

Equal Improvement in Men and Women in the Treatment of Urologic Chronic Pelvic Pain Syndrome Using a Multi-modal Protocol with an Internal Myofascial Trigger Point Wand

Rodney U. Anderson¹  · David Wise² · Tim Sawyer² · Brian H. Nathanson³ · J. Nevin Smith⁴

Published online: 31 December 2015
© Springer Science+Business Media New York 2015

Abstract Both men and women require treatment for urologic chronic pelvic pain syndromes (UCPPS), which includes interstitial cystitis/painful bladder syndrome, pelvic floor dysfunction, and chronic prostatitis/chronic pelvic pain syndrome. However, it is unknown if men and women respond differently to a protocol that includes specific physical therapy self-treatment using an internal trigger point wand and training in paradoxical relaxation. We performed a retrospective analysis by gender in a single arm, open label, single center clinical trial designed to evaluate the safety and effectiveness of a protocol for the treatment of UCPPS from October, 2008 to May, 2011. 314 adult men (79.9 %) and 79 (20.1 %) women met inclusion criteria. The median duration of symptoms was 60 months. The protocol required an initial 6-day clinic for training followed by a 6-month self-treatment period. The treatment included self-administered pelvic floor trigger point release with an internal trigger point device for physical therapy along with paradoxical relaxation training. Notable gender differences in prior treatments were observed. Men had a lower median [Interquartile Range] NIH-CPSI score at baseline than women (27 [21, 31] vs. 29 [22, 33], $p = 0.04$). Using a 1–10 scale with 10 = Most Severe, the median reduction in trigger point sensitivity was 3 units for both men and women after 6 months therapy ($p = 0.74$). A

modified Intention to Treat analysis and a multivariate regression analysis found similar results. We conclude that men and women have similar, significant reductions in trigger point sensitivity with this protocol.

Keywords Urologic chronic pelvic pain syndromes · Paradoxical relaxation · Myofascial trigger points · Pelvic pain · Gender

Abbreviations

CP/CPSS	Chronic prostatitis/chronic pelvic pain syndrome
UCPPS	Urologic chronic pelvic pain syndrome
NIH-CPSI	National Institutes of Health Chronic Prostatitis Symptoms
TrP	Trigger point

Introduction

Both men and women seek medical help for chronic or recurrent pelvic pain. Most urologists understand the challenges of treating urologic chronic pelvic pain syndrome (UCPPS) that lacks proven infection, neoplasm, or any other identifiable pathogenesis (FitzGerald et al. 2009). Moreover, leukocyte and bacterial counts when present do not correlate with the severity of chronic pelvic pain symptom (Schaeffer et al. 2002). Nevertheless, most physicians continue to treat these patients with the “Three A’s” of antibiotics, alpha-blockers, and anti-inflammatory agents, even though these treatments provide at most a modest, borderline reduction in symptoms (Anderson et al. 2005; Thakkinstian et al. 2012; Anderson and Nathanson 2011).

✉ Rodney U. Anderson
rua@stanford.edu

¹ Stanford University School of Medicine, 574 Junipero Serra Blvd, Stanford, CA 94305, USA

² National Center for Pelvic Pain Research, Sebastopol, CA, USA

³ OptiStatim, LLC, Longmeadow, MA, USA

⁴ Sonoma, CA, USA

Within the last 20 years, there have been two major changes in chronic pelvic pain management: First, instead of focusing solely on the prostate or bladder, a more systemic view of this symptom complex has evolved that includes the interaction of the genitourinary system with the central nervous system—a biopsychosocial model (Clemens et al. 2014). This in turn has changed the way the condition is described. The National Institutes of Health (NIH) and National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) now use the terms UCPPS, which includes interstitial cystitis/painful bladder syndrome (IC/PBS) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) to better reflect this new understanding (Clemens et al. 2014; Landis et al. 2014).

Second, physicians now realize many patients suffer from pelvic muscle tenderness (Shoskes et al. 2008). Both men and women with UCPPS have taut bands or nodules in the pelvic floor defined as “myofascial trigger points” (TrP) that reproduce pelvic pain symptoms upon palpation. These trigger points are clinically significant as physical therapy directed at relaxing them reduces pelvic pain symptoms (FitzGerald et al. 2009, 2012; Anderson et al. 2005, 2011a, b, 2015; Weiss 2001).

Few studies have compared men and women with UCPPS using the same physical therapy protocol. This is a serious gap in the literature as prior research has shown that women tend to report greater pain-related disability than men in general (Stubbs et al. 2010) and studies have shown chronic pelvic pain negatively impacts the level of quality of life in women more than in men (Clemens et al. 2015; Quaghebeur and Wyndaele 2014).

In prior research, we have shown that a protocol for pelvic pain that includes physical therapy and training in Paradoxical Relaxation reduced pelvic pain symptoms and trigger point sensitivity (Anderson et al. 2011a, b). A central component of this protocol is the use of a self-administered internal trigger point wand (hereafter referred to as the Wand) to do trigger point release. The Wand was recently approved by the Food and Drug Administration (FDA) as a Class II medical device (Internal Trigger Point Wand, National Center for Pelvic Pain) (Anderson et al. 2011b, 2015). We report herein a comparison of study results by gender.

