Effectiveness of Pelvic Floor Muscle Training in Incontinent Women at Maharaj Nakorn Chiang Mai Hospital: A Randomized Controlled Trial

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Objective: *To compare the effects of three different pelvic floor muscle training (PFMT) in stress urinary incontinence (SUI) women.*
Material and Method: *Sixty-eight eligible SUI women who could perform pelvic floor muscle contraction correctly were randomly allocated to the three different PFMT protocols, exercise every day (G1), exercise three days per week (G2), and exercise plus abdominal training three days per week (G3). The primary outcome was pad test. The secondary outcomes were pelvic floor muscle strength, and treatment satisfaction. The outcomes were evaluated before and after a 12-week of exercise.*
Results: *The weights of pad were decreased by 2.6 $\pm$ 0.8, 2.3 $\pm$ 1.3, and 3.1 $\pm$ 1.3 grams for group 1, 2, and 3, respectively. There was no statistical significant difference among the three groups. The pelvic floor muscle strength was increased by 18.4 $\pm$ 2.7, 13.9 $\pm$ 2.9, and 17.3 $\pm$ 3.0 cmH_2O for group 1, 2, and 3, respectively, with statistical significant difference among groups ($p < 0.00$). The increased muscle strength in group 2 was significant less than the other two groups ($p < 0.00$). Treatment Satisfaction showed the leakage was improved with non-significant difference between groups ($p > 0.05$). No complications were seen in any of the groups.*
Conclusion: *Even though the results showed non-significant decrease in pad's weight among the three training groups, the pelvic floor muscle strength were increased in all groups.*

Keywords: *Stress urinary incontinence, Pelvic floor muscle training, exercise, Quality of life*

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Stress Urinary Incontinence (SUI) is the complaint of involuntary leakage of urine that occurs with physical exertion and rise in intra-abdominal pressure. Coughing, sneezing, straining, jumping, and running are also commonly associated with leakage[1]. Dr Arnold Kegel formalized the concept of exercising the pelvic floor muscle (PFM). It can improve or eliminate the symptom of SUI and has reported a success rate of 84% in 1948[2,3]. Since then, many techniques of PFM rehabilitation have been introduced. In general, it has been proved effective, low cost, and without significant adverse effects. It is the least invasive and safest therapies that should be considered as the first line of treatment for urinary incontinence. During PFM contraction, the urethra will be pressed against the pubic symphysis, producing a mechanical pressure rise, which plays a role in the maintenance of continence[4-7]. Pelvic floor muscle training (PFMT) is the exercise by training muscle contraction and relaxation following the principles of the American College of Sport Medicine (ACSM). The recommendations for effective strength training for general skeletal muscle are 8-12 slow velocity maximum contraction, 3-4 series, 3-4 times a week, recommends the exercise period to be a minimum of 15-20 weeks[8]. PFMT leads to hypertrophy of muscle fibers, enhanced cortical awareness of muscle groups, strengthening of connective tissue in the muscles, and more effective

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recruitment of active motor neurons. It is suggested that increasing the power and tone of the pelvic floor leads to a permanent elevation of the levator plate to a higher resting position inside the pelvis, "lifting" the pelvic viscera and restoring normal reflex activity and other protective continence mechanisms[9]. In a study of prospective observation, it found PFMT and behavioral modification resulted in significant elevation of the bladder neck position in all three positions and reduced displacement of the bladder neck on valsalva after treatment[10]. However, recent evidence revealed that specific abdominal exercises could effectively activate PFM in healthy subjects[6-10]. It is considered that abdominal muscle contraction could increase bladder pressure and aggravate urinary incontinence or bulge the perineum caudally. Thus, a rehabilitation program generally relies on isolated cognitive maximum pelvic floor muscle contraction to improve muscle strength and to counteract increases in IAP. Strength training may increase muscular volume, forming a structural support for the bladder and the urethra, and it may be postulated that fast and strong PFM contraction during increased abdominal pressure can prevent urethra descent[11]. Furthermore, increasing of intra-abdominal pressure can affects urinary leakage and can increase the hypertrophy according strong PFM contraction. Previous reports showed that co-contraction of the abdominal muscle (lower transverses abdominis and internal oblique) during attempts of a correction with maximum contraction or near-maximum PFM contraction is important to achieve the best training effect[6,9]. If the subject does the pelvic floor muscle exercise plus abdominal muscle training, the PFM should be stronger than doing PFMT alone. Less evidence has shown that the effectiveness of PFM plus abdominal muscle exercise in SUI women. The aim of the present study was to find the optimum PFMT in SUI women to increase the strength in order to reduce the leakage.

