ORIGINAL ARTICLE

Comparison of Kegel exercises and a combination of Kegel exercises with the use of the KegelSmart biofeedback device in the treatment of static urinary incontinence

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ABSTRACT

Aim To determine which of the two methods, Kegel exercises or combination of Kegel exercises with the use of the KegelSmart biofeedback device, has better therapeutic effects on the symptoms of SUI in females.

Methods Fifty female patients with SUI were randomly divided into two groups: 25 treated with Kegel exercises, and 25 with the combination of Kegel exercises with the use of the KegelSmart biofeedback device. Patients in both groups performed Kegel exercises 30 minutes daily for 30 days. Patients in the second group, in addition to Kegel exercises, applied the KegelSmart device intravaginally for 20 minutes daily for 30 days. All patients filled out a questionnaire based on 12 questions consisting of an objective and a subjective component.

Results The basic characteristics of the patients from both groups were not statistically significantly different: age 55.16 vs 54.52 years; number of births 1.80 vs 1.96; body mass index 29.12 vs 28.40. There was a statistically significant reduction in the values of all analysed objective and subjective parameters in the group treated with combination of Kegel exercises with the use of the KegelSmart biofeedback device compared to Kegel exercises group.

Conclusion Combination of Kegel exercises with the use of the KegelSmart biofeedback device has better therapeutic effects than Kegel exercises on the objective and subjective symptoms of SUI.

Key words: female patients, Kegel exercise, pelvic floor muscles

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Original submission:
07 January 2023;
Revised submission:
22 February 2023;
Accepted:
31 March 2023
doi: 10.17392/1584-23

Med Glas (Zenica) 2023; 20(2):276-281

INTRODUCTION

Urinary incontinence (UI) affects 15-35% of the adult ambulatory population over 60 years of age, with a higher prevalence in females (twice as many females as males) (1). Static urinary incontinence (SUI) is the most common form of UI and it manifests with the involuntary swelling of urine during physical exertion, e.g. coughing, sneezing, running or lifting weights (2). It is considered that the initial therapy of SUI should always be conservative (3).

Kegel exercises are the most common method of physical treatment for strengthening the pelvic floor muscles (PFM), and were first described in 1948 by the American gynaecologist Arnold Kegel (4). Most studies show that Kegel exercises strengthen PFM, however, in practice the results differ depending on whether patients do exercises after identifying PFM, how seriously they exercise, and how much confidence they have in the exercises themselves (5).

The biofeedback (BF) technique was popularized during the 1970s, along with a number of other behavioural therapies. BF device inserted into the vagina or anal canal measures the level of muscle activity generated by PFM contractions (6). BF is not an independent therapy, but most often a supplement when performing PFM strengthening exercises, by measuring the response of the musculature during the performance of contractions through the device and receiving feedback on the effectiveness of the exercise (7). BF can be useful for patients who cannot independently contract the PFM correctly and strongly enough, because the provision of feedback helps more conscious muscle contraction and better motivation when performing exercises (8). One of the latest BF devices - KegelSMart, presents a patented touch-sensitive sensor technology that transmits the strength of the pelvic floor every time the user uses the device (9).

The application of Kegel exercises is not standardized. The method and intensity of training for the exercises can vary from short verbal instructions in the office by a therapist, written materials, to individual sessions with a therapist trained to carry out this treatment. The intensity of the treatment will vary depending on the number of training sessions and the frequency with which the patient practices exercises at home (10). The main problem with Kegel exercises is that after verbal instructions given by the therapist, only 50-60% of patients can properly contract the PFM (11). Many patients have difficulties in identifying, controlling and coordinating the PFM function. When they receive oral instructions for exercises, the patients often perform them ineffectively later on at home (12).

Many studies have compared the effects of PFM strengthening exercises with and without BF, and conflicting results have been obtained (13). The results of studies published in recent years are clearly different from the results of earlier ones, i.e. favouring positive effects of combined therapy with Kegel exercises and BF (14). One of the reasons for this could be the insufficient standardization of earlier studies, which was later corrected, and the second was the imperfection of the previous devices for BF therapy (15).

