Rectal Balloon Training as an Adjunctive Method for Pelvic Floor Muscle Training in Conservative Management of Stress Urinary Incontinence: A Pilot Study

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Background: *Pelvic floor muscle training (PFMT) is currently considered as the first line conservative management for women with stress urinary incontinence (SUI). However, it is difficult for some women to self-identify the contraction of the pelvic floor muscle after they were trained by verbal instruction. Various techniques including rectal balloon probe have been developed to improve PFMT.*
Objective: *To compare vaginal squeezing pressure, one-hour pad test, leakage episodes, rating scores about severity of SUI, and patient satisfaction between traditional PFMT and rectal balloon training (RBT).*
Material and Method: *Twenty-eight patients with SUI were randomized into two groups, PFMT, and RBT groups. The PFMT group was verbally instructed to perform exercise as the traditional technique. In the RBT group, a Foley catheter filled with tap water to create balloon was inserted into the rectum in combination with the same exercise as in the PFMT group. The vaginal squeezing pressure before and after 6-week exercise program was measured by biofeedback machine model MYO420.*
Results: *One patient in each group was lost to follow-up . This left 13 patients in each group. Both groups had statistically significant gained in vaginal squeezing pressure after exercise. The different pressure between pre and post exercise were 9.9 mmHg and 9.2 mmHg in PFMT and RBT group respectively ($p = 0.84$). Significant improvement of leakage episodes and self-rating scores assessed the severity of SUI after exercise was reported in both groups, although there was no significant difference between both groups. The number of patients wearing protection after exercise was lowered in both groups, which were 75% in PFMT group and 80% in RBT group. However, satisfaction was greater after completing exercise in both groups.*
Conclusion: *PFMT is an effective conservative treatment of SUI. PFMT combined with rectal balloon training did not provide greater strength of the pelvic floor muscle than isometric contraction.*

Keywords: *Pelvic floor muscle training, Rectal balloon, Stress urinary incontinence*

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Female stress urinary incontinence (SUI) is one of the worldwide problems that affect the quality of life[1,2]. This problem also has high prevalence among Thai women[2-5]. Loss of urethral support from damage or weakness of the endopelvic fascia and the pelvic floor muscles is the main pathophysiology of SUI. Women treated with pelvic floor muscle training (PFMT) reported that they have improvement of SUI[6,7]. Although PFMT had low to moderate level of evidence support of its effectiveness, it is currently considered as the first line conservative management for women having SUI[6,7]. PFMT could improve the strength of the pelvic floor muscles and endurance as well as co-ordination of muscle contraction when rising in intra-abdominal pressure[7]. These outcomes could prevent urinary leakage. Although PFMT is considered as an effective program, it is difficult for some patients to self-identify of pelvic floor muscle contraction. PFMT is usually conducted by verbal instruction, as this results, up to half of them are unable to correctly contract their pelvic floor muscle[8]. Therefore, various techniques including weighted

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vaginal cone, biofeedback, and electrical stimulation have been developed to improve PFMT[9-15].

Weighted vaginal cone was introduced as the self-treatment method to lessen reliance on therapist and hospital visiting. Action of vaginal cone is a self-perceiving and also self-feedback of pelvic floor muscle contraction[10]. Moreover, weighted vaginal cone are used as resistance training exercise by increasing in weight of cone. It is considered to be equally as effective as PFMT. However, its clinical applicability is limited in long-term use due to low patient's compliance[10]. Moreover, some women may be uncomfortable inserting the vaginal cones especially sexually inactive or nulliparous women.