Material and Method

Subjects were recruited from the outpatient clinic Department of Obstetrics and Gynecology, Maharaj Nakorn Chiang Mai Hospital, Faculty of Medicine, Chiang Mai University, between July 2008 and August 2009. Eligible criteria were each of the following: (i) age 35-65 years, (ii) had SUI screen by International Consultation on Incontinence Questionnaire (ICIQ-SF)[12,13], frequency volume chart for three days, physical examination, and positive in cough stress test, pad test weight more than 2 grams, and (iii)signed consent form. All subjects met gynecologist for physical assessment and urine analysis to rule out urinary tract infection. The criteria of exclusion were prolapsed of uterus, reversible cause of urinary incontinence (*e.g.* fecal impaction, drug effect), uncontrolled metabolic condition (*e.g.* diabetes mellitus), serious chronic condition that may result in neurogenic bladder dysfunction, residual urine > 100 mL, urinary tract infection, genitor urinary fistula, previous surgery for SUI, inability to correctly perform a pelvic muscle contraction on digital examination, neurological disease that resulted in combination of bladder and sphincter dysfunction[4].

After doing pelvic floor muscle exercise correctly, the subjects were randomly allocated into each of three treatment arms using block randomized allocation with block sizes of 3, 6 and 9 enclosed in envelopes. Participants were asked to perform maximum PFM contractions. Each contraction, holding for 6-8 seconds, then added 6-8 fast contractions, rest period was 6-8 seconds. Eight to 12 contractions were completed in one session of exercise.

Participants aimed at with maximal contraction effort encouraged[4]. Group 1 was encouraged to exercise three sessions daily. Group 2 was encouraged to have three sessions daily and three days a week. Group 3 was encouraged to do PFM plus abdominal contraction three sessions daily and three days a week. Participants needed to do the PFMT as in the assigned group and recorded in the log sheet for 12-weeks. To increase compliance, participants needed to come back to the hospital with the complete log sheet and get new logsheet every month. The present study used telephone calls to confirm the appointment and gave an appointment on the same day that the subject had to come to the hospital. If postponed, a new appointment was given within a week. They also advised to stick the log sheet at a place where they can see clearly every day or find a symbol that can remind them to do the exercise. The present study was approved by the ethical committee of the Faculty of Medicine, Chiang Mai University.

Outcome measures

Primary outcome was a weight of urine that was measured before and after a standard one hour pad test[14,1] with a sanitary pad (Carefree, super dry, Thailand) contained in a plastic zipped bag (size 7 x 11 inch), by digital scale (GF-300, Diethelm Limited, Japan). Pad test procedure composed of wearing the pre-weighted pad and drinking fresh water (500 ml)

(while resting for 15 min), walking (30 min), 10 repetitive of sit-to-stand and powerful coughing, jogging on the spot for one min, 5 repetitive picking an object off the floor, and washing hands within one minute, finally the pad was removed and sealed within the plastic zipped bag for reweighting. All subjects were voided and the urine volume was measured.

Secondary outcomes were pelvic floor muscle strength (PFMS), and Treatment satisfaction. The pelvic floor muscle strength and exercise was done and measured by an investigator using a perineometer (peritron cat 9300v, Cardio Design, Australia). The probe with rubber-coated, un-inflated transducer covered with a condom and collar, was inserted (about 3-3.5 cm) into the vagina introitus. Then, the transducer was inflated 100 cm H_2O and the apparatus was set to zero. The patient was asked to perform maximum contraction of the pelvic floor muscle as strong and as long as possible. This contraction was repeated three times at an interval of 3-5 minutes to avoid fatigue. At the same time, the patient was observed relaxing their abdomen, buttock, and inward movement of the perineum muscle. At the end of training, subjects rated their satisfaction of incontinence condition on a 5 point scale (1 = worse, 2 = unchanged, 3 = improved, 4 = almost continent and 5 = continent)[4].