Currently, there are no studies that analyse the effects of the KegelSmart device in combination with Kegel exercises on SUI symptoms.

The aim of this research was to determine which of the two methods, Kegel exercises or the combination of Kegel exercises with the use of the KegelSmart biofeedback device, has better therapeutic effects on the symptoms of SUI in female patients.

PATIENTS AND METHODS

Patients and study design

The prospective randomized study included 50 female patients diagnosed with SUI adjusted for age, body mass index (BMI) and number of births. The patients were divided into two groups according to the therapeutic method used: 25 patients treated with Kegel exercises, and 25 patients treated with the combination of Kegel exercises with the use of the KegelSmart biofeedback device.

The study was conducted at the Clinic for Physical Medicine and Rehabilitation of the University Clinical Centre Tuzla in the period from November 2019 to November 2021.

All patients signed a written consent for the study. The research was approved by the Ethics Committee of the University Clinical Centre of Tuzla.

Methods

Kegel exercises. The patients in both groups performed Kegel exercises daily for 30 days. After emptying the bladder, the patients took the appropriate position, after which they performed exercises. A total of 10 exercises were performed with 10 repetitions for each, lasting for 30 minutes. The exercises were performed strongly, controlled and slowly.

Combination of Kegel exercises with the use of the KegelSmart biofeedback device. Patients in the second group, in addition to Kegel exercises, applied the KegelSmart device intravaginally for 20 minutes daily for 30 days. After activating the device and starting the vibration, the patients alternately contracted the pelvic muscles and relaxed them when the vibrations stopped. The device guided the patients through each contraction with gentle vibrations and automatically determineed the duration and rhythm of the exercises. After the end of the stimulation, the device was automatically switched off.

Survey questionnaire. All patients filled out a questionnaire based on the modified International Consultation on Incontinence Questionnaire (16). The questionnaire contained 12 questions that were answered before starting the therapy, and 30 days after the end of the therapy. All 12 questions consisted of an objective ("a") and a subjective component ("b") (Tables 1, 2).

All questions under "a" (objective component) were evaluated by the patients as follows: 0=never; 1=under certain circumstances, 2=sometimes, 3=most of the time, 4=always; except for two questions:

1.a. (During the night, how many times do you have to urinate on average?) 0-never, 1-once, 2-twice, 3-three times, 4-four times,

4.a. (How often do you urinate during the day?) 0=1-6 times, 1=7-8 times, 2=9-10 times, 3=11-12 times, 4=13 times and more.

All questions under "b" (subjective component) were evaluated by patients from 0-10: 0=doesn't bother me at all, and 10=extremely bothers me.

Statistical analysis

The normality of distribution was tested by the Kolmogorov-Smirnov test. Values were presen-

Table 1. Value of objective parameters before and after the treatment in patients treated with Kegel exercises and patients treated with the combination of Kegel exercises with the use of the KegelSmart biofeedback device