De Paepe et al used anal-plug EMG biofeedback to train the pelvic floor muscles in young children with dysfunctional voiding and obstipation. The present study experienced that PFMT with anal-plug EMG biofeedback as the combination therapy could improve urological symptoms and encopresis in young children[16]. Whitehead et al used rectal balloon probe as the EMG biofeedback to train the anal external sphincter and other perianal muscles and augment this muscle strength in the elderly with fecal incontinence. This sphincter exercise under biofeedback significantly reduced the frequency of fecal incontinence[17]. Before starting the protocol, the authors did the survey among the 405 women who had visited the gynecology clinic. One hundred four women (25.1%) reported more favor on the rectal device than vaginal device. All of these women were sexually inactive, had recurrent vaginal infection and concomitant fecal incontinence (unpublished data). As a result, PFMT with rectal balloon might be helpful in particular patients.

According to De Paepe and Whitehead's findings, the authors hypothesized that using the rectal balloon could help women with SUI to recognize the pelvic floor muscle contraction as self-feedback and to improve their exercise. Furthermore, up to our knowledge, there was limited data on PFMT with rectal balloon in women with SUI. Therefore, the present study aimed to compare pelvic floor muscle strength and clinical outcomes between PFMT and PFMT with rectal balloon among these patients.

Material and Method

A two-armed controlled, non-blind clinical trial was conducted in patients with SUI. This trial is carried out at the King Chulalongkorn Memorial Hospital between November 1, 2010 and November 1, 2011. Quasi randomization determined by order of sign in protocol was generated to allocate patients into two groups, which were the PFMT group and the Rectal Balloon Training (RBT) group. Inclusion criteria were women aged between 25 and 70 years, diagnosed with SUI, able to follow commands and able to participate in the protocol. Patients with the following conditions would be excluded which were mixed urinary incontinence (MUI) that was defined as a combination of SUI and urgency urinary incontinence (UUI), previously received a surgical treatment of SUI, received medication alleviating symptoms within 3 weeks, impaired either recent or recall memory, central nervous system disorders, urinary tract infection, anorectal disease, pelvic organ prolapse, rectal prolapse, previous pelvic trauma, pregnant, and postpartum women. Knowledge about SUI and the anatomy of the pelvic floor were initially introduced to all enrolled patients.

The PFMT group was verbally instructed to follow a daily exercise program in standing position. The six-week exercise program was taught as vaginal squeezing concomitant with abdominal muscle contraction. One treatment session started with a series of 15 single maximum contractions, which was sustained for 5 seconds followed by a series of 15 single fast contractions. One cycle is repeated three times and 10 seconds of rest is allowed between cycles[12,13,18]. Both groups were instructed to perform three sessions per day and continue the exercise every day. The RBT group performed the same exercise as the PFMT group. In addition, a Foley catheter was self-inserted into the rectum during exercise and self-removed after completing exercise. The patients were instructed to know the landmark of Foley catheter Lubricated gel was used during catheter insertion. The 5 centimeters length of catheter insertion was ensured that the balloon was located in the rectum. Tap water was infused after catheter insertion and was released before catheter removal. Tap water was infused to fill up the balloon. The volume was started at 10 ml in the first and second week then progressed to 15 ml in the third and fourth week to 20 ml in fifth and sixth week. The patients were supervised by the first author at the first visit aiming to reassure that the patients could do it correctly. After that, patients had to continue the exercise by themselves at home.

Patients were followed at the fourth and sixth week after exercise. Patient would be followed-up for compliance of the exercise in the fourth week. The assessment after the exercise would be performed at the sixth week. All patients were asked to record their

exercise in their daily logs. They were recorded as the date, frequency, duration, and amount of the exercise. If the patients did the exercise incompletely as instructed, it would be considered as skipped exercise. The patients who did not perform exercise, skipped the exercise more than eight days in the 6-week program (less than 80%), or were lost to follow-up would be considered as a drop out. All adverse events were also recorded.

