Research Paper Optimal Duration for Supervised Pelvic Floor Muscle Training in Stress Urinary Incontinence Women: A Prospective Study

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Citation Hakim S, Mistivani I, Tambunan D, Santoso BI, Djusad S, Priyatini T, et al. Optimal Duration for Supervised Pelvic Floor Muscle Training in Stress Urinary Incontinence Women: A Prospective Study. Iranian Rehabilitation Journal. 2023; 21(1):107-116. http://dx.doi.org/10.32598/irj.21.1.1774.1

doi http://dx.doi.org/10.32598/irj.21.1.1774.1

Article info: Received: 07 Apr 2022 Accepted: 21 Dec 2022 Available Online: 01 Mar 2023

Keywords:

Pelvic floor, Biofeedback, Conservative treatment, Urinary incontinence, Stress Urinary incontinence

ABSTRACT

Objectives: We evaluated the optimal duration of pelvic floor muscle training (PFMT) in stress urinary incontinence (SUI) patients.

Methods: This cross-sectional study was conducted at Cipto Mangunkusumo Hospital from November 2018 to June 2019. We recruited 55 subjects diagnosed with SUI based on the questionnaire for urinary incontinence diagnosis (QUID) score >4 and more than 2 grams of 1-hour pad test. Considering the inclusion and exclusion criteria, we taught and supervised them for PFMT and evaluated them every four weeks to observe the urogenital distress inventory-6 (UDI-6), incontinence impact questionnaire-7 (IIQ-7), 1-hour pad test, and perineometer score. We used the Wilcoxon test to evaluate the improvement at a significance level of P<0.05.

Results: Our subjects were mostly obese (65%), 30-55 years old (60%), and had >2 children (90%). There were improvements in UDI-6 and IIQ-7 for every four weeks up to 12 weeks of PFMT (P<0.05, 95% CI). Pelvic floor muscle strength only improved significantly (P=0.001 and P=0.006, respectively) after eight weeks of PFMT. Also, the 1-hour pad test score decreased significantly after four weeks of training (P<0.001).

Discussion: SUI distress and symptoms decrease after four weeks of Kegel exercises and continue to improve until 12 weeks of therapy. However, the 1-hour pad test reaches clinical and statistical significance during the first month of exercise with no further improvement clinically. Pelvic floor muscle strength increased significantly after eight weeks of training.

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Highlights

• Pelvic floor muscle training improves symptoms of stress urinary incontinence every four weeks up to twelve weeks.

• Patients with stress urinary incontinence improved significantly by doing 1-hour pad test after one month of pelvic floor muscle training.

• Pelvic floor muscle strength improvements are only seen after eight weeks of pelvic floor muscle training.

Plain Language Summary

Sometimes, women feel an involuntary loss of urine during coughing, sneezing, or doing an activity called stress urinary incontinence. Pelvic floor muscle training (PFMT) is the mainstay treatment for women with stress urinary incontinence to improve their quality of life (QoL). However, 12 weeks of pelvic floor muscle training seems too long for women to comply. We evaluated the optimum duration needed to reach the optimal effect of therapy. We recruited some women with stress urinary incontinence and measured the symptoms using questionnaires (UDI-6 and IIQ-7), a 1-hour pad test, and a perineometer. After teaching them PFMT, we evaluated the women every four weeks up to 12 weeks. This research found that symptoms improved significantly based on questionnaires and objectively based on a 1-hour pad test after four weeks of training. At last, the muscle in the pelvis started to strengthen after eight weeks of training. It is recommended to do pelvic floor muscle training for eight weeks minimally for a significant improvement in such aspects.

1. Introduction



tress urine incontinence (SUI) is an involuntary loss of urine during an effort, exertion, sneezing, or coughing [1]. It is a spectrum of pelvic floor disorders that significantly affect women's quality of life

(QoL) and sexual function [2]. It is predicted that 17-45% worldwide have urinary incontinence (UI), including SUI. SUI is the most common type of UI for almost 49% of cases [3]. Considering the region, older women in Asia, have the highest prevalence of SUI at 45.1%, and America is the lowest at 25.8% [4, 5]. At last, the rapid increase in the geriatric and obese women population may increase the prevalence of SUI and raise the burden of healthcare cost

There are some treatment options for SUI, from conservative therapy to surgery [6]. International continence society (ICS) approved that the first-line treatment for SUI is conservative management, such as weight reduction, Kegel exercises, or pelvic floor muscle training (PFMT) [6, 7]. Kegel exercises developed by Arnold Kegel can strengthen and restore the pelvic floor muscle [8]. The patient must contract their pelvic floor muscle three times a day with a total duration of 20 minutes and 300 contractions daily. Nowadays, the ICS recommends doing PFMT every day for 12 weeks to cure SUI with a less intense regimen [9].