Data analysis

A sample size per group was estimated to detect a difference of 1 SD of weight of the pad test among the three groups with 80% power of the test and alpha level of 0.05[4]. The sample size needed in the study using a pre-constructed table by Alan (Alan Phillips. 1998)[15], each group was 23. Pad test weight gain and pelvic floor muscle strength were analyzed by using ANOVA and treatment satisfaction by Kruskal-Wallis test. Bonferronni was used for the post hoc comparison. The analysis followed the intention to treat principle. A p-value of less than 0.05 was considered statistically significant.

Results

Three hundred sixty nine women answered the ICIQ-SF questionnaires. One hundred and seventy eight women (48.24%) were incontinent, 101 were excluded according to various reasons as presented in Fig. 1. Finally, sixty-eight subjects signed the consent forms and were randomly allocated into three groups according to pre-arranged balance block randomization to receive PFMT. Twenty-three subjects were randomly selected to Group 1, twenty-two subjects in Group 2, and Group 3 was composed of twenty-three subjects. Some participants dropped out due to various reasons (Fig. 1). Finally, 60 subjects completed the PFMT program, Group 1, 2, and 3 were 20, 19, and 21 respectively.

The baseline characteristics were similar among the three groups at entry (Table 1). After 12 weeks, weights of pad test decreased 2.6 ± 0.8, 2.3 ± 1.3, and 3.1 ± 1.3 grams for group 1, 2, and 3, respectively, from baseline. There was no significant difference of the decreases among the three groups (Table 2). Pelvic floor muscle strength (PFMS) were 18.4 ± 2.7, 13.9 ± 2.9, and 17.3 ± 3.0 cmH_2O for Group 1, 2, and 3 respectively. The increase in muscle strength was statistically significant between groups ($p < 0.00$). The multiple comparison found significant difference only in Group 1 vs. Group 2 and Group 2 vs. Group 3 ($p < 0.00$). Treatment satisfaction is shown in Table 3. Participants rated improvement at 5%, 10.5%, and 4.8% in group 1, 2, and 3 respectively. Almost continent were 75.0%, 68.4%, and 66.7% for group 1, 2, and 3 respectively. Continence were 20.0%, 21.2%, and 28.6% in group 1, 2, and 3. There was no statistical difference among the three groups.

Discussion

The results showed a decrease in weight of the pad test, increase in pelvic floor muscle strength (PFMS), and improved treatment satisfaction. However, statistical difference of improvement was found only in pelvic floor muscle strength between groups. The presented findings were comparable to previous studies[15,16], in comparing PFMT with other pelvic floor exercise the result found no significant difference, but in comparing PFMT with control, the result found both significant difference within groups and among groups. The present study found increase in all three groups, but significantly more increase in Group 1 and Group 3 than Group 2. Thus, the intensity of the contraction and frequency of training seem to be the most important factors in both building up and maintaining muscle strength. In Group 3, intensity of contraction from exercise three days a week are stronger due to forcefully contracted abdominal muscles from transversus abdominis (TrA) and internal obliques, which increase the urethral pressure as much as maximum pelvic floor contraction[6]. The PFMS between Group 1 and Group 3 was not different. The more the strength of PFM increase the more decrease of the leakage. The weight of the pad decreased. Even though the present study was unable to detect