Methods

This is a retrospective analysis of a single arm, open label, single center observational clinical trial to evaluate the safety and effectiveness of a psycho-physiological protocol for the treatment of UCPPS; the methodology has been described in detail in prior publications (Anderson et al. 2011a). Briefly, male and female patients aged

18–80 years who were diagnosed with UCPPS by study urologists were enrolled from October 2008 to May 2011. All patients signed an informed consent form before enrollment and the study was approved by an Institutional Review Board (Integreview, Austin, TX). The protocol required initial participation in a 6-day intensive treatment and training period clinic followed by a 6-month self-treatment period. The 6-month management included self-administered pelvic floor physical therapy with the Wand along with Paradoxical Relaxation. Patients paid to attend the clinic but were provided the Wand at no additional charge.

The Study Protocol During the 6-Day Clinic

A urologist performed a baseline patient evaluation that included a detailed medical history to rule out exclusionary conditions such as carcinoma of the prostate, an active genitourinary infection, or any medical or psychiatric condition that would exclude participation or compromise the ability to give written informed consent or comply with the study protocol. A physical therapist repeated the manual pelvic muscle examination to document active pelvic floor muscle related internal and external pelvic myofascial trigger points (TrPs) to develop anatomical maps of the TrPs for the patient’s use. Then, over the next five consecutive days, the same physical therapist performed myofascial TrP release and trained the patient to use the Wand for self-treatment with a focus on applying appropriate pressure for TrP release.

A clinical psychologist provided daily instruction in paradoxical relaxation therapy (PRT) focusing on reducing nervous system arousal in the presence of catastrophic thinking and perceived pain in pelvic floor muscles (Anderson et al. 2005). Participants also received an extensive set of audio recordings as a guide for home practice of the PRT to be used daily following the 6-day clinic.

The Trigger Point Wand

During the 6-day clinic, patients are taught techniques for: finding internal and external TrPs associated with pelvic muscles, especially around sensitive areas of the anus, vagina, and/or pelvic floor; and releasing the TrP associated pelvic muscle tension by carefully pressing on TrP with the Wand. Patients were instructed to use their fingers with a lubricated glove when the finger could easily reach internal TrPs and then use the Wand as an “extended finger” for internal trigger points that their finger could not reach. The Wand was recommended for regular, ad hoc

internal trigger point release averaging two to four times per week during the 6 months of self-treatment.

The Wand provided feedback to patients via an integrated strain gauge that provides a relative digital measure of pressure applied by the user. The integrated strain gauge provides readings that correspond to relative pressures ranging between 0 and 2 kg/cm². A maximum pressure of 0.62 kg/cm² (equal to 8.7 pounds per square inch) is possible. Details on the use of the Wand have been published elsewhere (Anderson et al. 2011b). A figure of the Wand is in “Appendix 1”.

Measurements

Baseline symptom severity was measured with the National Institute of Health-Chronic Prostatitis Symptoms Index (NIH-CPSI) (Turner et al. 2003). Trained staff administered a questionnaire at months 1 and 6 after the 6-day clinic to document patient experiences of TrP sensitivity using a scale of 1–10 with 10 being most severe. The questionnaire was expanded to assess total symptoms (e.g., pelvic pain and urinary function) and emotional distress also using the same scale from 1 to 10 for patients enrolled since November, 2009.

Statistical Analyses

Descriptive statistics are expressed as proportions, medians with interquartile (25th, 75th) percentiles, or means with standard deviations. Comparisons of means were done with the Student’s *t* test. The Mann–Whitney test assessed median differences by gender. The Chi-square test or the Fisher’s exact test (when cell counts were <4) was used to compare proportions. In addition, a modified intention to treat (mITT) analysis was performed that assumed TrP sensitivity did not change from the last known measurement when missing values were due to withdrawals or loss to follow-up. The exception being when withdrawals were due to the patient reporting a resolution of symptoms and in these cases we assigned a 1 to trigger point sensitivity at 6 months. As an additional sensitivity analysis, a linear regression model was created with the mITT derived change in trigger point sensitivity as the outcome and the predictors being gender, age, symptom duration and baseline NIH-CPSI score broken down into its 3 separate components of Pain, Quality of Life, and Urinary Scores. Analyses were conducted with Stata/SE 13.1 (StataCorp, College Station, TX). Based on prior studies (Anderson et al. 2015), we estimated that for 200 men and 50 women, we would have over 90 % power at alpha = 0.05 to detect a difference of 2 units on the 1–10 Trigger Point Sensitivity scale by gender. *p* values less than 0.05 or their Bonferroni-

adjusted equivalents were interpreted as statistically significant.

Results

There were 393 patients met study inclusion criteria, with 314 (79.9 %) men and 79 (20.1 %) women. Table 1 shows patient characteristics and medical histories at the time of study enrollment. Women were somewhat older than men (median age 49 vs. 41, *p* = 0.002) but age did not correlate with NIH-CPSI scores (*r* = −0.05, *p* = 0.36). Both men and women had a median duration of symptoms of 60 months (*p* = 0.45). The median [IQR] Total CPSI score was 27 [22, 32] for men and 29 [22, 33] for women, *p* = 0.04. Women also had higher (worse), but clinically similar Quality of Life component scores. A majority of patients saw multiple physicians before study enrollment, with women seeing more physicians on average than men (*p* = 0.003).

