Thai Journal of Obstetrics and Gynaecology
May 2021, Vol. 29, No. 3, pp. 169-176

GYNAECOLOGY

Verbal, Mirror-assisted Feedback Instructions vs. Conventional Instructions for Pelvic Floor Muscle Training to Prevent Urinary Incontinence in Late Pregnancy: A randomized controlled trial

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ABSTRACT

Objectives: To study the efficacy of verbal feedback with mirror-assisted pelvic floor muscle training (PFMT) for prevention of urinary incontinence in late pregnancy.

Materials and Methods: One hundred and sixteen nulliparous singleton pregnant women without urinary incontinence were randomized into two groups, the study group was individually instructed verbal feedback using mirror for twelve weeks of training by standardized physician to perform PFMT. The control group received only educated PFMT. Urinary incontinence event, urinary symptoms and quality of life were evaluated by Urogenital Distress Inventory Questionnaire (UDI), Incontinence Impact Questionnaire (IIQ) and incontinence episodes were recorded between 36 and 38 weeks of gestation.

Results: After complete of training the incidence of urinary incontinence was significantly higher in the control group compared with study group (18.2% vs 1.9%, p = 0.008). Urinary symptoms were improved in study group. The quality of life (physical activity, travel and emotion) in study group was better than control group.

Conclusion: Verbal feedback with mirror assisted PFMT was effective for prevention of urinary incontinence in late pregnancy.

Keywords: urinary incontinence, pelvic floor muscle training, pregnancy.

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Received: 27 September 2019, **Revised:** 11 December 2019, **Accepted:** 24 December 2019

การใช้กระจกร่วมกับการให้ข้อมูลย้อนกลับเปรียบเทียบกับการให้คำแนะนำในการสอนบริหารกล้ามเนื้ออุ้งเชิงกรานเพื่อป้องกันการเกิดภาวะปัสสาวะเล็ดในไตรมาสสุดท้ายของการตั้งครรภ์:การทดลองแบบสุ่ม

จิณัฐนภัส ธนาพงศ์ศิริกุล, มาลีชาติ ศรีพิพัฒนะกุล, ทุมวดี ตั้งศิริวัฒนา

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพของการสอนบริหารกล้ามเนื้ออุ้งเชิงกรานโดยใช้กระจกร่วมกับการให้ข้อมูลย้อนกลับในการฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานเพื่อป้องกันการเกิดภาวะปัสสาวะเล็ดในไตรมาสสุดท้ายของการตั้งครรภ์*

วัสดุและวิธีการ: *สตรีตั้งครรภ์เดี่ยวและครรภ์แรกที่ไม่มีภาวะปัสสาวะเล็ดมาก่อนทั้งหมด116 ราย ถูกสุ่มออกเป็น 2 กลุ่ม เพื่อฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานเป็นระยะเวลา 12 สัปดาห์ กลุ่มศึกษาวิจัยจะได้รับการสอนบริหารกล้ามเนื้ออุ้งเชิงกรานโดยใช้กระจกร่วมกับการให้ข้อมูลย้อนกลับตัวต่อตัวจากแพทย์ผู้ที่มีความรู้เกี่ยวกับการบริหารกล้ามเนื้ออุ้งเชิงกราน กลุ่มควบคุมจะได้รับเพียงความรู้เกี่ยวกับการบริหารกล้ามเนื้ออุ้งเชิงกราน ภายหลังเสร็จสิ้นการฝึกการเกิดภาวะปัสสาวะเล็ดจะได้รับการประเมินอาการของระบบปัสสาวะรวมถึงคุณภาพชีวิตจะได้รับการประเมินจากแบบสอบถามเกี่ยวกับภาวะปัสสาวะเล็ดและกระบังลมหย่อนและการจดบันทึกจำนวนครั้งของการปัสสาวะเล็ด*

ผลการศึกษา: *หลังจากครบระยะเวลาการพบว่าอุบัติการของการเกิดภาวะปัสสาวะเล็ดในกลุ่มควบคุมสูงกว่ากลุ่มศึกษาวิจัยอย่างมีนัยสำคัญทางสถิติ (ร้อยละ 18.2 ในกลุ่มทดลอง และร้อยละ 1.9 ในกลุ่มศึกษาวิจัย)*

สรุป: *การสอนบริหารกล้ามเนื้ออุ้งเชิงกรานโดยใช้กระจกร่วมกับการให้ข้อมูลย้อนกลับในการฝึกบริหารกล้ามเนื้ออุ้งเชิงกรานมีประสิทธิภาพในการป้องกันการเกิดภาวะปัสสาวะเล็ดในไตรมาสสุดท้ายของการตั้งครรภ์*

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Introduction

Urinary incontinence is the involuntary loss of urine[1]. The type of urinary incontinence includes stress urinary incontinence (SUI), urgency urinary incontinence (UUI), overflow incontinence, and mixed incontinence. Urinary incontinence significantly disturbs quality of life[2]. Pregnancy and childbirth are the main risk factors for development of urinary incontinence[3]. The respective incidence for UUI and SUI is 27% and 42% in nulliparous late pregnancy[4].

Pelvic floor muscle training (PFMT) is the primary prevention and first line conservative treatment for urinary incontinence. PFMT increases the strength of the pelvic floor muscles and periurethral muscles, leading to enhanced sphincter function by increasing the intraurethral closing pressure[1, 5].

In most studies, PFMT is taught by a physiotherapist, which is more effective than only the usual self-care. A few trials have investigated the effect of implementing PFMT over against verbal PFMT education among pregnant women, there were no significant difference in results, adherence and power as both were low[6, 7].

A Cochrane review concluded that feedback or biofeedback-assisted PFMT was more effective than PFMT without these adjuncts[8]. Biofeedback using a machine has limited use due to equipment cost, lack of physician familiarity, and contraindication in pregnancy. A study among non-pregnant women reported the efficacy of verbal feedback was not statistically different from biofeedback for management of urinary incontinence[9].

In the current study, we evaluated the effect of verbal feedback instructions using a mirror to enhance awareness of the correct pelvic floor muscle contraction compared to conventional PFMT for prevention of urinary incontinence during late pregnancy.

Materials and methods

Between October 2018 and May 2019, we recruited nulliparous, singleton pregnant women attending the antenatal care clinic at Khon Kaen Hospital. Informed consent was obtained from each eligible participant. The study was approved by the Khon Kaen Hospital Institute Review Board for Human Research.

The inclusion criteria were pregnant women (a) 18 or older, (b) between 24 and 26 weeks of gestation, (c) without urinary incontinence, and (d) who understood the Thai language. The exclusion criteria were pregnant women who had medical and obstetric complications such as heart diseases, asthma, diabetes mellitus, uncontrolled thyroid diseases, abortion, gestational diabetic mellitus, pregnancy-induced hypertension, antepartum hemorrhage, preterm labor, pain during pelvic floor muscle contraction, history of pelvic surgery and genitourinary pathology, or urinary tract infection.

The participants were randomly allocated into two groups: the study and control groups, by using a computer-generated block of four. The randomization list was kept in a sealed opaque envelope. A physician gave each member of the study group individual, verbal and feedback instructions on the use of a mirror for performing PFMT, while the control group received only PFMT education.

At the beginning of the intervention, the participants in both groups were introduced to (a) PFMT in general, (b) PFMT at home, and (c) the PFMT checklist and incontinence episode record sheet. All participants were assessed using the validated Thai version of the Urogenital Distress Inventory (UDI) questionnaire before starting the intervention; the UDI is used to evaluate urinary symptoms such as frequency urination, urine leakage related to the feeling of urgency, and urine leakage related to physical activity.

Overall the 12-week study period, the study group was given about 10 minutes of individual, physician-directed, verbal feedback training with a mirror in the first session, they learned about PFMT including how to contract the pelvic floor muscle correctly and how to perform PFMT at home (particularly in terms of duration, intervals, and frequency). This group was assessed by a physician every 4 weeks in a private room. A day before each session, the researcher made an appointment via telephone to

remind the participant of the date and time. Appointments for the groups were made for different days so as to prevent cross-contamination.

All Participants performed 15 sets of pelvic floor muscle exercises three times a day for a total of 45 sets a day, three days a week in any position, including lying down, sitting, and standing. Compliance with PFMT was followed up by using the PFMT checklist, which recorded the number of daily PFMT performed. One set of pelvic floor muscle contractions comprising a strong contraction should be sustained for 6 to 10 seconds followed by relaxing the muscles.

The primary outcome was incidence of urinary incontinence including stress urinary incontinence and urgency urinary incontinence between 36 and 38 weeks of gestation. The secondary outcomes included the scores from the UDI questionnaire and the Incontinence Impact (IIQ) questionnaire at 36 to 38 weeks of gestation. The score from UDI questionnaire was analyzed into total scores and urinary symptoms. The IIQ questionnaires provided an evaluation of quality of life vis-à-vis urinary symptoms including physical activity, social relationships, travel, and emotional health. In addition, a 3-day bladder diary tracked daytime night-time frequency and urinary incontinence episodes. The severity of frequency in urinary incontinence was scored as: none (no symptoms), mild frequency (once a week or occasionally), moderate frequency (twice a week), and severe frequency (symptoms experienced three or more times a week).

The sample size was calculated based on the data from a pilot study which had a reduction of 20% in urinary incontinence with a 90% power at the 5% level of significance and a 10% dropout rate. The appropriate sample size was thus 116 participants (58 in each group).

Data were analyzed using intention to treat. Differences in continuous variables were analyzed using the student t-test or the non-parametric test due to characteristics of data distribution and presented as means with standard deviation (SD) or median and interquartile range (IQR). Categorical variables were analyzed using the chi-square or Fisher's exact test and presented as a number and percentage. P value < 0.05 was considered statistically significant.

Results

Initially, 155 eligible participants were screened. Thirty-one of these did not meet the criteria and eight declined to participate. A total of 116 pregnant women were randomized into the study and control groups. Fig. 1. shows the study flow with the number of dropouts and their reasons. The data from 107 participants were analyzed.

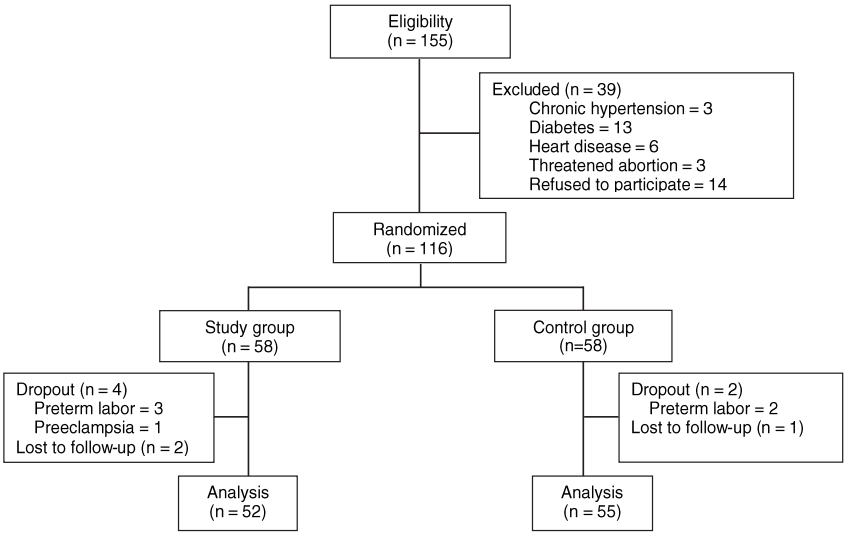

Fig. 1. Study flow.

Both groups had similar baseline characteristics such as age, gestational age at the beginning, gestational age at the end of the trial, body mass index (BMI) before pregnancy, BMI at the end of trial, birth weight, route of delivery, and UDI scores before pregnancy (Table 1).

Table 1. Baseline characteristics of study population.

	Study group (n=52)	**Control group (n=55)**	**p value**
Age, years (median (min - max))	23 (18 - 39)	24 (18 - 36)	0.13
GA at beginning, days (median (min - max))	172 (168 - 184)	174 (168 - 184)	0.82
GA at end of trial, days (median (min - max))	258 (251 - 268)	259 (252 - 268)	0.99
BMI before pregnancy, n (%)			0.45
< 18 kg/m^2	14 (26.9)	10 (18.2)	
18-20 kg/m^2	11 (21.2)	13 (23.6)	
21-25 kg/m^2	21 (40.4)	20 (36.4)	
26-29 kg/m^2	3 (5.8)	3 (5.5)	
> 29 kg/m^2	3 (5.8)	9 (16.4)	
BMI at GA 36-38 weeks, n (%)			0.17
18-20 kg/m^2	5 (4.7)	2 (3.6)	
21-25 kg/m^2	39 (36.5)	15 (27.3)	
26-29 kg/m^2	30 (28.0)	19 (34.6)	
> 29 kg/m^2	33 (28.0)	19 (34.6)	
Birth weight, g (mean ± SD)	2928.3 ± 349.3	2978 ± 403.2	0.48
Route of delivery, n (%)			0.85
Vaginal	34 (65.4)	35 (63.6)	
Cesarean	18 (34.6)	20 (36.4)	
Constipation, n (%)	1 (1.9)	1 (1.8)	1.00
UDI scores before PFMT total (median (min – max))	8 (0 - 34)	9 (0 - 24)	0.91
UDI score before PFMT urinary symptoms (median (min-max))	6 (0-22)	7 (0-18)	0.75

GA: Gestational age, BMI: Body mass index, UDI: Urogenital distress inventory, PFMT: Pelvic floor muscle training, SD: Standard deviation

After the intervention period, the incidence of urinary incontinence in study group was significantly lower than the control group (1.9% vs 18.2%, p = 0.01). The most common type of urinary incontinence in this study was stress urinary incontinence (Table 2). The proportional severity of frequency in urinary incontinence was mild (45.4%), moderate (36.5%), and severe (18.1%).

The results of the UDI scores, IIQ scores, and frequency of incontinence episodes between 36 and 38 weeks of gestation of the two groups are presented in Table 3. The UDI scores in urinary

symptoms were no difference in both groups. Notwithstanding, there was a statistically significant difference in IIQ scores (including physical activity, travel and emotional health) and incontinence episodes between the two groups after the intervention period.

Table 2. Primary outcome: incidence of urinary incontinence.

	Study group (n=52)	Control group (n=55)	Relative risk (95%CI)	p value
Urinary incontinence, n (%)	1 (1.9)	10 (18.2)	0.11 (0.01 - 0.80)	0.01
SUI	1 (1.9)	7 (12.3)		
UUI	0	3 (5.5)		

CI: Confidence interval, SUI: stress urinary incontinence, UUI: urgency urinary incontinence

Table 3. Secondary outcomes.

	Study group (n=52)	Control group (n=55)	p value
UDI scores after PFMT total (median (min-max))	7 (0-39)	8 (0-23)	0.64
UDI scores after PFMT urinary symptoms (median (min-max))	6 (0-32)	6 (0-22)	0.57
IIQ scores (median (min-max))			
Physical activity	0 (0-18)	0 (0-24)	0.02
Social relationships	0 (0-6)	0 (0-11)	0.07
Travel	0 (0-11)	0 (0-10)	0.04
Emotional health	0 (0-5)	0 (0-10)	0.04
Frequency, times (median (min-max))			
Daytime	5 (3-10)	6 (3-15)	0.39
Nighttime	3 (1-10)	3 (0-10)	0.43
Incontinence episode, times (median (min-max))	0 (0-1)	0 (0-3)	0.01

UDI: Urogenital distress inventory, PFMT: Pelvic floor muscle training, IIQ: Incontinence impact questionnaire

Discussion

In the current randomized controlled trial, we studied the efficacy of verbal feedback with mirror-assisted PFMT for prevention of urinary incontinence during late pregnancy. The incidence of urinary incontinence was significantly lower in the study group (1.9% vs. 18.1%, p = 0.01).

Pregnancy and childbirth frequently result in major loss of pelvic floor muscle strength and important risk factors of urinary incontinence. Pelaez ,et al[2] and Ko, et al[10] reported that the performance of antenatal pelvic floor muscle exercise in nulliparous women effectively prevented urinary incontinence during pregnancy. Fritel, et al[6] reported that supervised antenatal pelvic floor muscle exercise was not superior to written PFMT instruction for prevention of postpartum urinary incontinence because of low adherence to the protocol and inadequate development of strength. A Cochrane review concluded that PFMT is efficient when supervised training is conducted but the conclusions

are moot due to large heterogeneity in the population, inclusion and exclusion criteria, outcome measures, and content of the interventions. Additionally, none of the trials used specific questionnaires, instructions to assess adherence, reported the number of urinary incontinence episodes[11].

In the present trial, the study group received individual PFMT, mirror-assisted instructions from a physician, while the control group received only PFMT education. Each group then performed 15 sets of pelvic floor muscle exercise three times a day for a total of 45 sets per day. We monitored compliance using the PFMT checklist and found that 86.2% and 79.3% had good compliance in the study and control groups, respectively. Incorrect practice and poor compliance might affect the incidence of urinary incontinence.

A previous trial showed that the frequency of urination during pregnancy in the PFMT group was lower than the control group[12]. By contrast, there was no significant difference between groups in our study. In previous studies the control group did not receive any intervention but in our study the control group received education and compliance was monitored. Incontinence episodes in the study groups were significantly lower than the control groups. There was, however, no significant difference in UDI scores between 36 and 38 weeks of gestation but there were significant difference in IIQ scores including for physical activity, travel, and emotional health between groups (except social relationships). Accordingly, education can promote the benefit of PFMT for prevention of urinary incontinence compared with previous studies in which the control groups did not receive any intervention.

The strengths of the current study included that it was a randomized, controlled trial in which the practice of PFMT was standardized and specific questionnaires were used to evaluate outcomes. The limitations of the study included that there (a) were no objective assessments of the pelvic floor muscle strength using the modified Oxford grading scale or vaginal manometry, (b) was no evaluation of patient competency vis-à-vis pelvic floor muscle contraction, and (c) was a lack of long-term follow-up. Further research is needed to measure the power of pelvic floor muscles and to complete a long-term follow-up.

Conclusion

Verbal feedback with mirror-assisted PFMT, as well as 12 weeks training was more effective for prevention of urinary incontinence in late pregnancy than conventional PFMT instruction alone.

Acknowledgements

The authors thank (a) the participants for their cooperation and (b) staff and residents in Obstetrics and Gynecologic department, Khon Kaen Hospital (c) nurses at antenatal care unit, Khon Kaen Hospital (d) Mr. Bryan Roderick Hamman for assistance with the English-language presentation of the manuscript.

Potential conflicts of interest

The authors declare no conflict of interest.

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