6-Day Intensive Treatment Protocol for Refractory Chronic Prostatitis/Chronic Pelvic Pain Syndrome Using Myofascial Release and Paradoxical Relaxation Training

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Abbreviations and Acronyms

CBT = cognitive behavioral therapy

CP = chronic prostatitis

CPPS = chronic pelvic pain syndrome

CPSI = Chronic Prostatitis Symptom Index

GRA = global response assessment

NIH = National Institutes of Health

PPSS = Pelvic Pain Symptom Scale

PRT = paradoxical relaxation therapy

TrP = trigger point

UPOINT = urinary, psychosocial, organ-specific, infection, neurologic/systemic and tenderness

VAS = visual analog scale

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Purpose: Chronic prostatitis/chronic pelvic pain syndrome continues to elude conventional therapy. Evidence supports the concept that phenotypes of pelvic muscular tenderness and psychosocial distress respond to myofascial trigger point release and specific relaxation training. This case series reports long-term outcomes of a 6-day intensive combination of such therapies in refractory cases.

Materials and Methods: A total of 200 men with pain for a median of 4.8 years referred themselves to Stanford University Urology for participation in an established protocol. Daily 3 to 5-hour sessions including intrapelvic/extrapelvic physiotherapy, self-treatment training and paradoxical relaxation training provided a solid introduction to facilitate self-management. Subjects answered baseline and followup questionnaires at variable intervals after initiation of therapy including the National Institutes of Health Chronic Prostatitis Symptom Index, global response assessment and a psychological query.

Results: We followed 116 men for a median of 6 months. Baseline total symptom index was 26 out of a maximum 43 points. Scores decreased by 30% ($p < 0.001$) at followup with 60% of subjects demonstrating a 6-point or greater decrease (range 6 to 30). Domains of pain, urinary dysfunction and quality of life showed significant improvement ($p < 0.001$). Global response assessment revealed that 82% of subjects reported improvement (59% marked to moderate, 23% slight).

Conclusions: Men with chronic pelvic pain refractory to traditional treatment benefit from intensive myofascial trigger point therapy and concomitant paradoxical relaxation training. Education in techniques for self-administered trigger point release and continued pelvic muscle relaxation help patients reduce pain and dysfunction. Refinement of clinical phenotyping and selection of patients with pelvic muscle tenderness should enhance the success rate with this treatment modality.

Key Words: prostatitis, pelvic pain, physical therapy modalities, myofascial pain syndromes

MALE urological pain syndromes include CP/CPPS (called prostate pain syndrome in Europe), interstitial cystitis, isolated testicular pain, pudendal neuralgia and levator ani syndrome, among others.[1–3] We have failed to elucidate clear pathogenic mechanisms for any of these named conditions and remain challenged regarding effective treatment modalities. For the majority of men with CP/CPPS referred to urologists, traditional

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therapeutic modalities such as antibiotics, analgesics and α-blockers fail to relieve symptoms. There is a current logical trend to improve the clinical phenotyping of CP/CPPS to enhance scientific investigation and selective therapy outcomes.[4,5]

Some investigators have evaluated and attempted to treat associated muscular tenderness of chronic pelvic pain, particularly painful myofascial TrPs.[6–12] One premise focuses on the concept that chronic tension of pelvic muscles coupled with psychosocial stress and dysfunction contributes to the possible onset and promulgation of CP/CPPS.[7,13] Palpation of specific, painful pelvic myofascial TrPs elicits strong association with reported patient description of painful anatomical locations.[10] This investigation reviews the value of a 6-day protocol of physiotherapy, training patients in intrapelvic and extrapelvic muscular manipulation, as well as specific pelvic floor relaxation including cognitive behavioral therapy components as an alternative treatment modality for men with long-term and treatment refractory CPPS.

MATERIALS AND METHODS

Patients primarily referred themselves to participate in the treatment protocol, which received institutional review board approval. Male patients were accepted without regard to differentiation between inflammatory or noninflammatory prostatitis (NIH categories IIIA/IIIB) or specific location of pelvic pain. Cases of isolated orchialgia and pudendal neuralgia were included in the analysis. Men with no pain, no pelvic floor tenderness, no identifiable trigger point sensitivity or absence of pain recreated from a trigger point palpation, and those with only sexual dysfunction were excluded from study. All men had symptoms for 3 of the last 6 months, an NIH-CPSI total score of at least 12 and a nonzero pain domain score. To spend more time with each patient and to accommodate the treatment needs of patients from international, out of state or distant California commute locations, we conducted a 6-day intensive (immersion) treatment protocol including training of participants in self-treatment of intrapelvic and extrapelvic myofascial trigger point release therapy, and training in paradoxical relaxation including some cognitive behavioral methods.[14] The ultimate goal was to train patients in all aspects of the treatment protocol including self-administered manipulation and relaxation therapy to be done at home.

