Efficacy of Transvaginal Biofeedback And Electrical Stimulation in Women With Urinary Urgency and Frequency and Associated Pelvic Floor Muscle Spasm

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Urinary urgency and frequency in women can range from a simple nuisance to an incapacitating quality-of-life issue. When this population does not respond to standard therapies, both patient and clinician are dissatisfied. A significant proportion of women with urgency and frequency have demonstrable pelvic floor muscle spasm with high pelvic muscle resting tones (Abbott, 2009; Clemens et al., 2000). In 1973, the concomitant existence of levator spasm and interstitial cystitis was described, postulating that the high pelvic floor muscle tone was a response to the afferent pain impulses from the bladder wall (Lilis, Oravisto, & Valtonen, 1973), Schmidt and Vapnek (1991) evaluated patients with interstitial cystitis and pelvic floor spasm, showing that pressure applied to the levators elicited pain in the suprapubic and perineal areas. Bernstein, Philips, Linden, and Fenster (1992) observed a significant association with high pelvic muscular tone in patients with urinary urgency and frequency. In the rat model, Pinter and Szolcsanyi (1995) showed that pelvic floor spasms may propagate central nervous system stimulation along the bladder afferents, resulting in neurogenic inflammatory changes. Although little is reported on the subject, from this rat model it appears that in humans, the urinary symptoms associated with pelvic floor muscle tone may be related to cross-communication among the pelvic S 2,3,4 afferents, which innervate both structures (Pinter & Szolcsanyi, 1995).

Therapies directed toward the relief of pelvic floor muscle spasm have been reported. Thiele (1963) first described that direct transrectal massage of the spastic levator ani muscles resulted in less discomfort and pain in the pelvis. Oyama et al. (2004) showed that in

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Introduction
A significant proportion of women with urinary urgency and frequency also have demonstrable pelvic floor muscle spasm with high pelvic muscle resting tones. Urinary urgency and frequency associated with pelvic floor spasm can be a diagnostic and therapeutic challenge. The efficacy of biofeedback and electrical stimulation to specifically treat pelvic floor spasm is poorly described in the literature. The efficacy of biofeedback and electrical stimulation for the treatment of stress urinary incontinence is well investigated; however, there has been little investigation into its use in the treatment of urinary urgency and frequency and pelvic floor spasm.

Purpose
The purpose of this study was to investigate the role of transvaginal biofeedback (TVBF) and electrical stimulation (ESTim) in the treatment of women with urinary urgency and frequency associated with pelvic floor spasm.

Method
A retrospective chart review was conducted over a 14-month period of women presenting to a urology clinic with symptoms of urinary urgency and frequency associated with pelvic floor spasm. Women were treated with 6 weekly one-hour sessions led by a registered nurse trained in pelvic floor rehabilitation biofeedback and electrical stimulation. Nurses collected data during treatment to track changes in behavior as well as urinary symptoms. Before and after the 6-week sessions, patients completed an AUA Symptom Score and rated their quality of life on a Like rT scale.

Findings
Fifty-two women underwent therapy with TVBF/ESTim and reported a mean symptom improvement of 64.5%. At 6-week follow up, patients reported continued a subjective improvement of 75.1% (n = 27, SD = 24, range 0 to 100). Results for the AUA-SS and bother score before and after treatment demonstrated statistically significant improvement at 3-month follow up. The visual analog scale (VAS) for symptom severity and effect on daily life was also much improved at 3-month follow up. Symptom severity demonstrated statistically significant improvement from 5.96 to 3.52 (n = 23, p < 0.001), and effect on daily life from 6.30 to 3.74 (n = 23, p < 0.001).

Conclusions
In this small retrospective study of women presenting with urinary urgency and frequency with associated pelvic floor muscle spasm, TVBF/ESTim with behavioral therapy as a combined modality targeting relaxation of the pelvic floor demonstrated statistically significant improvement in urinary symptoms for up to 3 months. Further study of this low-risk intervention for refractory patients is warranted.

Level of Evidence – VI
(Melynky & Fineout-Overholt, 2005)

Materials and Methods
Institutional Review Board approval was obtained to review charts of data collected for clinical management. The charts reviewed consisted of women referred to this practice with diagnoses of urgency frequency syndrome and interstitial cystitis, urinary tract symptoms with negative cultures, and pelvic pain. The women were screened for urgency and frequency and pelvic floor spasm at the initial visit. Charts were reviewed for a 14-month window.

