocation.

After randomization, all of the participants underwent a standardized assessment using the Australian pelvic floor questionnaire (APFQ),[12] followed by a physiotherapist-conducted pelvic floor assessment using the modified Oxford scale (MOS) to assess patients' suitability for planned treatment and collection of baseline data. The questionnaire and pelvic floor muscle assessment were conducted before training at week 0, 4, and 16 by an evaluator and a physiotherapist, respectively.

Outcome Measures

The primary outcomes for this study were SUI score and pelvic floor muscle strength, with secondary outcomes of total urinary score, social life score, bothersome score, and subjective cure. The evaluations of both groups were conducted before and after treatment completion by 1 nonblinded physiotherapist and 1 nonblinded investigator.

The APFQ,[12] which was used to assess the urinary score, is a validated questionnaire comprising 41 questions divided into 4 domains: bladder function, bowel function, prolapse symptoms, and sexual function. We chose to focus on the bladder function domain, which contains 15 questions (see Supplementary Fig. S1).

The total urinary score represented the total score for the bladder function domain, whereas the SUI score was specifically based on question 6, the social life score was based on question 14, and the bothersome score was based on question 15.

For the pelvic floor muscle assessment, our physiotherapist used the MOS[13] to measure muscle strength on a 6-point Likert-type scale (0 = no contraction, 1 = flicker, 2 = weak, 3 = moderate [with lift], 4 = good [with lift], 5 = strong [with lift]). The participants were asked to perform three maximum voluntary contractions and the best was taken as the score.

Both groups were encouraged to do PFMEs daily and record their exercise frequency. At the end of treatment, the women treated were questioned regarding their perception of urinary leakage improvement. They were given the response option of unchanged or improved, and if they reported improvement, they were asked whether they considered themselves continent. The participants with no improvement were followed-up in a urology clinic with different treatment options.

Treatment Protocol

All of the participants underwent a standardized pelvic floor muscle training protocol,[3] which consists of endurance and speed training. Endurance training involved slow velocity close to maximum contraction for 3-10 seconds, followed by relaxation for 3-10 seconds. Speed training involved quick, moderately strong contractions for 2 seconds followed by relaxation for 2 seconds. The participants were required to complete 3-5 sets of each type of training; that is, 10 contractions in a row or until fatigue.

The participants were treated individually by the physiotherapist in monthly sessions of 20 minutes for 16 weeks. During the sessions, the participants were re-educated on pelvic floor training and their progression was noted.

For the VKD group, during the initial training under the physiotherapist's supervision, the device was placed inside the vagina and the participant conducted PFME training according to the standard protocol. Both groups were encouraged to do daily pelvic floor training at home, one group with biofeedback (VKD) and the other without (control). The questionnaire and pelvic floor muscle assessment were conducted at week 0, 4, and 16.

Statistical Analysis

All of the statistical analyses were performed using SPSS software (version 17; SPSS Inc., Chicago, IL). The χ^2-test and *t*-test were used to verify the homogeneity of the groups at baseline. For intragroup analysis, the Wilcoxon test was used. A subjective cure was analyzed using the χ^2-test. The differences were considered significant when the *P* value was $<.05$.

RESULTS

Forty participants were recruited and randomized (control 19; VKD 21) (Fig. 1). The VKD group had no dropouts, whereas 15.8% of the participants from the control group dropped out. The reasons given for dropping out were family death, lack of transportation, and work commitments.

There were no significant differences in outcome variables between both groups at baseline, except for total urinary score ($P = .045$), which showed a significant difference (Table 1). All of the participants had regular pelvic floor muscle training during the 16 weeks treatment period, and there was no significant difference in the training frequency between the groups.

Table 1. Demographic and outcome variables at baseline

Demographic Variables	VKD Group (n = 21)	Control Group (n = 19)	*P*
Age (y)	50.7 (11.0)	53.2 (14.3)	.538
Race (n, %)			.859
Malay	12 (57.1)	10 (52.6)	
Chinese	4 (19.0)	5 (26.3)	
Indian	5 (23.8)	4 (21.1)	
Parity	3.2 (0.9)	2.8 (1.2)	.284
SVD (n, %)			.962
0	1 (4.8)	2 (11.1)	
1	1 (4.8)	1 (5.6)	
2	8 (38.1)	6 (33.3)	
3	7 (3.3)	6 (33.3)	
>3	4 (19.0)	3 (16.7)	
Forceps (n, %)			.651
No	15 (71.4)	14 (77.8)	
Yes	6 (28.6)	4 (22.2)	
Vacuum (n, %)			1.000
No	20 (95.2)	17 (94.4)	
Yes	1 (4.8)	1 (5.6)	
LSCS (n, %)			.379
No	15 (71.4)	15 (83.3)	
Yes	6 (28.6)	3 (16.7)	
Menopause (n, %)			.184
No	11 (52.4)	6 (31.6)	
Yes	10 (47.6)	13 (68.4)	
SUI score	2.6 (0.7)	2.3 (0.9)	.217
Total urinary score	15.8 (7.7)	11.6 (4.4)	.045
Bothersome score	2.3 (0.7)	1.9 (1.0)	.118
Social life score	2.1 (1.0)	1.6 (1.3)	.163
Pelvic floor muscle strength (MOS)	2.3 (0.7)	2.6 (0.8)	.304