For some patients, the 12-week duration of PFMT may feel too long. Some women may not feel patient enough, and the long course will affect their compliance and decrease their motivation [10]. Thus, women that do not adhere may end with therapy failure [11]. In women failing PFMT, surgery methods, such as bulking agents, sling procedures, and colposuspension could be the following options. However, despite its short-term efficacy, there are still limited data about complications and longterm effects [6, 12]. In some cases, the duration ought to affect compliance; thus, this study evaluated the optimal duration of PFMT necessary to achieve significant improvement. The previous research by Yoon et al. found a similar pelvic floor muscle strength for women who had done PFMT for eight weeks and 12 weeks long [13]. Even more, Shahali et al. discovered no differences in QoL after eight weeks of Kegel exercises compared to 12 weeks [14].

Hence, we hypothesized that a shorter duration than 12 weeks of Kegel exercises will provide similar benefits. The main objective of this research was to evaluate the optimal course of PFMT in SUI patients necessary to achieve significant improvement.

2. Materials and Methods

This is a prospective study of Kegel exercises conducted at Cipto Mangunkusumo National Hospital from November 2018 to June 2019. The committee of ethics from the Faculty of Medicine Universitas Indonesia and Cipto Mangunkusumo National Hospital reviewed and approved the study.

The study population was all adult women who complained of urinary incontinence that came to Cipto Mangunkusumo National Hospital, Central Jakarta, from November 2018 to June 2019. We interviewed the patients and used the questionnaire for urinary incontinence diagnosis (QUID) to diagnose SUI. We included the patients with positive SUI based on the QUID, aged >20, with good cognitive function, providing informed consent, and willing to record the training activities. The exclusion criteria were patients taking drugs for urinary incontinence or affecting urinary function (we listed the medicines consumed by the patient), had recurrent urinary tract infections, had grade 3 or grade 4 pelvic organ prolapse, had urinary incontinence before surgery, such as Kelly plication, urethral sling, or colposuspension, had low back pain, were on chemotherapy or radiation treatment in the pelvic area, and had a 1-hour pad test weight <2 g.

We consecutively recruited 55 subjects with SUI based on a type I error of 5% and type II error of 10%. The patient recruitment was described in a flowchart below (Figure 1). Considering the inclusion and exclusion criteria, 20 patients completed the study protocol and were analyzed. All patients were diagnosed with SUI using our urogynaecologist assessment and their QUID \geq 4 and 60 minutes pad test results. After the subject agreed and filled in the informed consent, we recorded their past medical history and obstetric history. We did a physical examination and measured the patient's weight, height, body mass index (BMI), and vaginal examination, including pelvic organ prolapse quantification (POP-Q). We also assessed their QoL using the urogenital distress inventory-6 (UDI-6), incontinence impact questionnaire-7 (IIQ-7), and their pelvic floor muscle strength by biofeedback, a perineometer (Myomed 932), and the 60-minutes pad test at baseline.

After the examinations, we referred the patient to a therapist at Cipto Mangunkusumo National Hospital Medical Rehabilitation Polyclinic. The therapist taught the pelvic floor muscle exercises using the standard regimen. The pelvic floor muscle training regimen consists of two exercises: Fast-twitch movements and slow-twitch movements. In fast-twitch exercises, the patients contract their pelvic floor muscle for 2 s and relax it immediately; the movements were repeated five times in a session. However, in slow-twitch exercises, the patients contract their pelvic muscle and hold it for 5 s before releasing it. The movement was repeated five times in each session. Each session consisted of five fast contractions and five slow contractions.

We recommended the patients do five sessions each day and be supervised by their caretaker or husband. A book was given to the patients to record their daily training and serve as a guideline and a reminder. We also used biofeedback (Myomed 932) to teach them to contract the levator ani muscles and re-evaluate their Kegel exercises every two weeks.