The use of drugs for UCPPS symptoms was common. Table 1 shows the current or prior drug history for the most commonly used drug classes. The most frequently used drug class for men was antibiotics and for women, it was psychotropics or benzodiazepines. Antibiotic use was significantly greater among men (62.4 vs. 26.6 %, *p* < 0.001). However, psychotropics or benzodiazepines and narcotics or analgesics were more frequently used by women as well as medications for interstitial cystitis (antihistamines). For men, 29.3 % had a history (current or prior use) of alpha-blockers and 2.6 % had used drugs for male sexual dysfunction.

Table 1 also depicts relevant surgical history. Certain gender-specific surgeries in women were common: 22.8 % had hysterectomies, 7.6 % had oophorectomies, and 12.7 % had cesarean sections. Women were more likely than men to have had a pudendal block injections or nerve surgery (10.3 vs. 3.5 %, *p* = 0.01) and cholecystectomy (6.3 vs. 1.6 %, *p* = 0.02). However, men were more likely to have hernia repair surgery (11.8 vs. 2.5 %, *p* = 0.01). Cystoscopy was common for both men (25.8 %) and women (27.9 %), *p* = 0.71). Prostate biopsy was performed in 2.9 % of men. Women were more likely than men to have previously tried various modes of physical therapy, botulinum toxin injections, or acupuncture before study enrollment.

The Use of the Wand

Both men and women used the Wand the same number of times a week and for the same amount of time (Table 2). However, the men were more likely to exert more pressure

Table 1 Patient characteristics by gender

Baseline characteristics	Total N = 393	%	Men N = 314	%	Women N = 79	%	<i>p</i> value	
Age in years	42	–	41	–	49	–	0.002	
Median [25th, 75th percentile]	[32, 55]		[31, 53]		[36, 60]			
Duration of symptoms (months)	60	–	60	–	60	–	0.45	
Median [25th, 75th percentile]	[24, 144]		[24, 156]		[24,120]			
NIH CPSI score (266 Men, 69 Women)								
Median [25th, 75th percentile]								
Pain component	13	–	13	–	13	–	0.13	
	[10, 15]		[10, 15]		[10,16]			
Urinary component	5	–	5	–	5	–	0.85	
	[2, 7]		[2, 6]		[1, 8]			
Quality of life component	10	–	10	–	11	–	0.001	
	[8, 12]		[8, 11]		[10, 12]			
Total CPSI score	27	–	27	–	29	–	0.04	
	[22, 32]		[21, 31]		[22, 33]			
Treatment history		N	%	N	%	N	%	<i>p</i> value
Physician visits for CPPS before enrollment								
3 or more		180	45.7	136	43.3	44	55.7	0.003
2		74	19.0	54	17.2	20	25.3	
1		113	28.8	99	31.5	14	17.7	
Unknown		26	6.6	25	8.0	1	1.3	
Drug history (current or prior use)								
Antibiotics		217	55.2	196	62.4	21	26.6	<0.001
Psychotropics or benzodiazepines		169	43.0	127	40.5	42	53.2	0.04
Alpha blockers		92	23.4	92	29.3	0	0	NA
Narcotics or analgesics		74	18.8	43	13.7	31	39.2	<0.001
Pain medications (over the counter)		65	16.5	48	15.3	17	21.5	0.18
Nerve pain medications		43	10.9	31	9.9	12	15.2	0.18
Interstitial cystitis medications or antihistamines		36	9.2	20	6.4	16	20.3	<0.001
Muscle relaxants		31	7.9	21	6.7	10	12.7	0.08
Sexual dysfunction medications		8	2.0	8	2.6	0	0	NA
Surgical procedures before study enrollment								
Hernia repair		38	9.9	37	11.8	2	2.5	0.01
Appendectomy		31	7.9	24	7.6	7	8.9	0.72
Pudendal block injections or pudendal nerve surgery		19	4.8	11	3.5	8	10.3	0.01
Hemorrhoid surgery		19	4.8	13	4.1	6	7.6	0.20
Hysterectomy		18	4.6	0	0	18	22.8	NA
Vasectomy		13	3.3	13	4.1	0	0	NA
TURP/TUNA		13	3.3	13	4.1	0	0	NA
Cesarean section		10	2.5	0	0	10	12.7	NA
Cholecystectomy		10	2.5	5	1.6	5	6.3	0.02
Prostate biopsy		9	2.3	9	2.9	0	0	NA
Meatotomy		6	1.5	6	1.9	0	0	NA
Sphincterotomy		6	1.5	4	1.3	2	2.5	0.35
Oophorectomy		6	1.5	0	0	6	7.6	NA
Anal fissure treatment		5	1.3	4	1.3	1	1.3	1.00
Additional interventions/diagnostic procedures								
Cystoscopy		103	26.2	81	25.8	22	27.9	0.71

Table 1 continued

Treatment history	N	%	N	%	N	%	<i>p</i> value
Physical therapy before study enrollment	97	24.7	56	17.8	41	51.9	<0.001
Colonoscopy	28	7.1	18	5.7	10	12.7	0.03
Botulinum toxin injections	19	4.8	11	3.5	8	10.1	0.01
Acupuncture	9	2.3	2	0.6	7	8.9	<0.001