Question No.	Before/ after	Mean value±SD		p
		KE	KE+KS	
1.a. During the night, how many times do you have to urinate on average?	before	2.92±0.91	2.80±0.81	0.626
	after	1.24±0.59	0.68±0.48	0.001*
2.a. Do you have a strong urge to rush to the toilet to urinate?	before	2.92±0.76	3.04±0.84	0.599
	after	1.28±0.61	0.84±0.47	0.007*
3. a. Do you feel pain in your bladder?	before	2.40±0.87	2.08 ±0.76	0.171
	after	1.28±0.54	0.76±0.59	0.002*
4.a. How often do you urinate during the day?	before	2.68±0.85	2.60±0.57	0.699
	after	1.36±0.49	0.92±0.49	0.003*
5.a. Do you have to wait before you urinate?	before	2.40±0.87	2.36 ±0.49	0.842
	after	1.40±0.65	0.88±0.60	0.005*
6.a. Do you have to strain to urinate?	before	2.60 ±1.00	2.32±0.69	0.255
	after	1.24±0.59	0.68±0.47	0.001*
7.a. Do you stop and start repeatedly while urinating?	before	2.48±0.59	2.40±0.50	0.606
	after	0.92±0.49	0.56 ±0.50	0.014*
8.a. Do you start urinating uncontrollably before you reach the toilet?	before	2.60±0.58	2.64±0.57	0.806
	after	1.08±0.49	0.56±0.51	0.031*
9.a. How often do you urinate uncontrollably?	before	2.76±0.78	2.96±0.61	0.317
	after	1.08±0.49	0.76±0.44	0.019*
10.a. Do you urinate uncontrollably when you are physically active, when you strain, cough or sneeze?	before	2.88±0.88	3.00±0.41	0.540
	after	1.24±0.43	0.92±0.40	0.009*
11.a. Do you urinate uncontrollably for no apparent reason even when you don't feel the need to urinate?	before	2.16±0.55	2.28±0.81	0.408
	after	1.04 ±0.61	0.68±0.48	0.024*
12.a. Do you urinate uncontrollably while you sleep?	before	1.76±0.43	1.88±0.33	0.279
	after	0.76±0.43	0.44±0.51	0.021*

*p<0.05; All questions under "a" (objective component) were evaluated by the patients as follows: 0=never; 1=under certain circumstances, 2=sometimes, 3=most of the time, 4=always; except for two questions: 1.a. 0-never, 1-once, 2-twice, 3-three times, 4-four times; 4.a. 0=1-6 times, 1=7-8 times, 2=9-10 times, 3=11-12 times, 4=13 times and more; KE, patients treated with Kegel exercises; KE+KS, patients treated with the combination of Kegel exercises with the use of the KegelSmart biofeedback device;

ted as the mean±SD. The collected data were analysed by the Student T test. All results with $p<0.05$ were considered statistically significant.

RESULTS

Basic characteristics of the patients from both groups were not statistically significantly different (Table 3).

Before the start of the treatment there were no statistically significant differences between the groups in any of the analysed objective parameters (all 12 "a" questions). After the end of the treatment, there was a statistically significant reduction in the values of all analysed objective parameters in the group of patients treated with the combination of Kegel exercises with the use of the KegelSmart biofeedback device compared to Kegel exercise group (Table 1).

Analyses of the values of the subjective parameters, i.e. all 12 "b" questions before the start and after the treatment, obtained with these two therapeutic methods, showed the same results. It is noticeable that before the start of the treatment there were no statistically significant differences between the groups in any of the analysed parameters. After the end of the treatment, in all analysed subjective parameters in the group of patients treated with the combination of Kegel exercises with the use of the KegelSmart biofeedback device, there was a statistically significant reduction in values compared to the Kegel exercise group (Table 2).

Table 2. Value of subjective parameters before and after the treatment in patients treated with Kegel exercises and patients treated with the combination of Kegel exercises with the use of the KegelSmart biofeedback device

Question No.	Before/ after	Mean value±SD	Mean value±SD	p
1.b. How much does the above bother you?	before	7.64±1.29	7.72±1.28	0.826
	after	2.68±0.75	1.60±1.85	0.009*
2.b. How much does the above bother you?	before	6.88±0.97	7.00±0.82	0.638
	after	2.56±0.77	1.68±1.60	0.017*
3.b. How much does the above bother you?	before	7.76 ±1.17	8.04±1.02	0.370
	after	2.76±0.78	1.44 ±1.44	0.000*
4.b. How much does the above bother you?	before	8.24 ±0.88	7.80±1.16	0.136
	after	2.92±0.81	2.16±1.34	0.019*
5.b. How much does the above bother you?	before	7,64±1.29	7.52±1.09	0.723
	after	2.76±0.78	1.44 ±1.71	0.001*
6.b. How much does the above bother you?	before	8.20±1.11	8.04±1.02	0.599
	after	2.52±0.57	1.48±1.48	0.002*
7.b. How much does the above bother you?	before	6.96±0.94	7.00±1.00	0.884
	after	2.44±0.58	1.52±1.71	0.014*
8.b. How much does the above bother you?	before	7.48±1.12	7.44±1.12	0.900
	after	2.52±0.77	1.68±1.52	0.017*
9.b. How much does the above bother you?	before	7.44±1.16	7.80±1.08	0.261
	after	2.84±0.85	1.88±1.79	0.016*
10.b. How much does the above bother you?	before	7.64±1.29	8.16±0.94	0.110
	after	2.84±0.80	1.84 ±1.84	0.019*
11.b. How much does the above bother you?	before	7.48±1.13	7.52±1.00	0.900
	after	2.52±0.87	1.44±1.50	0.003*
12.b. How much does the above bother you?	before	6.52±1.39	6.44 ±1.61	0.852
	after	2.48±0.77	1.56±1.82	0.025*

