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Original Article

A nurse-led long-term pelvic floor muscle training program in the management of female patients with overactive bladder – A study protocol for a randomized controlled trial



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ABSTRACT

Background: Previous research has suggested that pelvic floor muscle training (PFMT) offers a therapeutic benefit in patients with overactive bladder.

Methods: We conducted a single-blind, randomized trial of pelvic floor muscle training (PFMT) as compared with usual care. The intervention group ($n = 54$) received a 6-month nurse-led long-term pelvic floor muscle training program (three sessions a day, 15–20 times per session) and the control group ($n = 53$) received usual care. All patients received 3-month solifenacin succinate tablets (5 mg – once daily). The treatment outcomes were measured by the Modified Oxford Scale (MOS), Overactive Bladder Symptom Score (OABSS) and the King's Health Questionnaire (KHQ) at baseline, 3 months and 6 months respectively.

Results: Of the 91 randomly assigned patients, 46 patients in the PFMT group and 45 patients in the control group completed the trial. The trial revealed statistically significant differences between groups in pelvic muscle strength at 3 months following the intervention ($p < 0.05$), but no significant difference was found between two groups in OABSS scores ($p > 0.05$). In regards to quality of life, the experimental group showed significant improvements compared to the control group on 6 of 10 domains ($p < 0.05$). At 6 months, there were significant improvements in OABSS scores and quality of life in the experimental group compared to the control group ($p < 0.05$). No adverse events were observed.

Conclusion: A nurse-led long-term (6 months) pelvic floor muscle training program may alleviate OAB symptoms effectively and improve the quality of life more than a short term (3 months) pelvic floor muscle training program combined with solifenacin succinate tablets.

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1. Introduction

Overactive bladder (OAB) is a syndrome complex characterized primarily by urgency, with or without urgency urinary incontinence, usually with frequency and nocturia [1]. Based on this definition, the first large population-based survey to evaluate the prevalence of all LUTS in five countries in 2006 reported the global prevalence of OAB was 11.8% (10.8% men; 12.8% women) [2]. In 2010 Yuliang Wang et al. reported the prevalence of OAB was 6.0% in china [3], though it is lower than most of other countries, it still brings detrimental impacts on patients' health-related quality of life [3,4] such as emotional distress, sexual problems, and influence on relationships with family members [2,5], and in recent years, OAB has become a hot issue among urologists.

Because of symptom variability, for a long time, OAB is believed to be a chronic condition that has no cure. In recent years, a focus was gradually placed on behavioral therapy [6]. Behavioral therapy includes bladder training, pelvic floor muscle training (PFMT), biofeedback, dietary changes, and multi-component approaches that combine bladder training with PFMT and/or biofeedback. And behavioral therapy and pharmacologic treatment were recommended to be the first line treatment according to the 2011 Chinese Urological Association (CUA) guideline [7]. Although behavioral therapy for OAB has been used to manage urinary incontinence for more than 50 years [8], the outcomes are still controversial. Some studies reported behavioral approaches can be effective in reducing episodes of incontinence and daily voids [9,10], some studies reported managing OAB with behavioral approaches treatment is moderate to weak for short term outcomes and weak for long term outcomes and harms [1,11]. As part of behavioral treatment, pelvic floor muscle training (PFMT), defined as repetitive selective voluntary contraction and relaxation of specific pelvic floor muscles [12], can modulate overactive bladder syndrome through both afferent and efferent stimuli of the detrusor muscle. Afferent stimuli from pelvic organs such as the vagina, cervix, and rectum can inhibit the sacral preganglionic innervation to the bladder as well as increase urethral pressure through the visceral–visceral reflex otherwise called the guarding reflex [12]. It was originally suggested for patients with stress incontinence since it is useful in inhibiting detrusor contractions. Because a detrusor involuntary contraction (detrusor overactivity) was observed in urodynamic study. It is spontaneous or provoked, during the filling phase, involving a detrusor pressure rise of greater than 15 cm H₂O above baseline [13]. Based on the above mentioned outcome, we speculate PFMT can be used to control bladder function in OAB patients. PFMT was also integrated into the treatment of urge incontinence and OAB as part of a broader behavioral urge suppression strategy in recent years [8]. However, a lack of consistency in study design, and comparison groups makes it impossible to provide consistent results regarding the effectiveness of PFMT in patients with OAB across studies. Wang et al. found that biofeedback associated pelvic floor muscle exercises resulted in greater change in muscle strength than electrical stimulation, but the clinical significance of the change was not examined [14]. Song C reported no additional benefit for

reducing incontinence episodes or voids per day was found by adding behavioral treatments to pharmacologic approaches for reduction in incontinence [15–17]. Wyman JF found significant improvement in quality of life immediately after intervention, but not at three months [18]. Based on the above mentioned information, the purpose of the current study was to investigate whether a 6-month PFMT combined with 3-month- tolterodine can improve OAB symptoms and quality of life in female patients with primary OAB (See Fig. 1).

2. Methods

2.1. Study participants

We conducted the trial from January 2012 through February 2013 at urological clinic of hospital, a comprehensive Hospital in Hangzhou, Zhejiang Province. The institutional review board of the hospital approved the study protocol. All eligible participants were diagnosed by one doctor who is the expert in overactive bladder at the urology clinic as primary overactive bladder using the 2002 ICS definition [1]. The inclusion criteria were as following: age ≥ 18 years, women who have a history of sexual life; Symptoms of OAB ≥ 3 months; Overactive Bladder Symptom Score (OABSS) ≥ 5 ; Urinary frequency ≥ 8 times/per day; At least 1 urgency in three days before being recruited; With or without urgency urinary incontinence; all of women will receive the treatment with tolterodine, no other antimuscarinic drugs. The exclusion criteria included pregnancy or planned pregnancy within one year, deafness, neurologic disorders, diabetes mellitus, and urinary tract infection. All patients provided written informed consent (See Fig. 2).

2.2. Study design

We assigned participants to PFMT or the control intervention in three randomization cycles, using computer-generated numbers. The randomized treatment assignments were sealed in opaque envelopes and were opened individually for each patient who agreed to be in the study.

Patients were randomly assigned, using computer-generated random assignment in a 1:1 ratio, to intervention group and control group. As randomization will be conducted via a centralized computer randomization service, allocation will be concealed until the point of randomization.

2.3. Intervention

At first, participants in experiment group were asked to perform PFMT under the guidance of a researcher, in which initially the researcher introduced the PFMT, explained its anatomy and principle. Then, participants were placed in lithotomy position, the researcher put her forefinger and middle finger into the participants' vagina after paraffin oil lubrication, the participants were asked to contract the pelvic floor muscles for 5–10 seconds, relax for 10 seconds after. If they could feel pressure surrounding the fingers, it was considered as correct muscle contraction. If participants

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