Effects of Patient Centered Interventions on Persistent Urinary Incontinence after Prostate Cancer Treatment: A Randomized, Controlled Trial

Amy Y. Zhang,* Donald R. Bodner, Alex Z. Fu, Douglas D. Gunzler, Eric Klein, Denise Kresevic, Shirley Moore, Lee Ponsky, Michael Purdum, Gerald Strauss and Hui Zhu

From the School of Nursing (AYZ, SM) and Department of Urology, University Hospitals of Cleveland (DRB, LP) and Center for Health Care Research and Policy (DDG), School of Medicine (DRB, HZ), Case Western Reserve University, Glickman Urological and Kidney Institute, Lerner College of Medicine, Cleveland Clinic (EK) and Urology Clinic (DRB, HZ), Louis Stokes Cleveland Department of Veterans Affairs Medical Center (DK, MP, GS), Cleveland, Ohio, and Cancer Prevention and Control Program, Georgetown University Medical Center (AZF), Washington, D.C.

Purpose: We examined whether an intervention combining pelvic floor muscle exercise and symptom self-management would improve urinary continence and quality of life in patients with prostate cancer.

Materials and Methods: In a randomized, controlled, longitudinal clinical trial 279 patients with prostate cancer with persistent urinary incontinence were randomized to 1 of 3 groups, including biofeedback pelvic floor muscle exercise plus a support group, the biofeedback exercise plus telephone contact and usual care without intervention. The biofeedback plus support and plus telephone groups received 1 session of biofeedback assisted exercise and 6 biweekly sessions of problem solving therapy. This delivered symptom management skills through a peer support group or telephone contacts for 3 months. All subjects were assessed in blinded fashion at baseline, and 3 and 6 months for urinary leakage frequency, leakage amount and disease specific quality of life.

Results: A total of 244 subjects completed the study. The biofeedback plus support and biofeedback plus telephone groups had a lower frequency of daily urinary leakage than the group with usual care without intervention at 3 months ($p = 0.019$ and $p \leq 0.001$, respectively) but not at 6 months. The biofeedback plus support group but not the biofeedback plus telephone group had 13.3 gm lower leakage at 6 months than the usual care group ($p = 0.003$). Overall the biofeedback plus support and plus telephone groups reported less symptom severity ($p \leq 0.001$) and fewer incontinence problems ($p \leq 0.01$) than the usual care group at 6 months.

Conclusions: Study findings show that pelvic floor muscle exercise practice plus symptom self-management in a peer support setting can significantly improve urinary continence and quality of life in patients with prostate cancer.

Key Words: prostatic neoplasms, urinary incontinence, pelvic floor, exercise, quality of life

Abbreviations and Acronyms

BF = biofeedback

BMI = body mass index

I-PSS = International Prostate Symptom Score

PFME = pelvic floor muscle exercise

PST = problem solving therapy

QOL = quality of life

UC = usual care without intervention

VAS = visual analog scale

Accepted for publication July 14, 2015.

Study received institutional review board approval.

Supported by National Institutes of Health/National Cancer Institute Grant R01CA127493 (AYZ), Cleveland Clinic, University Hospitals of Cleveland, Louis Stokes Cleveland Veterans Affairs Medical Center and MetroHealth System (affiliated with Case Western Reserve University).

ClinicalTrials.gov Identifier: NCT01365182.

* Correspondence: School of Nursing, Case Western Reserve University, 10900 Euclid Ave., Cleveland, Ohio 44106 (telephone: 216-368-0968; FAX: 216-368-3542; e-mail: Amy.Zhang@case.edu).

In the United States urinary incontinence affects more than 30% of patients with prostate cancer a year after surgery and 14% after 5 years.[1,2] The effect of PFME on persistent incontinence remains inconclusive due

0022-5347/15/1946-1675/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2015.07.090
Vol. 194, 1675-1681, December 2015
Printed in U.S.A.

to considerable variations in research methods.[3] Tested interventions for persistent incontinence often rely on provider assistance (eg clinician assisted electronic stimulation and repeated BF sessions).[3,4] To our knowledge their sustainability and cost-effectiveness have yet to be evaluated.