Treatment Procedures

The protocol involved the cooperative efforts of a urologist, a physical therapist trained in trigger point release and a psychologist trained in paradoxical relaxation. The urologist performed a baseline evaluation with medical history, pelvic examination including identification of internal and external muscle TrPs and prostatic fluid microscopic examination, and ruled out other genitourinary disorders. No urodynamic or cystoscopic studies were performed. A medical history included duration of symptoms and previous treatments. Symptoms were documented with NIH-CPSI symptom scores,[15] and symptom severity and frequency with the pain VAS and PPSS.[13]

Before commencing myofascial physiotherapy, a repeat methodical manual external and rectal muscle examination was performed by the physical therapist (TS) to document active myofascial TrPs. During the examination patients reported their subjective sensations of pelvic pain in the general locations of the penis, perineum, rectum, suprapubic region, testes, groin, and coccyx/buttocks, and sites of referred pain after manipulation of a trigger point. For 5 consecutive days the same physical therapist performed myofascial trigger point release and trained patients in the self-administration of the method. This consisted of placing the patient in a semilateral, prone position with pillows under the abdomen after external abdominal and pelvic muscles had been examined. Using a gloved finger the sphincter ani, internal posterior and anterior pelvic muscles were examined, turning the patient as necessary. A traditional palpation force of approximately 4 kg/cm^2 for tender points (recommended for examination of fibromyalgia) was used for the assessment of pain.[16] The therapist treated individual muscle groups and released TrPs with applied pressure (details have been previously described).[7] Therapy was delivered in 30 to 60-minute sessions each day, and patients were also instructed how to stretch and enhance relief of muscle tension.

A psychologist (DW) provided daily instruction in PRT focusing on reducing nervous system arousal in the presence of catastrophic thinking and perceived pain (3 to 5 hours). The paradoxical relaxation training was intended to modify the habitual tendency to tighten the pelvic muscles and reduce anxiety. A 2-year program of recorded relaxation instruction was given to patients at the end of the clinic as part of their home self- treatment.

Outcome Assessments

Extended followup evaluations of patient outcomes were conducted by mailed or Internet questionnaires, and included the NIH-CPSI, pain VAS, PPSS, a psychological status survey of 7 questions related to feelings about the disorder and coping with symptoms scored on a 5-point Likert scale of none to a lot, and GRA, a 7-point Likert scale to evaluate patient perception of the overall effect of the therapy: “How are you now in comparison to before intensive therapy/training?” Possible responses were markedly improved, moderately improved, slightly improved, no change, slightly worse, moderately worse or markedly worse. Participants were also surveyed about their continued use of physiotherapy and relaxation training after returning home from the immersion protocol.

Statistical Analysis

Descriptive statistics were generated on all demographic, medical history and physical examination findings including means and standard deviations for continuous variables, and frequencies and percentages for categorical variables. Differences between NIH-CPSI total and individual domain scores before and after treatment were analyzed with the paired sample t test (2-sided). Statistical significance was considered at $p < 0.05$. Statistical

Table 1. *Symptom scores*

	Before Treatment	Median (IQR) After Treatment
NIH-CPSI total score (0–43):	26 (22, 30)	19 (13, 25)
Pain domain (0–21)	12 (11, 14)	9 (7, 12)
Urinary domain (0–10)	4 (2, 6)	2 (1, 5)
Life quality domain (0–12)	10 (9, 11)	7 (4, 9)
PPSS scores:		
Pain VAS (1–10)	4 (3, 6)	3 (2, 5)
Pain domain (0–40)	13 (10, 17)	9 (6, 12.5)
Urinary domain (0–28)	10.5 (6, 16)	6 (3, 10)
Sexual health domain (0–20)	5 (2, 8)	3 (1, 6)

All values $p < 0.001$ (2-sided paired t test).