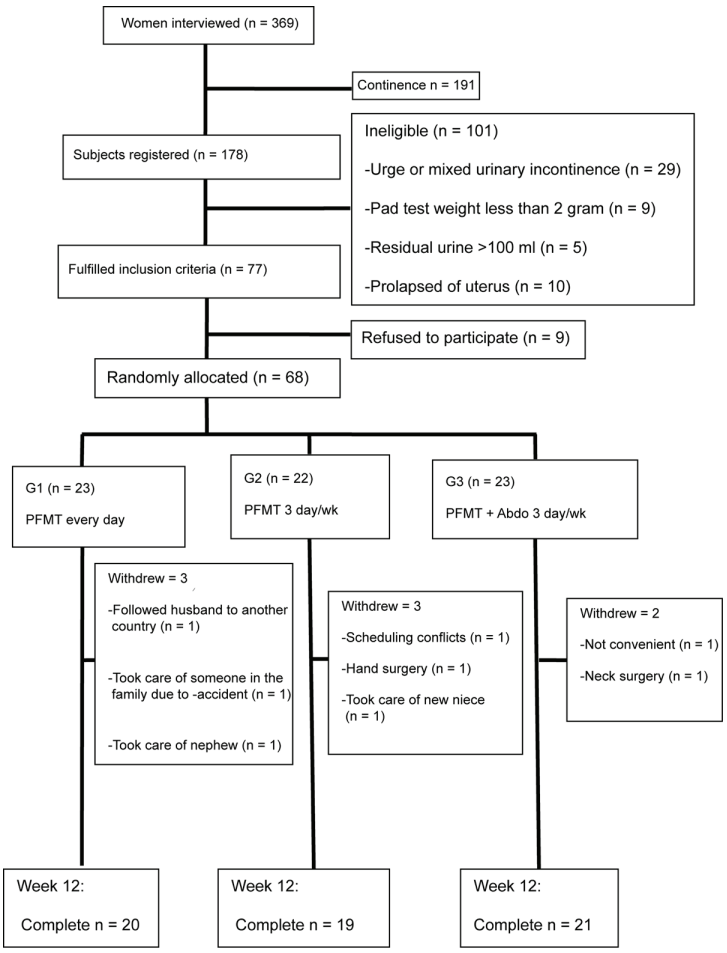

Fig. 1 Flow diagram of recruitments of subjects at each stage among the three groups

significant difference between different intensity of exercise, the exercise could improve the strength and the leakage. The reasons can be explained. Firstly, the authors' did not include control group (no exercise), so the pelvic floor muscles increased in all groups with slightly different magnitudes. Secondly, the exercise period of 12 weeks may be too short and the subjects might still comply well with the exercise. If the leakage was less and women did not do the exercise continuously, the SUI might recur. Future study needs to include a control group of non-exercise to determine whether continued exercise is necessary and the critical exercise intensity threshold needed to sustain the benefits of PFMT beyond 12 months. The authors used treatment satisfaction as self-reported to measure the outcome. The present finding was comparable to a previous study[4].

Although the result of PFM exercise in group 2 was increased in muscle strength, it was significantly less than the other two groups. However, all protocols slightly improved PFM strength. The present study indicates that the PFM training program can be applied in SUI women to prevent the leakage. Good benefit of PFM training program can be applied in SUI women with a specific type of the contraction, intensity and duration of the exercise.

The limitation of the present study

Urodynamic study was not done in most of the participants. In Thailand, it is costly and much effort is needed to do the urodynamic study. The authors used other standard routine for screening SUI women and did not blind outcome assessor according to a limited number of skilled staff in measuring the