Strengthening pelvic floor muscles requires continuity of PFME.[5] Patient knowledge of correct muscle contraction and adherence to the PFME regimen are critical.[6,7] Self-management of life-style factors (eg fluid intake and bladder voiding schedule) has shown effectiveness in women[8] but has yet to be applied to incontinent men. Because patients can acquire these skills through training, a patient centered intervention enabling patient activation and engagement is promising.

A patient centered approach requires that interventions be accessible and meet patient needs. Social support groups and individual telephone interventions have proved effective to promote adherence to therapeutic regimens.[9,10] The support group has shown an effect size of 0.31 to improve QOL in patients with cancer.[11] Because the telephone intervention is accessible and less expensive, it has broad appeal, especially for the elderly population.[12] To our knowledge these interventions have not been studied to treat urinary incontinence. An evaluation of these interventions would fill a gap in the current knowledge and also contribute to developing treatment solutions that work in different patients and situations.

Thus, we investigated the Stay Dry program designed to teach PFME and self-management skills to patients with early stage prostate cancer who had persistent incontinence. Interventions were delivered through a support group or telephone contact. We addressed the question of whether the intervention groups would have significantly better urinary continence and QOL than the usual care group at 3 and 6-month assessments after controlling for sociodemographic and medical covariates.

MATERIALS AND METHODS

Design

A randomized, controlled, longitudinal clinical trial was performed from 2010 to 2013 in Cleveland, Ohio. Subjects were randomly assigned to 1 of 3 study groups, including BF PFME plus a support group, BF PFME plus telephone and UC. The BF plus support and BF plus telephone groups received study interventions for 3 months. Subjects were assessed at baseline, 3 months after intervention and at 6 months for followup.

Sampling

Eligibility included early stage (I, II or III) prostate cancer, completion of cancer treatment for at least 6 months and presenting incontinent symptoms. Men with dripping, a common and bothersome symptom that can progress without adequate care, were considered eligible irrespective of incontinence pad use. Study exclusion criteria included concurrent hormonal treatment, urinary tract infection or urinary retention, cognitive impairment and an implant to correct incontinence.

After obtaining institutional review board approval research staff used hospital databases to identify and contact patients by mail with physician permission. During a followup telephone call they obtained patient oral consent and administered ICSmaleSF (International Continence Society Male Short Form) questionnaire[13] to screen for incontinence (cutoff 7 or greater). SPMSQ (Short Portable Mental Status Questionnaire) (cutoff 5 or greater)[14] and a symptom list were used to screen for cognitive impairment, urinary infection and urinary retention. Medical charts were reviewed to ascertain patient disease and treatment status.

Randomization

Trained research personnel performed the randomization procedure using the minimization method, a computerized approach that has been shown to achieve a better balance between study group assignments within levels of stratification variables than the permuted blocks approach.[15,16] We intended to balance study groups on key variables that can affect continence outcomes, including treatment type (surgery with and without radiotherapy vs radiotherapy alone), surgery type (open vs laparoscopic), radiotherapy type (brachytherapy vs external beam) and hospital site that was associated with surgeon expertise.

Interventions

The interventions consisted of 2 components. 1) At a 60-minute BF session BF plus support and BF plus telephone subjects learned PFME using a computerized BF machine. 2) Adapted PST[17] was delivered through 6 biweekly sessions during 3 months after BF to teach self-management skills. BF plus support and BF plus telephone subjects were asked to practice PFME 3 times daily (primary goal) and meet the target in a certain area (secondary goal) as prioritized by individual, including 1) consuming 2,000 cc noncaffeinated fluid with 2 or fewer caffeine drinks daily, 2) setting bladder voiding schedules, 3) maintaining a diet balanced with fiber and fluid to avoid constipation and 4) performing daily exercise such as walking.

The BF plus support group consisted of 3 to 5 subjects each and lasted 60 to 75 minutes per session. The BF plus telephone group had an individual telephone contact with a therapist for approximately 45 minutes per session. UC subjects continued receiving usual care without receiving any intervention training sessions. They periodically received print materials unrelated to study interventions to minimize potential attention bias.

All BF sessions were performed by a BF technician trained elsewhere by a BF device manufacturer. The technician was experienced with teaching PFME. Two health psychologists and a nurse specialist delivered PST. They were trained in an initial trial with 9 subjects in which PST was manualized and reliability across therapists was examined to ensure consistency and adherence