The primary outcome was vaginal squeezing pressure measured by biofeedback machine model MYO420 in units of mmHg (Fig. 1). All patients performed vaginal squeezing three times; afterwards the best one was recorded. The vaginal squeezing pressure was measured in two sessions, before and after the 6-week exercise program. The secondary outcomes were one-hour pad test, leakage episodes in one week, rating scores about quantity of urine leakage, incontinence severity, discomfort due to incontinence, discomfort due to wearing protection, and patient satisfaction. Scores were scaled as one to five levels (1, no problem; 2, a bit of problem; 3, quite a problem; 4, serious problem; and 5, very serious problem)[11]. The study protocol was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University.

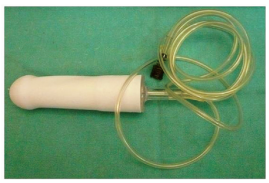
Statistical analysis

The data was analyzed by using SPSS program version 17.0. Vaginal squeezing pressure was compared between before and after 6-week exercise program in each group by using paired t-test and compared between two groups by using the unpaired t-test. Demographic data, as categorical data, and continuous data was analyzed by Chi-square or Fisher's exact and unpaired t-test, respectively. Non-parametric data was analyzed by using Mann-Whitney U test. Secondary outcomes were compared between before and after 6-week exercise program in each group by using paired t-test and Wilcoxon signed rank test if it was parametric and non-parametric data, respectively. In addition, comparison between

Foley catheter with tap water filled syringe | After 10 ml tap water infused into foley catheter | After 20 ml tap water infused into foley catheter

Fig. 1 Rectal balloon was applied by Foley catheter with tap water filled syringes

Biofeedback machine Model MYO 420



Pressure feedback by mean of vaginal pressure probe

Fig. 2 Vaginal squeezing pressure was measured by bio-feedback machine and vaginal pressure probe

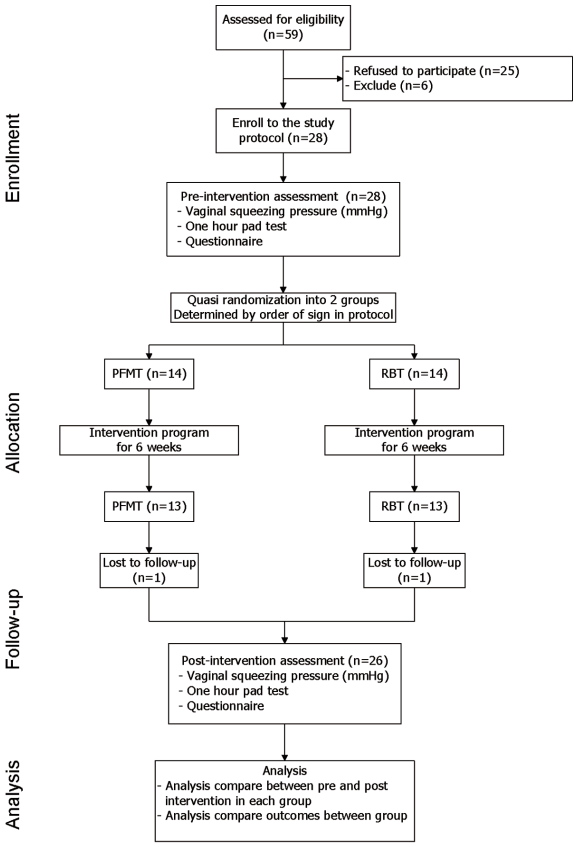


Fig. 3 Flowchart showing patients progression through the study

two groups was done by unpaired t-test and Mann-Whitney U test. Level of statistical significance was determined at p-value of less than 0.05.

Results

Fifty-nine patients with SUI were referred from gynecologists to the Department of Rehabilitation Medicine. However, 28 patients were eligible to the protocol. Thirty-one patients were excluded due to their refusal to join the protocol (25 cases), urinary tract infection (4 cases) and previously receiving surgical treatment for SUI (2 cases). For patients who refused to join the protocol, all of them informed that they were not available due to their work. Eligible patients were equally randomized into PFMT and RBT group. After the 6-week exercise program, only one patient in each group lost to follow-up . Therefore, 13 patients remained in each group.