Table 1. Baseline characteristics among the three groups

Factors	Group 1 n = 20 (%)	Group 2 n = 19 (%)	Group 3 n = 21 (%)
Age (year)*; mean ± SD	51.4 ± 6.1	51.5 ± 6.6	53.8 ± 5.6
Weight (Kg) *	56.8 ± 6.2	57.4 ± 7.4	58.3 ± 3.6
Height (cm) *	155.8 ± 4.6	155.3 ± 4.6	155.6 ± 6.1
BMI (Kg/m^2)*	23.5 ± 3.1	23.8 ± 2.7	24.1 ± 1.8
Marital status			
Married	18 (90.0)	17 (89.5)	19 (90.5)
Widow/divorce	-	2 (10.5)	1 (4.8)
Single	2 (10.0)	0	1 (4.8)
Occupation			
Official/retired	8 (40.0)	14 (73.7)	14 (66.7)
House wife	4 (20.0)	1 (5.3)	2 (9.5)
Merchant	3 (15.0)	1 (5.3)	3 (14.3)
Labor	5 (25.0)	3 (15.8)	2 (9.5)
Number of baby			
Nulliparous	3 (15.0)	2 (10.5)	2 (9.5)
One	3 (15.0)	5 (26.3)	3 (14.3)
Two	9 (45.0)	12 (63.2)	11 (52.4)
Three	4 (20.0)	-	4 (19.0)
Four	1 (5.0)	-	-
Five	-	-	1 (4.8)
Weight of the baby			
Nulliparous	3 (15.0)	2 (10.5)	2 (10.0)
Weight less than 2500	1 (5.0)	-	1 (5.0)
Weight among 2500-3500	11(55.0)	12 (63.2)	11 (55.0)
Weight more than 3500	5 (25.0)	5 (26.3)	6 (30.0)
Labor			
Nulliparous	3 (15.0)	2 (10.5)	2 (9.5)
Normal labor	15 (75.0)	13 (68.4)	16 (76.2)
Caesarian section	2 (10.0)	4 (21.1)	3 (14.3)
Menopause			
No	5 (25.0)	2 (10.5)	2 (9.5)
Yes	15 (75.0)	17 (89.5)	19 (90.5)

* Data shown in mean and standard deviation

Table 2. Outcome measures at baseline, 12 weeks and their changes among the three groups

Factors	Group 1 (n = 20)	Group 2 (n = 19)	Group 3 (n = 21)
Weight pad test pre (g)	4.0 ± 0.9	4.0 ± 1.5	4.7 ± 1.6
Weight pad test post (g)	1.4 ± 0.7	1.7 ± 0.7	1.6 ± 0.8
Δ weight pad (g) (95%CI)	2.6 ± 0.8 (-7,1.2)	2.3 ± 1.3 (-1.4,0.4)	3.1 ± 1.3 (-1.6,0.2)
PFMS pre (cmH_2O)	29.0 ± 10.2	28.7 ± 13.1	29.0 ± 7.4
PFMS post (cmH_2O)	47.4 ± 9.6	42.6 ± 12.4	46.3 ± 8.2
Δ PFMS (cmH_2O) (95%CI)	18.4 ± 2.7 (2.3,6.8)*[1]	13.9 ± 2.9 (-1.1,3.3)	17.3 ± 3.0 (-5.7,-1.2)*[1]

* Significant different between groups; p = 0.00

[1] Post hoc analysis with Bonferronni correction revealed significantly different only between G1 vs. G2, G2 vs. G3 at p = 0.00

Table 3. Compared participant's condition of SUI at the end of PFMT program among three groups

Outcome	G1 (n = 19)	G2 (n = 21)	G3 (n = 21)	p-value
Treatment satisfaction				
Worse				
Unchanged				
Improved	1 (5.0)	2 (10.5)	1 (4.8)	0.7
Almost continent	15 (75.0)	13 (68.4)	14 (66.7)	
Continent	4 (20.0)	4 (21.2)	6 (28.6)	

Comparison among three groups using Kruskal-Wallis test; significant $p < 0.05$

muscle strength. The dropout rate in the present study was quite high according to Thai culture, some subjects refused to participate because of shyness. Some participants may have agreed to participate because of the extent of their problems, which affected their quality of life. For outcome measurement on subjective assessment, it would be better if other person collected this information instead of the author.

The success of increased muscle strength is by doing continuous exercise. The difficulty is assessing true compliance of the treatment, which is essential to ensure successful rehabilitation. Monitoring the compliance and follow-up is the limitation of research investigating at home therapy interventions. There is little evidence of various type of pelvic floor exercise in Thailand. The present study suggests that pelvic floor exercise at home is beneficial to women with SUI.

According to women who forgot to do the exercise, or might not comply well, the next study should include one set of exercise per day for every day and measure whether the exercise can increase strength or maintain strength. It would be clearer, if there could be a different type of study or medical tools that can measure the muscle strength or visualized the contraction directly, such as computerize scan, electromyography, ultrasound, and magnetic resonance imaging (MRI).

