

SUCCESSFUL THERAPY FOR THE CHALLENGING PATIENT: TRANSVAGINAL BIOFEEDBACK AND ELECTRICAL STIMULATION IN URINARY URGENCY AND FREQUENCY ASSOCIATED WITH PELVIC FLOOR MUSCLE SPASM

Hypothesis / aims of study

Women with pelvic floor spasm can develop debilitating urinary urgency and frequency (U&F) with associated stress urinary incontinence (SUI) and urgency urinary incontinence (UUI) that is difficult to treat. Transvaginal Biofeedback and Electrical Stimulation (TVBEstim) is a behavioural modality that can be used to treat these symptoms and its efficacy was evaluated.

Study design, materials and methods

Between January 2006 and March 2007 – women referred to the urological clinic with diagnoses of urgency frequency syndrome, interstitial cystitis, urinary tract symptoms with negative cultures and pelvic pain were screened for pelvic floor spasm upon initial visit. A diagnosis of pelvic floor spasm was made based on clinical interview as well as a physical examination with findings of pelvic floor muscle tonus, also known as tense and tender levator ani, vaginismus, dyspareunia and increased urethral tone. TVBEstim consisted of 6 sessions of education, exercises monitored by graphic representation of vaginal probe activity, and passive electrical stimulation. Data were collected on a systematic tabular symptom quantification form by clinic interview at every visit. 10-point visual analogue scale (VAS) of symptom severity and effect on daily life as well as American Urological Association Symptom Scores (AUA-SS) and AUA quality of life score (AUA-QoL) were collected.

After completion of six-sessions of TVBF and EStim patients were asked to state their subjective improvement after therapy. Patients were also reassessed for residual spasm, pelvic asymmetry, or lower back asymmetrical spasm and may have been referred for additional sessions of transvaginal biofeedback and electrical stimulation and/or pelvic floor physical therapy. This was offered to the patient and carried out by a physical therapist specializing in the pelvic floor. Women returned to clinic 6 weeks and 3 months after treatment for re-evaluation and follow-up.

Results

A total of 86 patients were referred to the urology clinic with various diagnoses of pelvic pain, urgency frequency syndrome, interstitial cystitis and chronic UTI symptoms with sterile cultures and were found to have pelvic floor spasm upon examination. Of these patients, 19 patients were found to be ineligible for the study. Fifteen patients eligible for the study and referred for TVBF and EStim were unable to complete the TVBF and EStim protocol due to insurance restrictions and were offered alternate therapy. 51 patients completed TVBF and EStim and 1 patient declined EStim and only completed the TVBF. A total of 52 patients with pelvic floor spasm were entered for data analysis in the study. 100% of data is available at exit interview. 3 month follow-up for patients is 62%.

In the study, women with pelvic floor spasm were an average of 44.96 years old (17 SD, range 19-76). None of the women participating in this study reported any domestic abuse or feeling unsafe at home which has been reported in the literature as an underlying cause of vaginismus and pelvic floor spasm and guarding. Eight had a prior diagnosis of interstitial cystitis, 20 recurrent UTI symptoms with sterile cultures and 43 with refractory Urgency and Frequency syndrome. Nine patients had endometriosis, 4 herpes, 19 hematuria and 24 chronic pelvic pain. Most patients shared more than one morbidity. Of the patients with pelvic pain, 10 were found to have vaginismus, 18 dyspareunia and 18 with dysuria. In addition 16 patients complained of chronic constipation and 7 with Irritable Bowel Syndrome (IBS) as a specific diagnosis. 4 patients had both constipation and IBS. Mean Post void residual (PVR) by catheterization was 49.9 mL (49 SD, range 0-220). One patient did not have a PVR measured.

Upon completion of six sessions of TVBF and EStim patients reported a subjective improvement of 64.9% (27 SD, Range 0-100). 27 women returned for six week follow-up after the completion of treatment and reported a continued subjective improvement of 75.1% (24 SD, Range 0-100). The change is not statistically significant – indicating that the change from completion of treatment to 6 week follow-up indicates a maintenance of subjective improvement in symptoms.

Frequency (qxhour), nocturia and urge intensity measured on a scale from 0 to 5 all demonstrated statistical significant improvement. Frequency and nocturia demonstrated improvement at exit interview from 1.81 hours between voids to 3.03 hours between voids ($p=1.4 \times 10^{-9}$). 31 patients returned for 3 month follow-up and frequency was maintained at 3.0 hours in between voids ($p=8.97 \times 10^{-6}$). Nocturia also demonstrated statistical improvement from 2.23 times per night prior to treatment to 1.19 times per night after treatment ($p=0.0001$). At 3 months – the 31 patients that reported for follow-up sustained improvement in nocturia with 1.21 voids per night ($p=0.001$). Urge Intensity demonstrated statistically significant decrease from 3.64 intensity to 2.63 intensity after treatment ($p=2.62 \times 10^{-6}$).

A total of 21 patients – choose to complete the AUA-SS and AUA-QoL before and after treatment. Statistically significant improvement was seen in total Symptom Score as well as improvement in Quality of Life. AUA-SS improved from 15.4 to 7.43 ($p=9.24 \times 10^{-6}$). Quality of Life also demonstrated improvement from 4.29 to 2.76 ($p=0.000001$). All components of the AUA-SS demonstrated statistically significant improvement except straining and nocturia.

A total of 23 patients –choose to complete the VAS for symptom severity and effect on daily life. Symptom severity demonstrated statistically significant improvement from 5.96 to 3.52 ($p=0.0002$). Effect on Daily Life also demonstrated statistically significant improvement from 6.30 to 3.74 ($p=3.5 \times 10^{-5}$).

A total of 14 patients –choose to complete the FSFI before and after treatment. The lowest symptom scores for these women included Arousal and Lubrication at 1.86 and 1.61 respectively (Table 5). FSFI total score improved from 12.8 to 16.2 after treatment ($p=0.253$).

In the study population, 17 patients were found to have urge urinary incontinence (UUI), 10 with stress urinary incontinence (SUI) and 4 with Mixed urinary incontinence. Of the patients that utilized pads – a decrease in 5.35 pads were week was found (13 SD, $n=14$, $p=0.14$). Of the 17 patients with UUI, a decrease of 10.5 leaks per week was experienced (12 SD, $p=0.003$). In the 10 patients with SUI, a decrease of 10.6 leaks per week was found (8.4 SD, $p=0.004$).

Interpretation of results

TVBF and EStim is an effective treatment modality for women with pelvic floor spasm to improve pelvic pain, urgency, frequency, SUI, UUI and quality of life up to 3 months after completion of treatment.

Concluding message

These early results of this pilot study, showed that the combination of transvaginal biofeedback and electrical stimulation is a promising modality for the treatment of urinary urgency and frequency in female patients with pelvic floor spasm. Data from this cohort of patients will continue to be collected prospectively to evaluate long term durability.

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HUMAN SUBJECTS: This study was approved by the Internal Review Board, IRB of the Albany Medical College, Albany NY and followed the Declaration of Helsinki Informed consent was obtained from the patients.