Of all 26 patients, the mean age and body mass index (BMI) was 49.6 years and 24.4 kg/m^2, respectively. The patients aged between 30 years to 64 years. Most patients had history of at least one vaginal delivery (61.5%). The median parity was 1 in the PFMT group and 2 in RBT group (p = 0.43). About two-thirds of patients (69.2%) were physically fit. No patients had a history of chronic cough and pelvic trauma. Chronic constipation was reported in only one patient in the RBT group. The baseline characteristics were analyzed and did not show any significant difference between both groups (Table 1). After the exercise program, all patients had statistically significant gained in vaginal squeezing pressure. However, the vaginal squeezing pressure was statistically indifferent between both groups (Table 2). Only one patient in each group had positive result for one-hour pad test, 6 and 4 grams in the PFMT and RBT group, respectively. After the exercise, both of them had a negative result for the one-hour pad test. Significant improvement of leakage episodes and self-rating scores assessed about the severity of SUI after exercise was reported in both groups, although there was no significant difference between the two groups. The number of patients wearing protection after the exercise was lowered in both groups. In the PFMT group, four patients used wearing protection before exercise and only one patient remained after exercise (75% improvement). For RBT group, ten patients used wearing protection before exercise and reduced to two patients after exercise was (80% improvement). Moreover, the RBT group had significant improvement in the rating scores of discomfort due to wearing protection whereas the PFMT group did not (Table 3). The patient's satisfaction was greater after completing exercise in both groups.

The compliance of exercise in both groups was more than 80% and considered as good adherence to the program. All participants stated that they felt good for the assigned exercise program and would recommended it to their friends who having SUI. In terms of adverse events, there was only one patient in the RBT group who felt uncomfortable in the rectal area during exercise in the earlier sessions. However, this uncomfortable feeling disappeared after performing exercise for several times.

Discussion

The present study found that rectal balloon-assisted PFMT is not superior to the traditional PFMT. In the present study, both PFMT and RBT groups had significant increase in the strength of the pelvic floor

Table 1. Baseline demographic data between PFMT and RBT groups

	PFMT (n = 13)	RBT (n = 13)	p-value
Mean age, years (SD)	49.2 (9.5)	49.9 (7.7)	0.84[a]
Mean BMI, km/m^2 (SD)	23.9 (3.7)	25.0 (4.7)	0.50[a]
Menopause, n (%)	5 (38.46)	5 (38.46)	1.00[b]
Median parity, (range)	1 (0-4)	2 (0-3)	0.43[c]
Median duration of incontinence symptoms, months (range)	24 (12-96)	24 (1-240)	0.32[c]
History of vaginal delivery, n (%)	7 (53.9)	9 (69.2)	0.69[b]
Concomitant underlying disease, n (%)	2 (15.4)	6 (46.2)	0.20[d]
Chronic constipation, n (%)	0	1 (7.7)	1.00[d]
Wearing protection, n (%)	4 (30.8)	10 (76.9)	0.05[b]

p-value by [a] Unpaired-t test, [b] Chi-square test, [c] Mann-Whitney U-test, [d] Fisher's exact test

Table 2. Primary outcome: vaginal squeezing pressure

Vaginal squeezing pressure (mmHg)	Mean (SD)		Difference between groups	p-value between groups
	PFMT	RBT		
Before exercise	14.7 (5.8)	15.2 (10.5)	0.50 (12.3)	0.88
After 6-week exercise	24.6 (9.1)	24.4 (11.0)	-0.12 (15.4)	0.97
Difference between before and after in same group	9.9 (6.4)*	9.2 (9.5)*	0.70 (12.2)	0.84

* $p < 0.05$ by paired t-test
p-value between groups by unpaired t-test

Table 3. Secondary outcomes: change in incontinence severity and patient's satisfaction