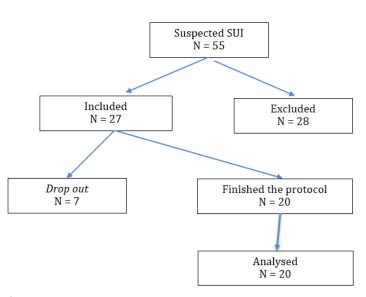


Figure 1. Flowchart of subjects recruitment

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The same therapist evaluated the improvement of the patient every two weeks by using biofeedback (Myomed 932) and every four weeks for their compliance, symptoms (UDI-6, IIQ7, and 1-hour pad test), and pelvic floor muscle strength using Myomed 932. The patients who had not come to their appointment were home-visited if possible. At last, we postponed the pad test for next week if the patient was menstruating. We evaluated their symptoms with UDI-6, IIQ-7, 1-hour pad test, and perineometer examination of the patient before PFMT (pretest) and after PFMT (posttest) for 4, 8, and 12 weeks, respectively.

We used SPSS software, version 20 for data analysis. Research data were presented in the form of a table and graph. Data (demographic data and outcome) are shown in numerical form according to the normality test results (Koglomorov-Smirnov). We analyzed the data normally distributed using paired t-test and a Wilcoxon rank test for data with nonormal distribution. We used an appropriate calculation test to determine the significance level of P<0.05 with 95% CI.

3. Results

The patients' characteristics are presented in Table 1. Most of our SUI patients were young, with the age range of 30-55 years (60%), obese (65%), and had multiple vaginal deliveries (90%). However, almost all of our patient's SUI severity was lightly based on the 1-hour pad test.

The results of UDI-6, IIQ-7, perineometer, and 1-hour pad test are presented in Tables 2 and 3. We presented a line chart to evaluate the progression of each parameter every four weeks in Figures 2-4. There was a significant decrease (P<0.05 with 95% CI) in symptoms based on UDI-6 and IIQ-7 scores at four, eight, and twelve weeks. On the other hand, the increments of pelvic floor muscle strength were only significant after eight weeks (Δ perineometer slow-twitch 7/fasttwitch 8 cmH₂O P=0.001/P=0.006 with 95% CI) and 12 weeks of pelvic floor muscle training (Δ perineometer slow-twitch 16/ fast-twitch 21 cm H₂O P=0.001/

Table 1. Demographic and physical characteristics of the subjects (n=20)

Subjects' Characteristic		No. (%)
Age group (y)	30–55	12(60)
	56–80	8(40)
	Normoweight (BMI <25)	1(5)
	Overweight (BMI 25.1-30)	6(30)
Nutritional status (BMI) (kg/m ²)	Obese (BMI >30)	13(65)
	Housewife	12(60)
Occupation	Nurses	8(40)
	Primipara	2(10)
	2-3 Children	6(30)
	≥3 Children	12(60)
Parity	Sectio caesarea	1(5)
	Vaginal delivery <2	2(10)
Delivery method	Vaginal delivery >2	17(85)
Denvery method	<2 Months	9(45)
Incontinence duration	2–5 Months	11(55)
incontinence duration	Light	19(95)
SUI severity	Moderate	1(5)

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Week	UDI-6 Score (min-max)	Р	IIQ-7 Score (min-max)	Р
Initial	50(29.1-66.6)		52.3(4.7-80.8)	
Four th weeks	33.3(12.5-50)	0.003*	33.3(4.7-61.8)	0.023*
Eight weeks	25(8.3-45.8)	0.002*	19.0(4.7-33.3)	<0.001*
Twelve weeks	8.3(0-29.1)	0.001*	4.7(0.0-28.5)	0.003*
*Significant value (P<0	()5)			ranian Rehabilitation Journal

Table 2. Treatment outcome of subjective outcome measures

*Significant value (P<0.05)

Table 3. Treatment outcome of objective outcome measures

Week —	Perineometer Value (cmH ₂ O)		Р	4 have Dad Tast	
	Slow-twitch	Fast-twitch	(Slow Twitch/Fast Twitch)	1-hour Pad Test	P (1-hour Pad Test)
Initial	23(7.0-53.0)	18.0(4.0-51.0)		4.0(3.0-11.0)	
4 th weeks	25.0(9.0-60.0)	21.0(4.0-54.0)	0.556/0.556	2.0(1.0-8.0)	<0.001*
Eight weeks	30.0(7.0– 55.0)	26(4.0-54.0)	0.001*/0.006*	2.0(0-8.0)	0.063
Twelve weeks	39.0(7.0-89)	39.0(7.0-100.0)	0.001*/0.001*	1.0(0-6.0)	<0.05*

*Significant value (P<0.05)

P=0.001 with 95% CI). The patient's 1-hour pad test results were significant after four weeks of pelvic floor muscle training (Δ pad test 2 gr, P<0.001 with 95% CI), but the improvement was not clinically significant anymore since the urine leak value was 2 g.