The diagnoses of urgency and frequency and pelvic floor spasm were made by clinical interview and physical examination. Clinical interview revealed components of a symptom complex, including urgency, urge urinary incontinence, frequency, dysuria, insert larger-sized vaginal probes and achieve satisfactory vaginal intercourse (Seo et al., 2005).

Urinary urgency and frequency associated with pelvic floor spasm can be a diagnostic and therapeutic challenge, engendering unsatisfactory clinical encounters. The efficacy of biofeedback and electrical stimulation to specifically treat pelvic floor spasm is poorly described in the literature. There are several discussions investigating the efficacy of biofeedback and electrical stimulation for the treatment of stress urinary incontinence. A recent study looked at the improvement of urinary incontinence with biofeedback and electrical stimulation in patients after radical prostatectomy and found very good results (Mariotti et al., 2009). The available literature supports an association between bladder symptoms and pelvic floor muscle tone, and that the increased tone is treatable. Given the clinical experience that TVBF/ESTim was effective, a retrospective chart review was completed in women with refractory baseline urgency and frequency or episodic urgency and frequency (irritative urinary tract symptoms with sterile cultures) associated with pelvic floor spasm.

patients with interstitial cystitis and high-tone pelvic floor spasm, pressure applied to the coccygeus, iliococcygeus, pubococcygeus, and obturator internus resulted in durable improvements at 4.5 months for urgency and pain.

Biofeedback therapy has been used to assist the re-education of patients with pelvic floor spasm resulting in symptomatic improvements. Nadler (2002) evaluated 11 men with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) who had pelvic floor spasm and who received biofeedback and pelvic floor re-education. Exercises concentrated on the voluntary contraction and relaxation of the pelvic floor muscles guided by pelvic floor electromyography (EMG). Eight of the 11 men showed significant pain relief. Aboseif, Tamaddon, Chalfin, Freedman, and Kaptein (2002) evaluated the efficacy of sacral neuromodulation for pelvic floor dysfunction associated with chronic pelvic and perineal pain. Eighty percent had a 50% or greater improvement in their pre-procedural symptoms at a mean follow up of 24 months (Aboseif, et al., 2002). Seo, Choe, Lee, and Kim (2005) demonstrated the use of transvaginal electrical stimulation and biofeedback in 12 women with vaginismus. At 8 weeks, all 12 women were able to

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intermittency, straining, recurrent urinary tract infection symptoms with variable cultures, deep dyspareunia, suprapubic pressure, and pain. The unifying hallmark symptoms were baseline urgency and frequency or episodic urgency and frequency. Only patients with urinary symptoms were included in the study because pelvic floor spasm can be identified in patients presenting for other purposes, such as hematuria, interstitial cystitis, and vaginismus.

There is currently no standardized method by which to evaluate the tonus of the pelvic floor (van Kampen, Dumoulin, Thompson, & Morin, 2007). Independently, physical therapists and clinicians have developed various methods to examine and evaluate the pelvic floor. In this study, a physical examination of the pelvic floor was performed in the dorsal lithotomy position as a component of a comprehensive pelvic examination as follows: two well-lubricated fingers were inserted (one if pain or stenosis was present). The levator ani muscle complex was palpated in the longitudinal direction to evaluate for spasm, asymmetry, and tenderness. The levator complex can be felt at 4 o’clock and 8 o’clock, approximately 2 cm within the introitus, laterally. Palpation is performed as a rotational sweeping motion. When relaxed, the levators should feel like the abductor pollicis between the first finger and thumb of an open hand. When in spasm, as seen in clinic, they feel more characteristic of forearm flexor muscles lifting an object. A diagnosis of pelvic floor spasm was assigned to patients who exhibited increased levator tonus or vaginismus in combination with discomfort on palpation of these muscles. In addition to the pelvic floor examination, a urinalysis and catheterized post-void residual were completed during the initial consultation. Increased urethral tone was often noted by the clinician, evidenced through resistance during catheter insertion.