*p<0.05; All questions under "b" were evaluated by patients from 0-10: 0=doesn't bother me at all, and 10=extremely bothers me
KE, patients treated with Kegel exercises; KE+KS, patients treated with the combination of Kegel exercises with the use of the KegelSmart biofeedback device;

Table 3. Characteristics of 50 female patients

Variable	Mean value±SD		p
	KE	KE+KS	
Age (years)	55.16±4.12	54.52±3.77	0.570
No. of births	1.80±0.65	1.96±0.61	0.373
BMI	29.12±3.10	28.40±2.88	0.400

KE, patients treated with Kegel exercises; KE+KS, patients treated with the combination of Kegel exercises with the use of the KegelSmart biofeedback device; BMI, body mass index

DISCUSSION

The results of this study showed that therapeutic effects obtained with the combination of Kegel exercises with the use of the KegelSmart biofeedback device were statistically significantly better in all analysed 12 parameters, both objective and subjective, compared to the therapeutic effects obtained only with Kegel exercises. The fact that these were very homogenous groups of patients, and that Kegel exercises were performed in the same way under the supervision of the same therapist in both groups, in favour of the positive therapeutic effects of the KegelSmart device.

Many studies have compared the effects of PFM strengthening exercises with and without BF, and conflicting results have been obtained. The most comprehensive systematic review of published literature on this topic from 1998 found strong evidence to support the view that adding BF to strengthening exercises for PFM does not offer additional benefits over exercise alone (17).

One of the first large studies that clearly demonstrated the positive effects of BF was a meta-analysis conducted by Weatheral (18) showing that BF is an effective aid in strengthening PFM, and that it leads to positive therapeutic effects. The systematic review that most contributed to the resolution of this dilemma, from 2021 (19) confirmed that the combined therapy with exercises to strengthen the PFM and BF achieves better results than exercises alone.

Mersden and Becker clearly showed a need to improve the technology of the BF device. Large Internet review identified 31 commercially available MDZ home training devices with intravaginal probes; only one device (KegelSmart) has no external connection, instead it simply communicates during training via vibrations and LED signals of intravaginal probes (20).

Advances in BF technology, and the ease of application and use of devices such as KegelSmart make it a promising therapeutic measure in the treatment of SUI symptoms, especially in combination with Kegel exercises. The device has a whole series of features that make it efficient but also very easy to use, which was one of the biggest problems with previous devices that caused discomfort to patients. However, the main problem with KegelSmart is lack of clinical studies in which the therapeutic effects of this new BF device have been analysed.

A limitation of this study is a small number of patients but it can be a good basis for new research with a larger group.

In conclusion, the combination of Kegel exercises with the use of the KegelSmart biofeedback device has better therapeutic effects than Kegel exercises on the objective and subjective symptoms of SUI. The insufficient effectiveness of unsupervised Kegel exercises in the home environment, when a certain number of patients are unable to perform them properly, could be overcome by introducing the KegelSmart device, for which the results of this research have undoubtedly shown to have positive therapeutic effects. So far, no scientific study has analysed the effect of the combination of Kegel exercises with the use of the KegelSmart biofeedback device, which represents the basic novelty and significance of this study.

FUNDING

No specific funding was received for this study.

TRANSPARENCY DECLARATION

Competing interests: Non to declare.

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