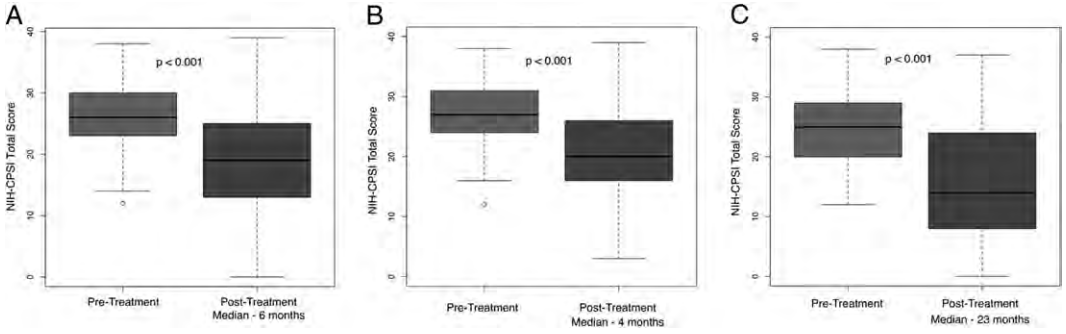
analyses were performed using R software, version 2.9 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Only patients who had urological evaluations at Stanford University urology clinic and responded to followup query are included in this report. A total of 200 men entered the protocol through the Stanford clinic and 116 provided followup questionnaires, whereas 102 (88%) originated from outside the local catchment area and were out of state or international residents. Median age was 48 years (range 19 to 80; IQR 36, 54). Median symptom duration was 4.8 years (range less than 1 to 30; IQR 2, 10). Except for 8 patients all participants had severely refractory CPPS previously treated with several modalities by many physicians. Patients included in this analysis were treated with the immersion protocol from February 2004 through August 2009. The initial examination revealed symptom severity measured with the pain VAS and NIH-CPSI total and domain scores with higher scores representing greater severity. Median pain VAS score was 4 out of a maximum 10 (range 1 to 8). The possible maximum NIH-CPSI total score was 43, the participants had a median NIH-CPSI total score of 26 (range 10 to 38; IQR 23, 30), a median pain domain score of 12 out of 21 maximum (range 1 to 19), a median urinary domain score of 4 out of 10 maximum (range 0 to 10) and median life quality of 10 out of 12 maximum (range 4 to 12). All men completed the entire 6-day protocol and had their first followup evaluation after a median of 6 months (IQR 3, 12).

Table 1 shows the initial severity scores compared with scores at a median of 6 months after completion of the immersion protocol. Median NIH-CPSI total scores decreased approximately 30% compared to before treatment ($p < 0.001$). Of 116 patients 70 (60%) had a 6-point or greater decrease (range 6 to 30) in NIH-CPSI total score at followup after a median of 6 months. The PPSS scores also corroborated the significantly improved symptom scores for pain, and urinary and sexual function. The figure shows the improved NIH-CPSI scores for the entire cohort of participants, and compares those patients with a followup of 9 months or less and to those with a longer or second followup of more than 10 months. Symptomatic improvement was sustained even in patients with the longer term median followup of 23 months after treatment in the immersion protocol. Patient self-reported GRA ratings of markedly and moderately improved were considered an index of clinical success. Most patients, or 106 of 116 (91%), answered the GRA questionnaire with 63 of 106 (59%) reporting symptoms as moderately or markedly improved. An additional 24 of 106 patients (23%) indicated a slight improvement. Table 2 shows the correlation ($r = -0.48$, $p < 0.001$) between GRA category and the changes in NIH-CPSI total symptom scores. Appendix shows the median response score to the psychological influence of the immersion protocol.

Most immersion protocol attendees, 91 of 116 (78%), continued use of relaxation audiotapes after the immersion protocol, and of those men 56 (62%) practiced relaxation exercises at least once weekly or more frequently. Approximately half of the pa-



A, NIH-CPSI total score before and after 6-day immersion protocol in 116 patients. *B,* NIH-CPSI total scores for followup of 9 months or less (79). *C,* NIH-CPSI total scores for followup of 10 months or more (37).

Table 2. *GRA and changes in NIH-CPSI total scores at 6-month followup*

	No. (%)	Median Improved NIH-CPSI Total Score (range)
Markedly improved	31 (29)	−11 (−1 to −30)
Moderately improved	32 (30)	−10 (2 to −21)
Slightly improved	24 (23)	−5 (12 to −14)
No change	18 (17)	−2 (5 to −18)
Slightly worse	—	—
Moderately worse	1 (less than 1)	−7
Markedly or moderately improved	63 (59)	—

tients with symptomatic improvement maintained an ongoing program of relaxation exercises, while the other half anecdotally reported they were feeling good and did not need the exercises. Information on continued manual physiotherapy was collected from 90 of 116 men (78%), and of those men 34 (38%) sought physiotherapy at varied frequencies. Skilled therapists were not available to many patients.