Conclusion

The results show that the three protocols of PFMT can increase the muscle strength and decrease the leakage, but there is no significant difference in decreased weight of the pad test among three exercise protocols. However, the success of PFM exercise depends on the patients performing the exercises correctly, with motivation, and finally long-term follow-up to ensure adherence of exercise.

Potential conflict of interest

None.

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ผลการออกกำลังกล้ามเนื้ออุ้งเชิงกรานในสตรีที่มีภาวะปัสสาวะเล็ดในโรงพยาบาลมหาราชนครเชียงใหม่

ธัญลักษณ์ ศรีบุญเรือง, สุปรียา วงษ์ตระหง่าน, วิชัย อึงพินิจพงศ์, มาลินี เหล่าไพบูลย์

การรักษาภาวะปัสสาวะเล็ดโดยการออกกำลังกล้ามเนื้ออุ้งเชิงกรานในสตรีเป็นที่นิยม แต่วิธีการที่ให้ประสิทธิผลสูงยังไม่เป็นที่ทราบแน่ชัด การศึกษานี้มีวัตถุประสงค์เพื่อประเมินประสิทธิผลของวิธีการบริหารกล้ามเนื้ออุ้งเชิงกรานที่ให้ความแข็งแรงสูงสุด โดยเปรียบเทียบวิธีบริหารกล้ามเนื้ออุ้งเชิงกราน 3 แบบ คือ 1) บริหารทุกวัน 2) บริหารสามวันต่อสัปดาห์ 3) บริหารกล้ามเนื้ออุ้งเชิงกราน ร่วมกับกล้ามเนื้อท้องสามวันต่อสัปดาห์ สตรีกลุ่มตัวอย่างที่มีปัสสาวะเล็ด ผ่านเกณฑ์คัดเข้า-คัดออก และสามารถบริหารได้ถูกต้อง 68 คน จับสลากสุ่มเพื่อเข้ากลุ่มบริหารระยะเวลา 3 เดือน ตัวแปรหลักคือน้ำหนักปัสสาวะเล็ด ตัวแปรรองคือความแข็งแรงของกล้ามเนื้ออุ้งเชิงกรานและความพึงพอใจหลังการบริหารโดยการวัดก่อนและหลังการบริหาร 12 สัปดาห์ ผลการศึกษาพบว่า น้ำหนักปัสสาวะเล็ดลดลง 2.6 $\pm$ 0.8, 2.3 $\pm$ 1.3 และ 3.1 $\pm$ 1.3 กรัม ในกลุ่มที่ 1, 2 และ 3 ตามลำดับ แต่พบว่า ความแตกต่างไม่มีนัยสำคัญทางสถิติ ($p > 0.05$) ความแข็งแรงของกล้ามเนื้ออุ้งเชิงกรานเพิ่มขึ้นทั้งในกลุ่มที่ 1, 2 และ 3 คือ 18.4 $\pm$ 2.7, 13.9 $\pm$ 2.9, 17.3 $\pm$ 3.0 เซนติเมตรน้ำ ตามลำดับ และความแข็งแรงของกล้ามเนื้ออุ้งเชิงกรานที่เพิ่มขึ้นในกลุ่มที่ 2 น้อยกว่ากลุ่มที่ 1 และ 3 อย่างมีนัยสำคัญทางสถิติ ($p < 0.00$) ด้านความพึงพอใจหลังการบริหารทั้งสามกลุ่ม มีความแตกต่างอย่างไม่มีนัยสำคัญทางสถิติ ในการศึกษานี้ไม่พบอาการข้างเคียงที่เกิดจากการบริหารกล้ามเนื้ออุ้งเชิงกราน โดยสรุปถึงแม้ว่าการศึกษานี้พบความแตกต่างทั้งสามกลุ่ม อย่างไม่มีนัยสำคัญทางสถิติในน้ำหนักปัสสาวะเล็ด แต่ภายหลังการบริหารทั้งสามกลุ่มสามารถเพิ่มความแข็งแรงของกล้ามเนื้ออุ้งเชิงกรานได้ จึงทำให้ปัสสาวะเล็ดลดลง ทั้งสามกลุ่มมีความพึงพอใจหลังการบริหารไม่แตกต่างกัน