	PFMT		RBT		p-value between groups
	Median (range)	p-value	Median (range)	p-value	
Leakage episodes					
Pre	2 (1-9)	0.002*	2 (1-6)	0.001*	0.35
Post	0 (0-2)		1 (0-3)		0.20
Quantity of urine leakage					
Pre	2 (1-4)	0.011*	2 (1-5)	0.004*	0.11
Post	1 (1-2)		1 (1-2)		0.63
Incontinence severity					
Pre	2 (1-4)	0.011*	2 (1-5)	0.004*	0.10
Post	1 (1-2)		1 (1-2)		0.36
Discomfort due to incontinence					
Pre	2 (1-4)	0.011*	2 (1-5)	0.006*	0.19
Post	1 (1-2)		1 (1-2)		1.00
Discomfort due to wearing protection					
Pre	1 (1-4)	0.102	1 (1-4)	0.039*	0.63
Post	1 (1-2)		1 (1-2)		1.00
Patient satisfaction					
Pre	3 (1-4)	0.001*	3 (1-4)	0.014*	0.80
Post	4 (3-5)		4 (1-5)		0.28

*$p < 0.05$ by Wilcoxon signed rank test
p-value between groups by Mann-Whitney U-test

muscles after exercise, which was measured by vaginal squeezing pressure. However, there was no significant difference in vaginal squeezing pressure between both groups. The similar findings were also found in clinical outcomes. This finding was correlated with the results from previous studies, which reported that weighted vaginal cone had no additional benefit compared to the conventional PFMT[9,14].

PFMT is effective and should be offered as the first line treatment for SUI. Correct PFMT could increase pelvic floor muscle strength and decrease urinary leakage[19]. Hence, supervised and more intensive training is more effective than the unsupervised ones[19,20]. Assisted PFMT by various devices including weighted vaginal cone, rectal balloon, and electrical stimulation were studied[13,15,20,21]. These devices mediate self-biofeedback, which may provide benefit in addition to PFMT in women with UI[10]. Due to limitation of weighted vaginal cone as above, the authors looked for more alternative devices. The efficacy of the rectal balloon in the treatment of fecal incontinence has been reported[20]. However, regarding our knowledge on the training of rectal balloon for SUI, there was limited data.

The limitations in the present study were small sample size and short evaluation time. Therefore, it may be a pilot study and give the useful information that PFMT with rectal balloon may not have an

additional benefit. Although, a six-week period may be inadequate to improve the strength of the pelvic floor muscles, all patients had significantly increase in the strength of the pelvic floor muscle which was indirectly measured by vaginal squeezing pressure. Furthermore, all of them had improvement of SUI symptom in terms of self-rating scores for their incontinence problem. Furthermore, high refusal rate for joining the protocol is a major concern. Many patients may feel uncomfortable to insert any device into their rectum or the measurement of vaginal squeezing pressure required probe inserted into the vagina.

In conclusion, rectal balloon training did not provide greater strength of the pelvic floor muscles than traditional PFMT. However, pelvic floor muscle strength was better after six weeks of exercise in both groups. PFMT is an effective conservative treatment without serious adverse effects.

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Potential conflicts of interest

None.

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การใช้ลูกโป่งทางทวารหนักร่วมกับการฝึกบริหารกล้ามเนื้อในอุ้งเชิงกรานสำหรับการรักษาภาวะปัสสาวะเล็ดเวลาไอหรือจาม: การศึกษานำร่อง

สุจิรา รุ่งศิริแสงรัตน์, สริสสา แรงกล้า, ธาริณี แม่นชนะ, ณัฏฐิยา ตันติศิริวัฒน์

ภูมิหลัง: *ปัจจุบันการฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานถือเป็นการรักษาลำดับแรกในสตรีที่มีปัญหาปัสสาวะเล็ดเวลาไอหรือจาม อย่างไรก็ตามเป็นการยากสำหรับสตรีบางคนในการรับรู้การหดตัวของกล้ามเนื้ออุ้งเชิงกราน ภายหลังจากที่ได้รับการฝึกด้วยการสอนแบบปากเปล่า หลากหลายวิธีถูกนำมาใช้เพื่อพัฒนาการฝึกกล้ามเนื้ออุ้งเชิงกรานรวมถึงการฝึกด้วยลูกโป่งทางทวารหนัก*