4. Discussion

PFMT or Kegel exercise can strengthen, control, and improve pelvic muscle coordination, preventing urinary incontinence after sudden abdominal pressure increases. Though pelvic floor muscle is the first line of treatment Iranian Rehabilitation Journal

in simple SUI, the best duration to do PFMT is still a mystery. This cohort study evaluated the SUI improvements monthly for three months with PFMT.

Most of our study participants were young (below 55 years old); however, most were overweight and had multiple parties with vaginal delivery. This finding of young participants in this study is in contrast with the study from the US that the highest prevalence of SUI was found in cases aged more than 80 years (31.7%), followed by 60-79 (23.3%), 40-59 (17.2%), and 20-39 years (6.9%) [15]. However, similar to Santoso et al.,

60.0 50.0 40.0 30.0 20.0 10.0 0.0 Initial 4 weeks 8 weeks 12 weeks UDI-6 Score 50.0 33.3 25.0 8.3 IIQ-7 Score 52.3 19 4.7 33.3

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Figure 2. Urogenital distress inventory-6 (UDI-6), incontinence impact questionnaire-7 (IIQ-7) median score progression during twelve weeks of pelvic floor muscle training (PFMT)



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Figure 3. Pad test median score progression during twelve weeks of pelvic floor muscle training (PFMT)

women under 40 had the most prevalence of pelvic floor dysfunction (PFD) in Indonesia, although, in the analysis, the age of more than 60 is one of the strongest risk factors for developing PFD [16]. In Indonesia, women had undergone multiple natural births at a younger age and had a higher BMI, which are the risk factors for developing urinary incontinence [15-17].

SUI severity was divided into three based on 1-hour pad test results, including 1-10 mg as mild, 11-50 mg as moderate, and >50 mg as severe [18]. Around 95% of our subjects had mild incontinence with less than 10 mg of urine leakage. This population is similar to other randomized controlled trials, such as those by Tsai et al. and Tosun et al., where most of their patients had mild incontinence [19, 20]. Most patients had mild incontinence since moderate or severe incontinence was related to more comorbidities and other PFD, including high-grade pelvic organ prolapse, and were excluded from the study. Subjective improvement of SUI significantly improved every four weeks evidenced by UDI-6 and IIQ-7. The SUI complaints and distress decreased from 50 to 8.3 (UDI-6 score) and 52.3 to 4.7 (IIQ-7 score) over the longer duration of Kegel exercises. The study proved that longer Kegel exercise duration positively improved the SUI subjective complaints evidenced by UDI-6 and IIQ-7 until 12 weeks. These results were similar to those by Kashanian et al. who found a significant improvement in IIQ-7 and UDI-6 scores after 4 and 12 weeks of Kegel exercises, and the study by Cavkaytar et al. that discovered a significant improvement in UDI-6 and IIQ-7 score after eight weeks of PMFT [21, 22]. Finally, subjective improvement significantly improved after four weeks of PMFT and kept increasing optimally until 12 weeks of training.

On the other hand, the objective improvement of SUI evidenced by a 1-hour pad test was unique. There was a significant improvement in the 1-hour pad test before therapy and four weeks of PMFT; however, there was

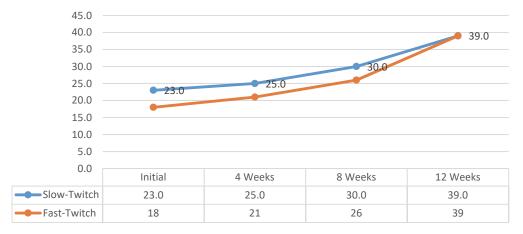


Figure 4. Perineometer median score progression during twelve weeks of PFMT

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no significant improvement after eight weeks of PMFT compared to four weeks ago. There was a decrease in pad test results after 12 weeks of Kegel training. Although it was significant statistically and clinically, it may not differ much. In this case, four weeks of Kegel exercises are enough to improve the 1-hour pad test result significantly. Nevertheless, similar to the study by Lee et al., there was a significant improvement in 1-hour pad test results after 12 weeks of Kegel exercises [23].