Primary inclusion criteria were the presence of painful pelvic floor spasm in combination with the stated urinary symptoms. Subjects were women between the ages of 18 and 80 who were fluent in English. Exclusion criteria included male patients; women with current positive catheterized urine culture more than two times in the past year, post-void residual greater than 150 cc; women with urodynamic evidence of obstruction secondary to previous anti-incontinence surgery; women with prior debilitating pelvic surgery or pelvic floor trauma; and women with neurologic disease, such as multiple sclerosis.

**Intervention**

The Hollister Biofeedback InCarePRS9500 office system was employed using standardized manufacturing settings. The Pelvic Floor Therapy system included a vaginal stimulation/EMG probe, diameters 1, three-quarter, or half-inch (based on patient comfort). Accessory abdominal muscles were monitored with a separate EMG allowing for correction and isolation of the pelvic floor musculature.

Each of the 6 weekly one-hour sessions was led by a registered nurse trained in pelvic floor rehabilitation biofeedback and electrical stimulation, and involved three phases of treatment. In the first phase, women learned to isolate their pelvic floor musculature aided by 10 minutes of pelvic floor transvaginal biofeedback (alternating repetitions of 5 seconds of pelvic floor contraction and 10 seconds of pelvic floor relaxation, gauging the degree visually on the computer screen). The second and third phases, conducted simultaneously, involved 1) 20 minutes of passive electrical stimulation via the vaginal probe, and 2) education regarding behavioral strategies (appropriate fluid intake, genitourinary anatomy, normal voiding patterns, constipation prevention, general and pelvic floor relaxation, and specific techniques to increase bladder capacity and suppress urge [quick flicks and behavior modification]). A standardized questionnaire tracked changes in behavior as well as urinary symptoms.

**Data**

All subjects were asked to complete an American Urological Association Symptom Score (AUA-S), AUA bother score, and 10-point visual analog scales (VAS) for symptom severity and effect on daily life at the initial visit and at least 3 months after completion of treatment. At each TVBF/EStim treatment session, in systematic interview, the registered nurse collected systematic tabular data (see Tables 1 and 2). An exit interview was conducted immediately at completion of TVBF/EStim and 6 weeks thereafter. On both occasions, patients were asked to state their “subjective percent improvement” after therapy on a scale of 0% to 100%.

At the completion of TVBF/EStim, patients were reassessed through vaginal and pelvic examination for residual spasm, pelvic asymmetry or lower back musculoskeletal pathology. Patients with residual symptoms were offered additional TVBF/EStim and referred for pelvic floor physical therapy. Some patients in the study required additional testing for concurrent symptoms. Hematuria was worked up by upper tract imaging and cystoscopy. Any concern for occult neurological disease led to full urodynamic testing and neurological consultation. Pelvic MRI was performed where appropriate to rule out urethral diverticulum.

**Statistical Analysis**

Descriptive statistics, including means and standard deviations, were calculated and reported. Two-tailed paired Student’s t-tests were used to compare before and after intervention. Bonferroni’s correction was used when multiple tests were applied using overlapping data sets.

**Results**

A total of 87 patients were referred to the authors’ practice with diagnoses of urgency-frequency syndrome, interstitial cyst-
titis, or chronic UTI symptoms with sterile cultures, and were found to have painful pelvic floor spasm upon examination. Nineteen patients were found to be ineligible for the study secondary to neurological disease or prior surgery leading to obstruction. Sixteen patients did not have TVBF/EStim due to disinterest in the intervention, insurance restrictions, or scheduling constraints, and were offered alternate therapy, such as anticholinergics or sacral neuromodulation. Fifty-one patients completed both the TVBF and EStim, with the exception of one patient who declined the EStim component, for a total of 52 patients. All patients completed the same 10-minute TVBF protocol of contractions and relaxations. For the EStim portion of the treatment, three different frequencies were employed depending on patient tolerance and primary complaint. Twenty-one patients completed EStim with 200 Hz, 6 patients with 50 Hz, and 24 patients with 12.5 or 20 Hz.

Average age was 45.0 years \((SD = 17, range = 19 to 76)\). None reported domestic abuse or feeling unsafe at home. Overlapping diagnoses were common. Eight carried a prior diagnosis of interstitial cystitis, 20 recurrent UTI symptoms with sterile or variable cultures, and 43 urgency-frequencyness syndrome. Nine patients had endometriosis, 4 herpes, 19 hematuria, and 24 chronic pelvic pain.