LSCS, lower segment Caesarean section; MOS, modified oxford scale; SUI, stress urinary incontinence; SVD, spontaneous vaginal delivery; VKD, Vibrance Kegel Device.

Data presented as mean (standard deviation) unless stated otherwise.

At 4 weeks, the SUI score improvement showed a significant difference in the VKD group compared with the control group ($P = .017$). The pelvic floor muscle strength (MOS score) improvement also showed a significant difference favoring the VKD group ($P = .027$). No significant difference was seen in the total urinary score ($P = .157$), social life score ($P = .554$), or bothersome score ($P = .906$) between the groups (Table 2).

At 16 weeks, there was a significant difference in the MOS scores in the VKD group ($P = .003$). However, the SUI score improvement was not significant between the groups ($P = .982$). Comparison of the secondary outcome variables such as total urinary, social life, and bothersome scores between the groups were not significant at the end of study (Table 2).

An intragroup analysis showed that both groups exhibited statistically significant improvements in SUI score and pelvic muscle strength at 16 weeks, compared with before training and after 4 weeks of training (Table 3).

Subjective cure (number of women stating they are continent after the treatment) showed no statistically significant difference ($P = .742$) between groups after week 16 (Table 2).

Table 2. Number of patients with improvement in outcome variables

Outcome Variables	VKD Group	Control Group	*P*
Stress urinary incontinence score (APFQ question 6)			
4 wk	11/19 (57.8)	11/19 (57.8)	.017
16 wk	13/16 (81.3)	13/16 (81.3)	.982
Pelvic muscle strength (MOS score)			
4 wk	5/14 (35.7)	0/11 (0.0)	.027
16 wk	14/16 (87.5)	4/12 (33.3)	.003
Social life score (APFQ question 14)			
4 wk	13/21 (61.9)	10/19 (52.6)	.554
16 wk	16/21 (76.2)	9/16 (56.3)	.199
Bothersome score (APFQ question 15)			
4 wk	14/21 (66.7)	13/19 (68.4)	.906
16 wk	18/21 (85.7)	11/16 (68.8)	.214
Total urinary score (APFQ Q1-15) (mean ± SD)			
4 wk	7.9 ± 6.8	5.2 ± 4.7	.157*
16 wk	11.3 ± 8.3	7.8 ± 5.1	.157*
Subjective cure (APFQ question 6; score = 0)			
4 wk	6/21 (28.6)	5/19 (26.3)	.873
16 wk	12/21 (57.1)	10/16 (62.5)	.742

APFQ, Australian pelvic floor questionnaire; SD, standard deviation; other abbreviations as in Table 1.

Data presented as number of patients (percentage) unless stated otherwise.

Comparisons using Pearson's χ^2-tests except *t-test.

Table 3. Improvement in SUI score and pelvic floor muscle strength from baseline to after treatment within each group

Outcome Variables	VKD Group	*P*	Control Group	*P*
Stress urinary incontinence score				
0-4 wk	19/21 (90.5)	<.001	11/19 (57.9)	.006
0-16 wk	17/21 (81.0)	<.001	13/16 (81.3)	.001
Pelvic muscle strength (MOS score)				
0-4 wk	5/15 (33.3)	.025	0/11 (0)	1.000
0-16 wk	14/16 (87.5)	.001	4/12 (33.3)	.059

Abbreviations as in Table 1.

Data presented as number of patients with improvement (percentage).

P value obtained using Wilcoxon signed rank test.

COMMENT

In this study, after 16 weeks of treatment, both groups showed significant improvement in SUI symptoms, as shown by improved SUI scores and pelvic muscle strength. The subjective cure rate was 57.1% in the VKD group and 62.5% in the control group. This result is in line with the Cochrane meta-analysis comparing pelvic floor muscle training with no treatment.[14]

Women treated with the VKD showed significantly earlier improvement in SUI symptoms, reflected in their SUI scores and pelvic floor muscle strength at 4 weeks. In this study, the VKD provided patients with easy, accurate recognition of which pelvic floor muscles needed to be contracted, enhancing correct pelvic floor training. This may have led to earlier improvement in pelvic muscle tone and neuromuscular function and a better urethral closure mechanism during a rise in intra-abdominal pressure. Another possible explanation for this result is that early improvement provided more motivation and encouragement for patients to continue doing PFMEs. These results essentially showed that the VKD played an important role by aiding patients in early recognition of the appropriate muscles to exercise.