Table 2 The use of the wand by gender over time

Variable median [25th, 75th percentile]	Men month 1	Women month 1	<i>p</i> value	Men month 6	Women month 6	<i>p</i> value
Number of times the Wand used on average each week ¹	3 [2, 3.5]	3 [2, 3.5]	0.553	2.5 [2, 3]	3 [2, 3.5]	0.21
Duration of Wand use for each session in minutes ²	12.5 [8, 18]	15 [7.5, 20]	0.830	15 [10,17.5]	15 [10, 22.5]	0.36
Number of TrPs or areas of restriction/tenderness palpated with the Wand ³	6 [4,7]	7 [6, 7]	<0.001	5 [3, 7]	7 [6, 7]	<0.001
Range of pressure on the readout of the Wand	N = 271 (% of patients)	N = 65 (% of patients)		N = 184 (% of patients)	N = 39 (% of patients)	
1–15	4.8	26.2		1.1	15.4	
16–25	39.1	44.6		25.5	33.3	
26–35	39.1	24.6		33.7	41.0	
36–40	13.3	4.6	<0.001	31.0	10.3	<0.001
40–50	3.0	0		6.0	0	
50+	0.7	0		2.7	0	

¹ Based on 282 men and 68 women responding at Month 1; 193 men and 37 women at Month 6

² Based on 277 men and 67 women responding at Month 1; 200 men and 43 women at Month 6

³ Based on 278 men and 66 women responding at Month 1; 194 men and 41 women at month 6

with the Wand than the women. Only men (3.0 %) used the Wand at 40 or more pressure units. By 6 months, 39.7 % of the men were palpating TrPs with the Wand using 36 units or more compared to 10.3 % of the women, $p < 0.001$. See Fig. 1.

The number of TrPs palpated varied by gender. Women tended to palpate one to two TrPs more than men (Table 2; Fig. 2). The number of TrPs palpated at 1 month was correlated weakly with the baseline NIH-CPSI score ($r = 0.13$, $p = 0.02$) and with TrP sensitivity at 1 month on the 1–10 scale ($r = 0.24$, $p < 0.001$). Correlations derived on men and women separately had similar values (results not shown).

Table 3 and Fig. 3 show TrP sensitivity over time. Baseline TrP sensitivity was similar by gender. In both the complete case and mITT analysis, both men and women had similar reductions in trigger point sensitivity. For the mITT analysis, we had 18 patients stop using the Wand before 6 months because their pain resolved. The median

reduction from baseline was 2.5 units on the 1–10 scale in both groups in the mITT analysis ($p = 0.08$) and 3 units in the complete case analysis ($p = 0.74$). This is approximately a one-third reduction in trigger point sensitivity in the mITT analysis. There was no difference by gender based on reasons for withdrawal ($p = 0.16$; See “Appendix 2”) and no patient reported a serious adverse event from using the Wand. Furthermore, in the multivariate regression model, the effect of gender on trigger point sensitivity after 6 months was not significant [coefficient for male gender (female gender is the referent) = 0.56; 95 % CI (–0.11, 1.22); $p = 0.10$].

For the Total Symptom and Emotional Distress outcomes on the same 1–10 severity scale used for TrP Sensitivity, the median reduction from baseline to 6 months was also similar by gender. For Total Symptoms, the median reduction for men was 2.5 [1, 4.5] versus 2.25 [1,4.5] for women, $p = 0.80$. For Emotional Distress, the median reduction for men was 2 [0,4] versus 3 [0.5, 4] for

Fig. 1 Range of pressure used with the wand by gender over time

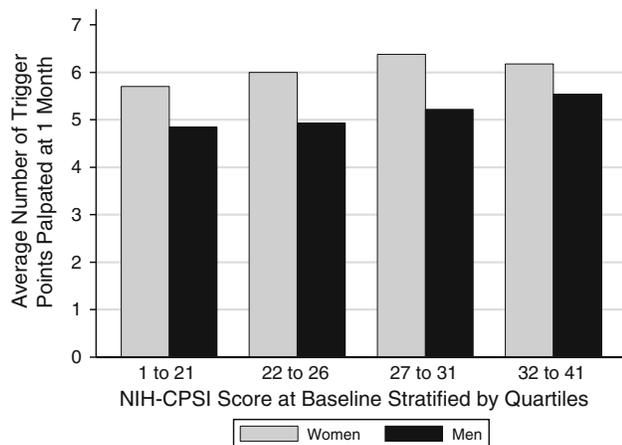
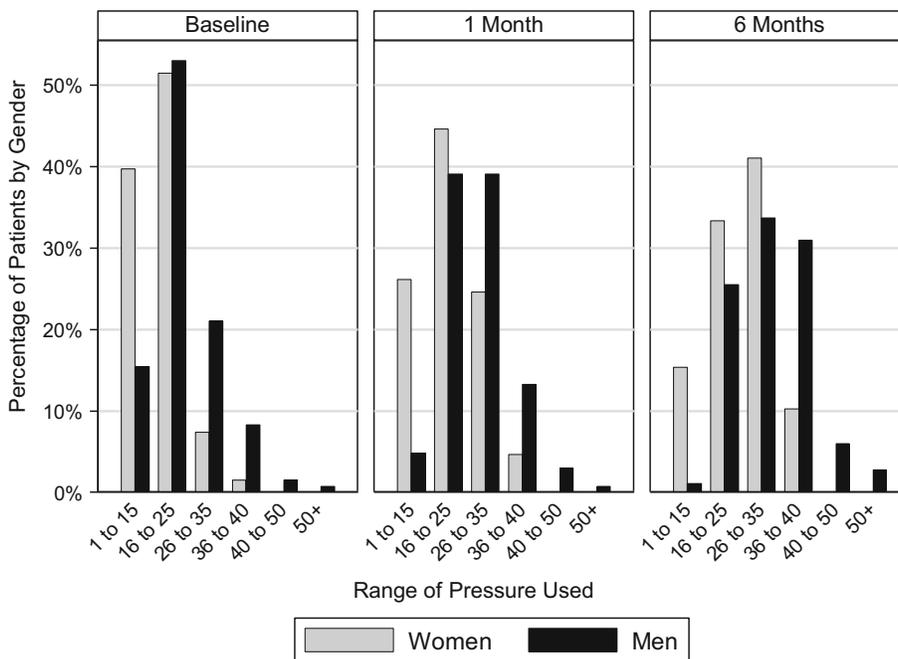


