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A pilot randomized control trial to evaluate pelvic floor muscle training for urinary incontinence among gynecologic cancer survivors

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HIGHLIGHTS

- Urinary incontinence is common among gynecologic cancer survivors.
- Evaluate pelvic floor muscle training (PFMT) for treatment of urinary incontinence
- PFMT is an effective intervention for incontinent gynecologic cancer survivors.

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ABSTRACT

Objectives. We previously reported high rates of urinary incontinence among gynecologic cancer survivors and aimed to evaluate the effectiveness of a simple intervention for treatment of urinary incontinence in this population.

Methods. We recruited 40 gynecologic cancer survivors who reported urinary incontinence on a validated questionnaire. Women were randomized to either pelvic floor muscle training/behavioral therapy (treatment group) or usual care (control group). The primary outcome measure, assessed at 12 weeks post intervention, was a 40% difference in the validated Patient Global Impression of Improvement (PGI-I) score. Fisher's exact test was used to identify differences between groups for frequency data; two-sample *t*-test was conducted for continuous measurements.

Results. Mean age of this cohort was 57 (range: 37–79). The majority of the survivors had uterine cancer (60%), 18% had received radiation therapy, 95% had received surgical therapy, and 35% had received chemotherapy. At three months, 80% of the treatment and 40% of the control group reported that their urinary incontinence was "much better" or "very much better" as evaluated by the Patient Global Impression of Improvement scale ($p = 0.02$). Brink's scores were significantly improved in the treatment group as compared to those of the controls ($p < 0.0001$). Treatment group adherence was high; the treatment group performed exercises with an average of 22 days/month.

Conclusions. Urinary incontinence negatively affects quality of life, and despite a high prevalence among gynecologic cancer survivors, it is often under-assessed and undertreated. We found a simple intervention that included pelvic floor muscle training and behavioral therapy, which significantly improved cancer survivor's urinary incontinence.

Introduction

There are over one million gynecologic cancer survivors in the United States as of 2009. Each year, approximately 80,000 women are diagnosed with a gynecologic cancer including uterine, cervical, ovarian and vulvar malignancies [1]. Cancer therapy has improved to the state where many people have curable disease or their cancer is considered a more chronic illness. With these advances have come the challenges of treating long term effects of cancer treatment. Treatment of gynecologic cancer often involves a multimodality approach with radical surgery, pelvic radiation, and/or systemic chemotherapy. All of these therapies cause direct or indirect injury to the pelvic organ anatomy and physiology and can impact pelvic floor function. Our group conducted a cohort study to define the prevalence of pelvic floor disorders in our gynecologic cancer survivors. Of 200 gynecologic cancer survivors that were disease and treatment free for >1 year, 67% of women

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reported moderate to severe urinary incontinence [2]. In contrast, in the general female population, the prevalence of urinary incontinence is estimated to range between 10 and 40% [3].

Treatment for urinary incontinence includes behavioral, medical or surgical interventions. The most common nonsurgical treatment for incontinence is pelvic floor muscle training (PFMT) or "Kegel's" exercises, named after the first physician to describe pelvic floor exercises as well as behavioral interventions regarding fluid intake, control and avoidance of constipation [4,5]. In 1948, Kegel reported a success rate of 84% in treating various types of incontinence with pelvic floor muscle training and behavior interventions. Despite proven effectiveness in the general female population, the effectiveness of PFMT and behavioral therapy, both being simple interventions, has not been evaluated in gynecologic cancer survivors. The effectiveness of these interventions may differ in cancer survivors since radiation, chemotherapy and radical pelvic surgery can result in significant anatomical functional changes in the pelvis and lower urinary tract, including damage of nerve fibers and compromise of vascular supply with resultant fibrosis. Data are lacking evaluating treatment options for gynecologic cancer patients who are incontinent. In this pilot study, we aimed to evaluate the effectiveness and feasibility of a simple intervention, pelvic floor exercise training and behavioral therapy, for the treatment of urinary incontinence among gynecologic cancer survivors. We hypothesized that cancer survivors randomized to a behavioral intervention would demonstrate improved continence and quality of life.