Of the patients with pelvic pain, 10 were found to have vaginismus, 18 dyspareunia, and 18 dysuria. In addition, 16 patients complained of chronic constipation, and 7 reported irritable bowel syndrome (IBS) as a specific diagnosis, 4 with both. Mean post-void residual (PVR) by catheterization was 49.9 mL \((SD = 49, range = 0 to 150)\).

All data (100%) were available for the exit interview with the nurse therapist. At completion of six sessions of TVBF/EStim, patients reported an average subjective improvement of 64.9% \((n = 52, SD = 27, range = 0 to 100)\). At 6-week follow up, patients reported continued subjective improvement of 75.1% \((n = 27, SD = 24, \ldots)\)
range = 0 to 100). There was no statistically significant difference between subjective improvement at exit interview and 6-week follow-up. Symptom improvements are tabulated in Table 1.

Results for the AUA-SS and bother score before and after treatment demonstrated statistically significant improvement at 3-month follow-up and are reported in Table 2. In order to accommodate the low response rate, an additional statistical analysis was performed assuming the 31 subjects who did not complete their questionnaires had no change in their AUA-SS and bother score, bringing the n to 52. The overall improvement in AUA-SS and bother score for the 52 patients after TVBF/EStim remained statistically significant.

The VAS for symptom severity and effect on daily life (0 to 10 with 10 representing the worst) was also much improved at 3-month follow-up. Symptom severity demonstrated statistically significant improvement from 5.96 to 3.52 (n = 23, p < 0.001), and effect on daily life from 6.30 to 3.74 (n = 23, p < 0.001). Similar to the AUA-SS and bother score, if researchers assumed that the 39 patients with no follow-up data experienced no improvement, the overall improvement was still statistically significant for the 52 patients as a whole.

Comments

Pelvic floor spasm should be evaluated on physical examination in patients with referring diagnoses of urinary urgency and frequency, interstitial cystitis, or recurrent urinary tract symptoms with negative cultures. Other etiologies, such as mycoplasma infection, neoplasm, multiple sclerosis, and urethral diverticulum, should be ruled out in this population, either before biofeedback or in non-responders, depending on the index of suspicion. Once pelvic floor spasm is diagnosed, pelvic floor relaxation therapies, such as TVBF and EStim, are an option.

The current pilot study has shown that TVBF and EStim resulted in clinically and statistically significant improvement in urinary symptoms at 6 weeks and 3 months. The overall subjective improvement was 65% and 75%, respectively. Patients gain a sense of which muscles in the pelvis they can control by manipulating feedback pathways and relaxing overall pelvic floor tone and afferent cross-stimulation, leading to symptomatic improvement.

Based on the underlying pathology identified in non-responders (for example, detrusor-sphincter dyssynergia, stitch erosion from prior surgery; urethral diverticulum), the researchers recommend aggressive pursuit of pathology in patients with urgency and frequency and pelvic floor spasm who do not respond to TVBF/EStim.

Limitations to this study included that it was a longitudinal analysis of one relatively small group of patients. Data were collected prospectively for clinical purposes. The full data set was collected in a systematic face-to-face interview, introducing the bias of the patient’s desire to please the treatment team as well as the potential for time-dependent resolution of the problem regardless of interventions, a placebo effect. Even though all patients were treated equally, asked the same questions, and evaluated equally, the same nurse did not treat the same patient each time. In addition, one data collection tool — the AUA symptom score — has not been validated as a data collection tool in women. The patients’ self-report data (see Table 1) were only completed in patients who returned for formal follow up. The reason for the low follow-up rate could have been resolution of symptoms. However, in order to estimate the effects of the low follow-up rate, researchers assumed that those who had not returned had experienced no improvement at all. Re-analysis with this assumption still showed a treatment effect for the group as a whole. It is possible that those lost to follow up worsened. This is unlikely given the success reported during the clinical interview, for which 100% of data were collected. Further investigation is still warranted.

Conclusion

Women presenting with urinary urgency and frequency, interstitial cystitis, and recurrent UTI symptoms with sterile cultures often have associated pelvic floor muscle spasm. TVBF and EStim with behavioral therapy is a combined modality that targets relaxation of the pelvic floor and may provide manipulation of feedback pathways along the two sacral nerve roots. This intervention resulted in statistically significant improvement in urinary symptoms for up to 3 months. Further study of this low-risk intervention for refractory patients is warranted.

References