Fig. 2 Average number of trigger points palpated at 1 month by gender and NIH-CPSI score

women, $p = 0.19$. At baseline, women had higher level of Emotional Distress than men (6.75 [4, 8.5] vs. 5 [4, 7], $p = 0.01$). This concurs with observed baseline NIH-CPSI Quality of Life differences by gender.

Discussion

This study is one of the first to compare medical histories and TrP sensitivity and symptom reduction outcomes by gender in UCPPS patients who were treated with a protocol using an internal TrP wand for physical therapy. We observed that baseline symptom severity measured by the NIH-CPSI was similar by gender, a finding that concurs with a recent study by Clemens et al. (2015). Patients with

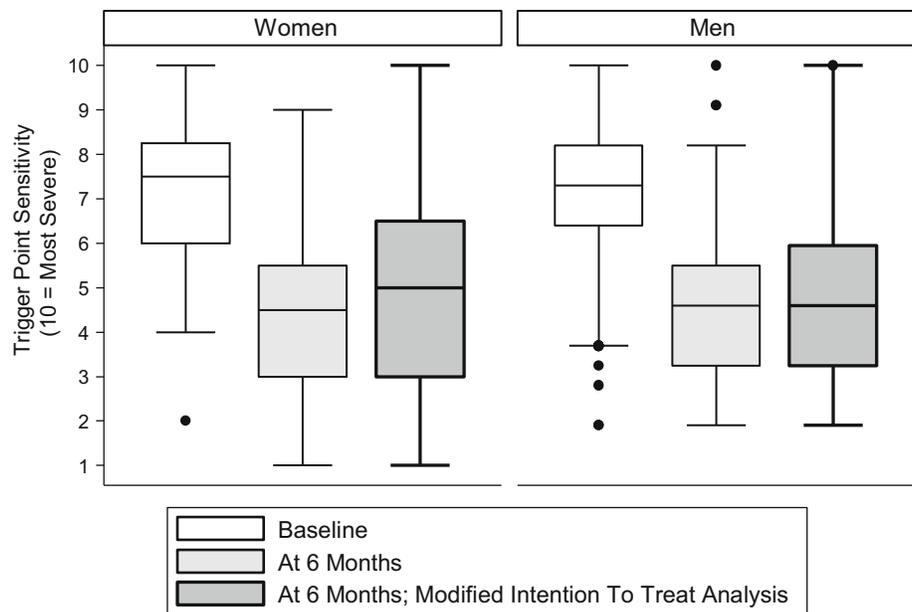
UCPPS that was “intractable” often saw multiple physicians and tried various therapeutic interventions. However, there were significant differences in how men and women were treated before they entered our study. This may reflect differences in physician training (e.g., urologists versus gynecologists) or different assumptions of the etiology of the patient’s pelvic pain based on the patient’s gender that do not reflect the new understanding of UCPPS (FitzGerald et al. 2009, 2012).

A major finding of our study was that both men and women derived a similar, clinically meaningful reduction in TrP sensitivity after 6 months of physical therapy and relaxation self-treatment. This adds to the growing body of literature that shows internal physical therapy self-treatment for the treatment of UCPPS is safe and effective, regardless of gender (FitzGerald et al. 2009, 2012, Anderson et al. 2015; Konkle and Clemens 2011). Importantly, we observed this finding in both a complete case and mITT analysis. Furthermore, we observed that both men and women had a similar reduction in Total Symptoms and Emotional Distress after 6 months.

Men and women used the Wand somewhat differently. Men tended to exert more pressure than women though the number of sessions with the Wand and session duration were similar. Significantly, we did not see a correlation between a reduction in TrP sensitivity and Wand use at these higher pressures. Furthermore, we emphasize that though the Wand was part of this multi-modal protocol, our study was not designed to determine how much improvement was due to using the Wand versus other components (e.g., paradoxical relaxation).

Table 3 Trigger point sensitivity over time by gender

Trigger point sensitivity scores	Men (N) median [25th, 75th percentile]	Women (N) median [25th, 75th percentile]	<i>p</i> value
Baseline (10 = most severe)	(281) 7 [6, 8]	(68) 7.5 [6, 8]	0.38
At 1 month	(281) 5 [4, 6]	(66) 5.5 [4.5, 8]	0.02
At 6 months	(196) 4 [2.5, 5]	(43) 4.5 [3, 5.5]	0.09
Reduction (difference) from baseline to 6 months	(194) 3 [1.5, 5]	(43) 3 [2, 4]	0.74
Reduction (difference) from baseline to 6 months (Modified intention to treat analysis)	(281) 2.5 [1.5, 4.5]	(68) 2.5 [0, 4]	0.08

Fig. 3 Trigger point sensitivity over time

We observed that women palpated approximately 1–2 more TrPs than men over time. The clinical significance of this is unclear. A patient's NIH-CPSI score and their TrP sensitivity scores were only weakly correlated with the number of TrPs palpated at 1 month. Moreover, the number of TrPs palpated did not correlate with the reduction in trigger point sensitivity. It is possible that women simply have more trigger points in their pelvic floor than men due to their physiology and further study is needed to test this hypothesis.