Materials and methods

This study was performed at the University of New Mexico through the Department of Obstetrics and Gynecology. Institutional review board approval was obtained and all women gave written informed consent. Participants were women who attended the gynecologic oncology clinics for routine surveillance visits who were ≥30 years old and had a history of uterine, cervical, ovarian, or vulvar cancer. All participants had been disease- and treatment-free for at least one year and currently had no evidence of cancer. Eligible patients based on cancer history and treatment free interval were then screened for urinary incontinence using the Incontinence Severity Index (ISI), a validated symptom severity scale, to determine the presence of urinary incontinence [6]. The ISI Scale categorizes mild incontinence for scores 1–2, moderate incontinence for scores 3–4, and severe incontinence for scores 6–8. If women had any degree of urinary incontinence, defined as a score >0, they were offered enrollment in the study. All study participants completed the Questionnaire for Urinary Incontinence Diagnosis (QUID) at enrollment. The QUID is a validated 6-item questionnaire for female urinary incontinence type diagnosis [7]. Participants also completed the Urinary Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7), which measure the bother from incontinence as well as its impact on quality of life, respectively. Patient demographics, cancer history, cancer treatment, surgical history, and previous incontinence treatments were recorded by the provider at the initial visit. Participants were then randomized to the treatment group or the usual or control group. Randomization assignment was by a research staff not involved in the clinical care of the patients. All randomization assignments were kept in sealed opaque envelopes, which were opened when women met inclusion criteria and gave written consent. The randomization assignments were generated from a random number table using the random allocation rule. If randomized to the treatment group, the participant began the training program on the first visit day. Women were given a handout and instruction describing behavioral management tips for urinary incontinence. This included information and suggestions about optimal volume fluid intake, constipation management, measures to reduce urinary urgency by decreasing fluid intake, and avoiding caffeine and other bladder irritants that have proved effective in other intervention trials [8]. The provider then conducted a training session during the clinic visit designed to teach the participant to contract her pelvic floor muscles correctly. The training session required approximately 15 min. The provider confirmed appropriate contraction of the pelvic floor by palpation of the levator ani during a contraction and rated the strength of the contraction using the Brink's scale. The Brink's scale rates pelvic floor contractions from 3 to 12 and has been validated for the evaluation of pelvic floor strength. Appropriate feedback was given to avoid contraction of abdominal, gluteal, or adductor muscles. The provider performing the training attended two pelvic floor physical therapy sessions with experienced pelvic floor physical therapists. The pelvic floor muscle training program was explained to the participant verbally and in written form. The training program consisted of the participant performing 10 pelvic floor muscle contractions with a goal of holding the contraction for 5 s; women were asked to perform 3 sets daily for the twelve week study period. To promote adherence to the training program, the participants in the training group received a reminder phone call approximately four weeks after the first study visit. The phone call reviewed the training instructions and addressed any concerns or questions the participant had. If randomized to the control group, the participant did not have the above training program and did not undertake exercises. This is representative of usual care in our gynecologic oncology clinics. The control participants completed the same questionnaires as the treatment group participants both at enrollment and at 12 weeks and underwent assessment of pelvic floor muscle strength using the Brink's scale. Because incontinent women may be interested in treatment, we did offer the training program to the women in the control group after they completed the study.

Twelve weeks after randomization, the participants returned for the second study visit. At this visit, participants completed questions regarding treatment compliance such as how many exercises they performed per day, and how well they complied with the exercise program. Participants also completed the validated Patient Global Impression of Improvement scale. In addition, they also completed the ISI, QUID, UDI-6, and IIQ-7 questionnaires. The trainer also completed a Brink's scale at both visits to evaluate the strength of the participant's contractions.

The control group did not undergo the above training program or receive the behavioral therapy handouts.

The primary outcome, assessed at 12 weeks, was improvement in Patient Global Impression of Improvement (PGI-I) rating. The PGI-I is a validated single item that asks the participant to rate improvement of her continence status using a seven-point Likert scale. The PGI-I global index is capable of reflecting a woman's overall appraisal of her condition and response to treatment. The PGI-I tool when developed correlated significantly with incontinence episode frequency, stress pad tests and disease specific quality of life questionnaires [9] Participants were considered "successfully" treated if they report that they are "very much better" or "much better". All other response options were defined as treatment failures. Secondary outcome measures included the change in the ISI, UDI, and IIQ scores which measure the impact of urinary incontinence on quality of life [10]. The Brink's scale was used by trainers for the treatment group visits to evaluate the strength of the contractions in a qualitative manner [11].

Statistical tests

Power analysis was performed. We anticipated a dropout rate of 10%. Previous studies suggest that approximately 23% of the usual care subjects will report substantial improvement. If this holds, then a two-sided *t*-test at the 5% level would have 60% power to detect a 40% improvement in the treatment group (i.e. an increase from 25% to 65%), and 80% power to detect a 48% increase in improvement with group sizes of 18. Baseline demographic and clinical characteristics were compared between the intervention and control groups with the use of the two sample *t*-test and the Mann–Whitney test for continuous measurements with and without normal distribution, respectively. The Fisher's exact test was used to identify difference between groups for frequency