PFMEs with VKD were not statistically significantly different from PFMEs alone after 16 weeks of training, although the VKD group still had better SUI scores and significantly better pelvic muscle strength by the end of the study. Mørkved et al[15] conducted a single-blinded, randomized controlled trial comparing pelvic floor exercises with and without a vaginal pressure probe. They reported better objective cure (58% in the biofeedback group and 46% in the control group) and subjective cure (69% in the biofeedback group and 50% in the control group). However, there was no statistically significant difference between the groups. Bø et al[16] and Arvonen et al[17] conducted randomized controlled trials comparing PFMEs with vaginal cones and found no statistically significant difference in the number of self-reported cures between the groups. A recent Cochrane meta-analysis comparing pelvic floor muscle training with and without biofeedback did not conclusively find a significant difference in the cure rate.[18] Our findings correspond to the aforementioned randomized controlled trials and meta-analysis.

There is no standardized outcome measure for urinary incontinence. The Urodynamic Society and the International Continence Society recommend using urinary leakage to evaluate treatment effects. We did not use pad tests in this study because the short pad test is difficult to perform in elderly women. Furthermore, the Cochrane meta-analysis reported that pad test outcomes did not correspond very well with data on leakage episodes, and that variability in reporting restricted the use of pad test results in comparing data from different studies.[14] Pad test evaluation should be considered for future studies regarding this biofeedback device as an objective assessment of urinary incontinence.

In this study, the Oxford grading scale is used to assess pelvic muscle strength. Although pelvic floor manometry was not used to assess pelvic muscle strength, Da Roza et al[19] revealed a moderate correlation between peak pressure on manometry and the Oxford grading scale score. Morin et al[20] also found a significant correlation between vaginal digital assessment with dynamometric measurements for continent and incontinent women, although the mean maximal forces between two adjacent categories do not differ. Thus, digital pelvic floor assessment is a feasible outcome measure. Moreover, the MOS score was not complete due to patients refusing pelvic floor assessment during menstruation.

The total urinary score was not used as a primary outcome measure because the score considers urge incontinence and overactive bladder symptoms, whereas our study focused on SUI symptoms. The significant difference in total urinary score between the groups at baseline could be due to the small number of participants, the simple randomization method, or the nonblinding method used in this study. However, the total urinary score was not significant between the two groups.

Bø et al[16] ran a randomized controlled trial comparing pelvic floor exercise, vaginal cones, and electric stimulation. They found that 54% of patients achieved subjective cure after 6 months. Our study showed similar subjective cure rates of 57.1% in the VKD group and 62.5% in the control group.

Subjective measures of the severity of incontinence and its effect on quality of life and the degree of bother experienced are important when evaluating urinary incontinence. In our study, parameters such as social life improvement and bothersome score were better in the VKD group, although not statistically significant. This could be due to the small sample size. It is important to note that the quality of life improvement recorded in the VKD group was mainly due to the ease of using the device, which led to a better compliance rate and results.

Compliance with treatment is important in muscle strength training because the results depend heavily on regular training. The VKD group exhibited better compliance, reflected in the lack of dropouts, whereas the control group had a 15.8% dropout rate. Studies on biofeedback such as vaginal cones training have reported poor compliance due to poor device tolerance; for example, Olah et al[21] reported an initial dropout rate of 27% that further increased to 42% after 6 months. Such increased dropout rates are possibly caused by adverse events, as those reported by Bø et al,[16] including the inability to use cones, pain, vaginitis, and bleeding.

All of our patients were compliant with the VKD training, as they found the device convenient to use and easy to clean. The patients in the VKD group gave mostly positive feedback regarding the device in terms of ease of use, portability, water resistance, and ease of cleaning. None of the patients reported adverse events, but one noted rust developing near the base. The patients were advised to keep the VKD device dry after washing it and battery life was good, with a mean usage of 8 weeks.

The patients in our study underwent monthly physiotherapy visits, which were comparatively less than the weekly physiotherapy required in other biofeedback trials such as those conducted by Mørkved et al,[15] Olah et al,[21] and Kondo et al.[22] In our trial, the patients in both groups were compliant with treatment, as their exercise frequencies were similar despite less follow-up. This equates to time and cost savings for patients and healthcare services.

CONCLUSIONS

This study showed that the VKD is a good adjunct to pelvic floor exercises, as it helps patients benefit from pelvic floor muscle training. It is a small, portable device that can be applied in clinical practice to provide patients with a convenient way to perform effective pelvic floor exercises. However, further studies should be performed to reach a definite conclusion about its efficacy.

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APPENDIX

Supplementary Data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.urology.2015.06.022.