We also observed that women were more likely to have higher (i.e., worse) baseline Quality of Life scores on the NIH-CPSI scale and higher Emotional Distress levels at baseline as measured with our 1–10 scale. This is consistent with other studies that found chronic pelvic pain had a

significantly higher negative impact on the level of quality of life in women than in men (Edwards et al. 2004, Quaghebeur and Wyndaele 2014). Other researchers have noted that for a variety of reasons, women are more likely than men to report somatic symptoms (Quaghebeur and Wyndaele 2014; Barsky et al. 2001). This includes those suffering from UCPPS symptoms (Barsky et al. 2001; Cepeda and Carr 2003; Quaghebeur 2015; Stubbs et al. 2010; Lai et al. 2012; Moldwin and Fariello 2013; Davis et al. 2011). Women appear to be more sensitive to pain in general which may be reflected in our findings as well (Edwards et al. 2004; Quaghebeur and Wyndaele 2014; Barsky et al. 2001; Cepeda and Carr 2003; Quaghebeur 2015; Stubbs et al. 2010; Lai et al. 2012; Moldwin and Fariello 2013; Davis et al. 2011). Though we note some

evidence suggests men with UCPPS to be more sensitive to pain than male controls (Davis et al. 2011).

Although it has been demonstrated that palpating trigger points replicates pelvic pain symptoms (Anderson et al. 2009), there are fewer studies on the efficacy of treating myofascial trigger points in pelvic pain than for other pain conditions such as for the trapezius muscle (Itza et al. 2010; Montenegro et al. 2008)). Therefore, examining trigger points and related fascial restriction and the morphology of the pelvic floor musculature before and after palpation requires further study. This is beyond the scope of our study as the goal here was to compare men and women using a multimodal protocol for pelvic pain relief.

While the detailed patient histories and sample size are study strengths, we acknowledge some limitations. First, patients were self-selected and endured symptoms for a median 60 months. Patients likely represent more extreme cases of UCPPS and may have been more motivated to follow the study protocol. How our protocol would affect randomly selected UCPPS patients with less severe symptoms is unknown. We note Clemens et al. (2015) tried to recruit subjects with a range of UCPPS symptoms to analyze by gender, but still assembled a cohort with similar

symptoms durations and baseline CPSI as ours. Finally, we do not know how patients fared after 6 months, though 6 months is a longer follow-up time than many UCPPS studies (FitzGerald et al. 2009, 2012).

In conclusion, our findings suggest that men and women derive similarly significant reductions in symptoms and TrP sensitivity after 6 months of our study’s protocol, which included a Wand for internal myofascial trigger point release.

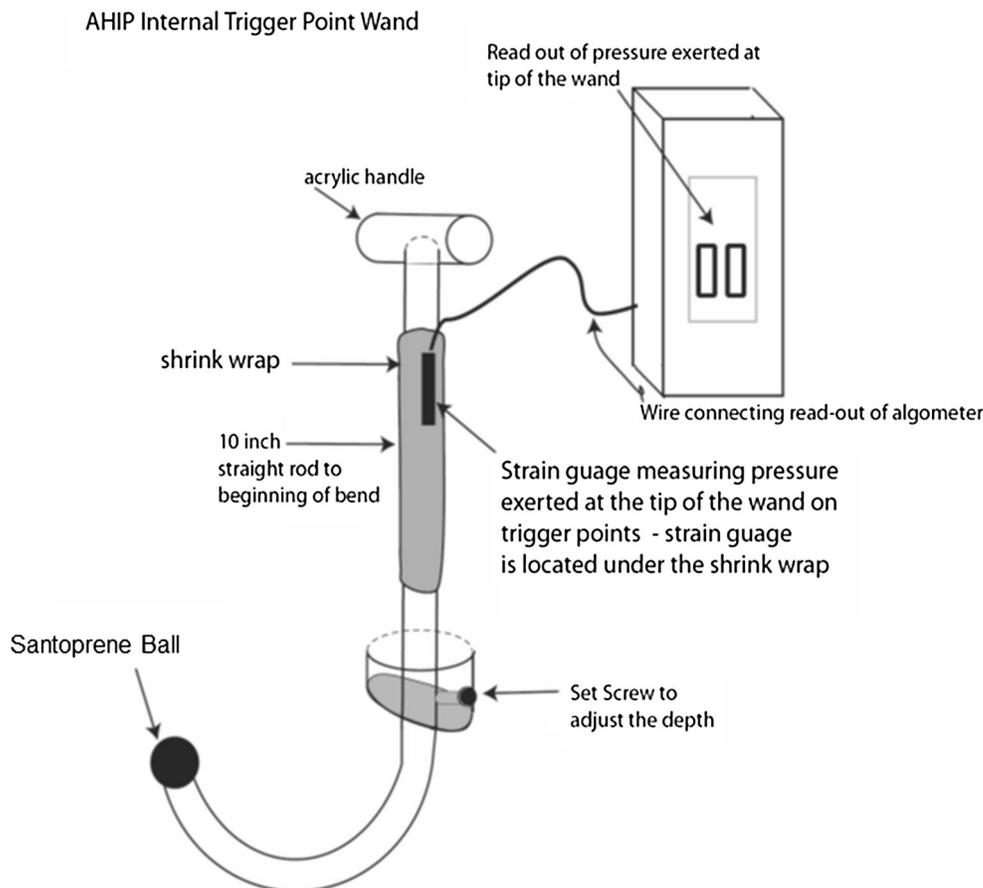
Compliance with Ethical Standards

Conflict of interest Rodney. U. Anderson is a consultant to New Pelvic Pain Technologies, Inc. and holds an intellectual property royalty relationship. David Wise is president of New Pelvic Pain Technologies, Inc. that licenses the patent for the Internal Trigger Point Wand. Tim Sawyer is a consultant and holds stock relationship with New Pelvic Pain Technologies, Inc. Brian H. Nathanson, through his company OptiStatim, LLC, has received consulting fees from New Pelvic Pain Technologies, Inc. J. Nevin Smith has no conflicts of interest to report.

Appendix 1

See Fig. 4.

Fig. 4 Internal trigger point wand



Appendix 2

See Table 4.

Table 4 Reasons for patient withdrawal

Reason	Total N (%)	Men N (%)	Women N (%)
Patient unable to be reached by phone or email after repeated attempts; lost to follow-up	34 (22.7)	30 (26.3)	4 (11.1)
Pain resolved, no longer required the device	18 (12.0)	15 (13.2)	3 (8.3)
Too busy to follow the protocol	16 (10.7)	12 (10.5)	4 (11.1)
Preferred finger over the wand	15 (10.0)	10 (8.8)	5 (13.9)
Too much transient pain or flare-ups to use the wand (It is common for some patients to stop pelvic floor physical therapy (PT) because of the transient pain associated with treatment)	14 (9.3)	8 (7.0)	6 (16.7)
Unrelated medical condition prevented the use of the wand	13 (8.7)	11 (9.7)	2 (5.6)
Did not find the wand helpful (It is common for some patients to not find PT helpful)	12 (8.0)	10 (8.8)	2 (5.6)
Never used the wand, decided not to participate in the study	9 (6.0)	6 (5.3)	3 (8.3)
Decided to have a physical therapist or other medical professional treat their pelvic pain	4 (2.7)	2 (1.8)	2 (5.6)
Did not specify the reason	4 (2.7)	2 (1.8)	2 (5.6)
Felt intimidated or uncomfortable using the wand	4 (2.7)	1 (0.9)	3 (8.3)
Felt clumsy using the wand	2 (1.3)	2 (1.8)	0 (0)
Technical difficulties using the wand	2 (1.3)	2 (1.8)	0 (0)
New drug(s) relieved symptoms	2 (1.3)	2 (1.8)	0 (0)
Allergic reaction to the gloves when using the wand	1 (0.7)	1 (0.9)	0 (0)

References

- Anderson, R. U., Harvey, R. H., Wise, D., Smith, J. N., Nathanson, B. H., & Sawyer, T. (2015). Chronic pelvic pain syndrome: Reduction of medication use after pelvic floor physical therapy with an internal myofascial trigger point wand. *Applied Psychophysiology and Biofeedback*, 40(1), 45–52.
- Anderson, R. U., & Nathanson, B. H. (2011). Pain: Drug therapies for CP/CPPS: help or hype? *Nature Reviews Urology*, 8(5), 236–237.
- Anderson, R. U., Sawyer, T., Wise, D., Morey, A., & Nathanson, B. H. (2009). Painful myofascial trigger points and pain sites in men with chronic prostatitis/chronic pelvic pain syndrome. *The Journal of Urology*, 182(6), 2753–2758.
- Anderson, R. U., Wise, D., Sawyer, T., & Chan, C. (2005). Integration of myofascial trigger point release and paradoxical relaxation training treatment of chronic pelvic pain in men. *The Journal of Urology*, 174(1), 155–160.
- Anderson, R. U., Wise, D., Sawyer, T., Glowe, P., & Orenberg, E. K. (2011a). 6-day intensive treatment protocol for refractory chronic prostatitis/chronic pelvic pain syndrome using myofascial release and paradoxical relaxation training. *The Journal of Urology*, 185(4), 1294–1299.
- Anderson, R., Wise, D., Sawyer, T., & Nathanson, B. H. (2011b). Safety and effectiveness of an internal pelvic myofascial trigger point wand for urologic chronic pelvic pain syndrome. *The Clinical Journal of Pain*, 27(9), 764–768.
- Barsky, A. J., Peekna, H. M., & Borus, J. F. (2001). Somatic symptom reporting in women and men. *Journal of General Internal Medicine*, 16(4), 266–275.
- Cepeda, M. S., & Carr, D. B. (2003). Women experience more pain and require more morphine than men to achieve a similar degree of analgesia. *Anesthesia and Analgesia*, 97(5), 1464–1468.
- Clemens, J. Q., Clauw, D. J., Kreder, K., Krieger, J. N., Kusek, J. W., Lai, H. H., et al. (2015). Comparison of baseline urological symptoms in men and women in the MAPP research cohort. *The Journal of Urology*, 193(5), 1554–1558.
- Clemens, J. Q., Mullins, C., Kusek, J. W., Kirkali, Z., Mayer, E. A., Rodríguez, L. V., et al. (2014). The MAPP research network: A novel study of urologic chronic pelvic pain syndromes. *BMC Urology*, 14(1), 57.
- Davis, S. N., Maykut, C. A., Binik, Y. M., Amsel, R., & Carrier, S. (2011). Tenderness as measured by pressure pain thresholds extends beyond the pelvis in chronic pelvic pain syndrome in men. *The Journal of Sexual Medicine*, 8(1), 232–239.
- Edwards, R. R., Haythornthwaite, J. A., Sullivan, M. J., & Fillingim, R. B. (2004). Catastrophizing as a mediator of sex differences in pain: Differential effects for daily pain versus laboratory-induced pain. *Pain*, 111(3), 335–341.
- FitzGerald, M. P., Anderson, R. U., Potts, J., Payne, C. K., Peters, K. M., Clemens, J. Q., et al. (2009). Randomized multicenter feasibility trial of myofascial physical therapy for the treatment of urological chronic pelvic pain syndromes. *The Journal of Urology*, 182(2), 570–580.

- FitzGerald, M. P., Payne, C. K., Lukacz, E. S., Yang, C. C., Peters, K. M., Chai, T. C., et al. (2012). Randomized multicenter clinical trial of myofascial physical therapy in women with interstitial cystitis/painful bladder syndrome and pelvic floor tenderness. *The Journal of Urology*, *187*(6), 2113–2118.
- Itza, F., Zarza, D., Serra, L., Gómez-Sancha, F., Salinas, J., & Allona-Almagro, A. (2010). Myofascial pain syndrome in the pelvic floor: A common urological condition. *Actas Urológicas Españolas (English Edition)*, *34*(4), 318–332.
- Konkle, K. S., & Clemens, J. Q. (2011). New paradigms in understanding chronic pelvic pain syndrome. *Current Urology Reports*, *12*(4), 278–283.
- Lai, H. H., North, C. S., Andriole, G. L., Sayuk, G. S., & Hong, B. A. (2012). Polysymptomatic, polysyndromic presentation of patients with urological chronic pelvic pain syndrome. *The Journal of Urology*, *187*(6), 2106–2112.
- Landis, J. R., Williams, D. A., Lucia, M. S., Clauw, D. J., Naliboff, B. D., Robinson, N. A., et al. (2014). The MAPP research network: Design, patient characterization and operations. *BMC Urology*, *14*(1), 58.
- Moldwin, R. M., & Fariello, J. Y. (2013). Myofascial trigger points of the pelvic floor: Associations with urological pain syndromes and treatment strategies including injection therapy. *Current Urology Reports*, *14*(5), 409–417.
- Montenegro, M. L. L. S., Vasconcelos, E. C. L. M., Candido dos Reis, F. J., Nogueira, A. A., & Poli-Neto, O. B. (2008). Physical therapy in the management of women with chronic pelvic pain. *International Journal of Clinical Practice*, *62*(2), 263–269.
- Quaghebeur, J. (2015). A review of techniques used for evaluating lower urinary tract symptoms and the level of quality of life in patients with chronic pelvic pain syndrome. *Itch and Pain*, *2*(1), 10–14800.
- Quaghebeur, J., & Wyndaele, J. J. (2015). Prevalence of lower urinary tract symptoms and level of quality of life in men and women with chronic pelvic pain. *Scandinavian Journal of Urology*, *49*(3):242–249.
- Schaeffer, A. J., Knauss, J. S., Landis, J. R., Propert, K. J., Alexander, R. B., Litwin, M. S., et al. (2002). Leukocyte and bacterial counts do not correlate with severity of symptoms in men with chronic prostatitis: The National Institutes of Health Chronic Prostatitis Cohort Study. *The Journal of Urology*, *168*(3), 1048–1053.
- Shoskes, D. A., Berger, R., Elmi, A., Landis, J. R., Propert, K. J., Zeitlin, S., & Chronic Prostatitis Collaborative Research Network Study Group. (2008). Muscle tenderness in men with chronic prostatitis/chronic pelvic pain syndrome: The chronic prostatitis cohort study. *The Journal of Urology*, *179*(2), 556–560.
- Stubbs, D., Krebs, E., Bair, M., Damush, T., Wu, J., Sutherland, J., et al. (2010). Sex differences in pain and pain-related disability among primary care patients with chronic musculoskeletal pain. *Pain Medicine*, *11*(2), 232–239.
- Thakkinstian, A., Attia, J., Anothaisintawee, T., & Nickel, J. C. (2012). α -blockers, antibiotics and anti-inflammatories have a role in the management of chronic prostatitis/chronic pelvic pain syndrome. *BJU International*, *110*(7), 1014–1022.
- Turner, J. A., Ciol, M. A., Von Korff, M., & Berger, R. (2003). Validity and responsiveness of the national institutes of health chronic prostatitis symptom index. *The Journal of Urology*, *169*(2), 580–583.
- Weiss, J. M. (2001). Pelvic floor myofascial trigger points: Manual therapy for interstitial cystitis and the urgency-frequency syndrome. *The Journal of Urology*, *166*(6), 2226–2231.

Applied Psychophysiology & Biofeedback is a copyright of Springer, 2016. All Rights Reserved.