The SUI significantly improved after eight and twelve weeks of PFMT. This result was similar to a study by Lee et al. who found a significant improvement in pelvic floor muscle strength after 12 weeks of Kegel exercises [23]. However, other studies have found a significant improvement in pelvic floor muscle after only four weeks of training. Fernandez-Cuadros et al. discovered an improvement in pelvic floor muscle after three weeks of Kegel exercises measured by Myomed 932, and Yoon et al. found a significant improvement after four weeks of Kegel exercises measured by peritro 9300+ [24, 13]. A slow progress of pelvic floor muscle strength after four weeks of training happened because four of our subjects decreased pelvic floor muscle tone. The slow progress of muscles may be attributed to the fact that the patients were more than 60 years old and it may take more time to increase their muscle tone than their younger partners. In older women with menopause, estrogen and collagen levels decreased. Thus, the lack of estrogen may reduce muscle strength and power and induce atrophic changes [25]. Thusmuscle remodeling will take more time for younger women.5 Nevertheless, like any other striated muscle in our body, the more the patient contract the muscle, the stronger they are.

Our study still has many limitations; seven participants (25.9%) left the study. Some patients were unable to follow this PFMT regimen because of reasons, such as developing other neurological conditions (3/7), moving out further to our hospital (2/7), and refusing to continue the treatment (2/7). Lifestyle and rehabilitation treatment was unpopular and unfavorable for some women, though compliance and motivation were essential to PFMT's success [22]. Efforts were made to increase the patient knowledge, motivation, and compliance with Kegel therapies. Based on Sluijis et al. and Peek et al., some methods are related to compliance, such as extensiveness of instructions (printed out instruction), patient motivation and repeating the instructions, therapist-patient relationship, and positive feedback [26, 27]. We tried those methods to the patients, such as explaining clearly the instructions, benefits, and information about their disease and Kegel exercises, creating online social media groups

to communicate and encourage the patients, giving them a note and a book to explain Kegel exercises, and writing their daily Kegel exercise repetitions, and at last, giving positive feedback with the help of biofeedback. Moreover, we could not analyze other confounding variables because the sample size was limited.

The strength of this research was using prospective methods to observe the patients every two weeks for feedback and every four weeks to measure improvements until 12 weeks. Since the follow-up was quite intensive, we could see the disease's progression and treatment in more detail. Moreover, we reduced the bias by ensuring that only one person measured the variables. The biofeedback we used could accurately measure the strength and evaluate the muscle during the training. The books also helped us record the patient's frequency and ensure their exercises were correctly done. Future research can determine the long-term progression of pelvic floor muscle strength and how much time is required for the pelvic floor muscle to be atrophied when they stop doing exercises related to their symptoms.

5. Conclusion

SUI distress and symptoms decreased after four weeks of Kegel exercises and continued to improve until 12 weeks of therapy. However, the 1-hour pad test reached clinical and statistical significance during the first month of PMFT with no further clinical improvement. Pelvic floor muscle strength increased significantly after eight weeks of training.

Ethical Considerations

Compliance with ethical guidelines

All subjects were willing to participate and filled the informed consent. The Ethics Committee of the Faculty of Medicine Universitas Indonesia and Cipto Mangunkusumo Hospital approved the study (Code: 0233/UN2.F1/ETIK/2018).

Funding

This research did not receive any grant from funding agencies in the public, commercial, or non-profit sectors.

Authors' contributions

Conceptualization and supervision: Surahman Hakim, Ira Mistivani and Suskhan Djusad; Methodology: Suskhan Djusad, Tyas Priyatini and Budi Iman Santoso; Investigation, Writing-original draft, review & editing: David Tambunan, Fernandi Moegni, Alfa Putri Meutia and Andrew Pratama Kurniawan; Data collection: David Tambunan and Ira Mistivani; Data analysis: Budi Iman Santoso, Fernandi Moegni and Alfa Putri Meutia; Funding acquisition and resources: Surahman Hakim and Suskhan Djusad.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

All nurses and physiotherapists in Cipto Mangunkusumo Hospital are appreciated.

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