วัตถุประสงค์: *เพื่อเปรียบเทียบแรงดันจากการขมิบของช่องคลอด ปริมาณปัสสาวะที่เล็ดบนผ้าอนามัยในระยะเวลาหนึ่งชั่วโมง (one-hour pad test), จำนวนครั้งที่พบปัสสาวะเล็ดราด การให้คะแนนถึงระดับความรุนแรงของอาการปัสสาวะเล็ดและความพึงพอใจระหว่างการฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานแบบมาตรฐานและการฝึกด้วยลูกโป่ง ทางทวารหนัก*

วัสดุและวิธีการ: *แบ่งผู้ป่วยที่มีปัสสาวะเล็ดเวลาไอหรือจามจำนวน 28 คน เป็นสองกลุ่ม กลุ่มแรกได้รับการฝึกกล้ามเนื้ออุ้งเชิงกรานแบบมาตรฐานด้วยการสอนแบบปากเปล่า อีกกลุ่มได้รับการฝึกกล้ามเนื้ออุ้งเชิงกรานด้วยลูกโป่งทางทวารหนักโดยใช้สายสวนปัสสาวะที่ถูกเติมด้วยน้ำประปาในการสร้างลูกโป่ง โดยประเมินแรงดันจากการขมิบของช่องคลอดด้วยเครื่องป้อนกลับทางชีวภาพรุ่น เอ็ม วาย โอ 420*

ผลการศึกษา: *ผู้เข้าร่วมการศึกษาไม่มาตรวจติดตาม 1 รายต่อกลุ่ม ดังนั้นจึงเหลือ 13 รายต่อกลุ่ม ภายหลังการฝึก ทั้งสองกลุ่มมีแรงดันจากการขมิบของช่องคลอดเพิ่มขึ้นอย่างมีนัยสำคัญเมื่อเปรียบเทียบกับก่อนการฝึก โดยกลุ่มที่ฝึกด้วยวิธีมาตรฐานและกลุ่มที่ฝึกด้วยลูกโป่งทางทวารหนักมีแรงขมิบของช่องคลอดที่เพิ่มขึ้นโดยเฉลี่ยเท่ากับ 9.9 และ 9.2 มม.ปรอท ตามลำดับ ($p = 0.84$) พบการพัฒนาในทางที่ดีขึ้นในประเด็นด้านจำนวนครั้งของปัสสาวะเล็ด และคะแนนประเมินความรุนแรงของอาการปัสสาวะเล็ด แต่ไม่พบความแตกต่างอย่างมีนัยสำคัญระหว่างสองกลุ่ม จำนวนคนที่ต้องใส่ผ้าอนามัยเพื่อป้องกันภาวะปัสสาวะเล็ดลดลงร้อยละ 75 ในกลุ่มที่ฝึกด้วยวิธีมาตรฐานและร้อยละ 80 ในกลุ่มที่ฝึกด้วยลูกโป่งทางทวารหนัก อย่างไรก็ตามทั้งสองกลุ่มให้คะแนนความพึงพอใจเพิ่มขึ้นอย่างมีนัยสำคัญทางสถิติภายหลังจากการฝึก*

สรุป: *การฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานเป็นวิธีการรักษาภาวะปัสสาวะเล็ดเวลาไอหรือจามที่มีประสิทธิภาพ การฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานด้วยลูกโป่งทางทวารหนักไม่ได้เพิ่มความแข็งแรงของกล้ามเนื้ออุ้งเชิงกรานเพิ่มขึ้นเมื่อเปรียบเทียบกับการฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานแบบมาตรฐาน*