A new biofeedback device to improve adherence to pelvic floor muscle training in women with urinary incontinence: a randomised controlled pilot trial (abridged secondary publication)

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KEY MESSAGES

1. The new biofeedback device is well accepted and safe for pelvic floor muscle training in women with stress urinary incontinence.
2. There are positive changes in the severity of urine loss and pelvic floor muscles strength after training with the new biofeedback device.

Hong Kong Med J 2022;28(Suppl 6):S23-4
HMRF project number: 17182171

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Introduction

Pelvic floor muscle training (PFMT) is a first-line treatment for urinary incontinence (UI) in women. A lack of adherence to PFMT may result from an inability to contract the correct muscles and a lack of motivation. Therefore, a biofeedback device is commonly used with PFMT. The conventional biofeedback device involves insertion of a vaginal probe to pick up signals during voluntary contraction, but this causes discomfort or pain and refusal to treatment. A non-invasive biofeedback device with wearable electromyographic sensor was therefore developed. This study aims to compare the new biofeedback device with the conventional biofeedback device and no biofeedback device in terms of adherence to PFMT, retention rate, safety, stress UI symptoms, severity of urine loss, and pelvic floor muscles strength.

Methods

Non-pregnant women aged 35 to 60 years who were having mild to moderate stress UI (a score of ≤12 in the International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form [ICIQ-UI SF]) and had a mini-mental state examination score of ≥24 were recruited from Kwong Wah Hospital and two community centres in Hong Kong. Women were excluded if they were obese (body mass index of ≥30) or in the post-partum stage of <6 months or had severe pelvic organ prolapse, urine retention as an adverse effect of medications, incontinence secondary to other medical conditions or previous surgeries, complicated UI secondary to radiation to the pelvic region, mixed or urge UI, or severe psychological problems.

Eligible women were randomised by permuted blocks of three stratified by age and assigned to the new biofeedback device group (with the wearable electromyographic sensors attached to the perineal region), conventional biofeedback device group (with the conventional biofeedback probe inserted in the vagina), or control group (without any biofeedback device).

All participants underwent supervised PFMT once a week for 4 weeks, followed by unsupervised home exercises for 24 weeks. PFMT was performed in a lying position and progressed to sitting and then standing positions when participants were able to hold a contraction for 10 seconds in the previous position.

Assessors were blinded to the study. Outcomes were assessed at baseline and 4, 12, and 24 weeks. Primary outcome measures included adherence to exercise, retention rate, and safety. Exercise adherence was measured using a scale ranging from 0 (low adherence) to 10 (high adherence). Secondary outcome measures included the ICIQ-UI SF (for stress UI symptoms), the 1-hour pad test (for severity of urine loss), and the modified Oxford scale (for pelvic floor muscles strength).

Statistical analysis was performed on an intention-to-treat basis. Missing data were replaced with the last observation carried forward approach. Adherence to PFMT between groups was compared. Two-way repeated-measures analysis of variance was used to compare the three groups to determine the time × group interaction. Statistical significance was defined as a P value of ≤0.05.

Results

Of 60 women recruited, nine were excluded. 17 participants were assigned to each of the three groups. There was no significant difference in baseline characteristics between groups. After 24 weeks, in the new biofeedback device group, three participants reported adherence as high and 12 reported as moderate, whereas in the conventional biofeedback device and control groups, no participant reported adherence as high and 10 participants in the control group and four participants in the conventional biofeedback device group reported adherence as moderate. The retention rate was 100% in the new biofeedback device and control groups and 71% in the conventional biofeedback device group. No adverse events were reported in the new biofeedback device and control groups, but participants in the conventional biofeedback device group reported itching and blisters in and around the vaginal region (n=2), burning and painful urination (n=2), skin lacerations (n=2), and discomfort with vaginal probe insertion (n=1). Participants in the new biofeedback device group reported good device acceptance.

There was a significant effect in PFMT with the new biofeedback device than PFMT with the conventional biofeedback device or no biofeedback device on 1-hour pad test (both $P<0.01$), whereas PFMT with no biofeedback device was significantly more effective than PFMT with the conventional biofeedback device on severity of urine loss ($P<0.05$). There was a significant effect in PFMT with the new biofeedback device than PFMT with the conventional biofeedback device or no biofeedback device on ICIQ-UI SF score (both $P<0.01$), whereas there was no significant effect between PFMT with no biofeedback device and PFMT with the conventional biofeedback device on stress UI symptoms. The new biofeedback device was superior to the conventional biofeedback device and no biofeedback device in improving the modified Oxford scale score for pelvic floor muscles strength ($P<0.05$), whereas there was no significant difference between PFMT with no biofeedback device and PFMT with the conventional biofeedback device in improving pelvic floor muscles strength.

Discussion

Women with mixed stress UI were excluded, but they were unhappy being excluded and expressed that their urinary incontinence was severe (especially during coughing and sneezing). Therefore, we plan to recruit women with stress UI or stress-predominant mixed UI for future trials. The new biofeedback device is well accepted and safe for PFMT in women with stress UI. There were positive changes in the severity of urine loss and pelvic floor muscles strength after PFMT with the new biofeedback device.

Funding

This study was supported by the Health and Medical Research Fund, Health Bureau, Hong Kong SAR Government (#17182171). The full report is available from the Health and Medical Research Fund website (https://rfs1.fhb.gov.hk/index.html).