The psychological benefits attributable to participation in the immersion protocol were assessed including ability to relax the mind, body and pelvic muscles, improved control and understanding of symptoms, and improved well-being and relationships. A median score of 14 (IQR 10, 17) out of a maximum total score of 21 was documented at the median 6-month followup. Of the patients 71% stated they would be willing to participate again in the immersion protocol as needed or recommend this therapeutic approach to other patients. Adverse events related to the physiotherapy were not routinely reported. However, consistent with previous experience, initial pain at the onset of therapy was the only adverse event and was never severe.[11]

DISCUSSION

Pain is the most prevalent and distressing symptom of the urological pelvic pain syndromes. We and others have identified abdominal and pelvic muscular tension and tenderness as a common underlying finding associated with typical complex pain complaints. The recent description by Shoskes et al of phenotype directed multimodal therapy revealed that 64% of patients demonstrated muscular tenderness as 1 of the 6 subgroup phenotypes, namely urinary, psychosocial, organ specific, infection, neurological/systemic and tenderness (UPOINT), and that treatment directed toward specific phenotypes achieved at least a 6-point decrease in total CPSI score for 84% of patients.[12]

The patients in our immersion protocol had notably refractory CP/CPPS, and with few exceptions most had multiple internal and external pelvic muscle tenderness. As these were the most therapeutically challenging cases of CP/CPPS, we found the 6-point or greater decrease in NIH-CPSI total score when assessed after a median followup of 6 months in 67% of patients, and the overall GRA response rate of 59%, to be encouraging outcomes. These responses compared favorably with the global response rates in a small NIH feasibility trial of myofascial physical therapy, with a GRA rate of 57% compared to 21% for the global therapeutic massage comparator group followed to 12 weeks.[11] Our work also supports the findings of others focusing on pelvic floor dysfunction in CP/CPPS.[17–20]

We advocate integration of TrP manual therapy and concomitant PRT based on our belief that chronic pelvic pain reflects tension in the pelvic floor, initiated or exacerbated by cycles of mental tension, anxiety and stress. In a previous study we observed that compared with age matched asymptomatic controls, men with CP/CPPS had more perceived stress and anxiety, and significantly increased scores on all psychological scales in the Brief Symptom Index including somatization, obsessive/compulsive behavior, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychoticism.[21] On a composite index of psychosocial severity the men with CP/CPPS scored in the 94th vs the 50th centile for the controls. Cognitive behavioral modification in conjunction with PRT has been an important component of the immersion protocol since its inception. It is used to shift cognition away from sympathetic nervous system arousal and controlling attention away from catastrophic thinking of pain symptoms. We have found this valuable in helping patients to quiet anxiety and develop coping strategies to deal with chronic pain. Inclusion of cognitive behavior programs in the management of CPPS has recently been advocated by others.[22]

Because traditional pharmaceutical agents have failed to demonstrate effectiveness in treating CP/CPPS, many investigators have turned to complementary and alternative therapies such as anti-inflammatory herbal agents,[23,24] and others pursue neuromodulation using electromagnetic and acupuncture approaches.[25–27] To our knowledge all of these approaches have been more successful than any oral medications or surgical intervention. Our current study contributes cognitive, relaxation and personal training with manual therapy for a more effective management strategy.

There were a number of strengths to our study. The immersion protocol was standardized for all participants and the team of therapists remained consistent throughout delivery of the protocol procedures. There was a high rate of continued use of relaxation exercises in the followup period, indicative of patient appreciation of the mind-body inter-

action and commitment to helping themselves cope with their symptoms, and hopefully also indicative of the success of the training sessions. However, the lack of available skilled physiotherapists in participant residence communities posed a disadvantage in the continuation of manual trigger point massage. An added feature of the current immersion protocol clinics is to provide more instruction in self-administered internal trigger point release using a personal wand.

We are also mindful of several potential limitations of our study. Because patients with refractory CP/CPPS were primarily self-referred to our tertiary center to enroll in the protocol, most were nonlocal residents and we were not involved in the initial management of their symptoms. We were unable to preselect those who might best benefit from the intensive protocol, we could not conduct personal return clinic visits to appraise treatment outcomes, use any other multimodal therapy, or insure compliance with posttreatment massage and relaxation therapy. Patients provided their perception of response to therapy with self-report questionnaires. Immersion protocol participants were highly motivated to try a new therapeutic approach for CPPS, and made a significant time commitment for 6 days of therapy and training. Most patients had little to no insurance coverage for the protocol treatments. The intensive personal interaction of the therapists with each patient may have contributed to the positive treatment responses. This study did not include a comparator treatment group using any other approach. We also did not compare the effectiveness of pelvic muscle TrP release alone vs behavioral and relaxation therapy alone because we strongly believe in the concomitant use of both approaches for CP/CPPS.

CONCLUSIONS

Patients with CP/CPPS with long-standing pain that is refractory to traditional treatment may benefit from focused myofascial TrP therapy and concomitant PRT. Education of patients in techniques for self-administered TrP massage and encouragement of continued pelvic muscle relaxation are assets in helping them to participate in the management of this chronic disorder. Refinement of clinical phenotyping and selection of patients with pelvic muscle tenderness should enhance the success rate with this treatment modality.

APPENDIX

Patient self-reported psychological assessment of degree of improvement from participation in the immersion protocol. Scoring: None = 0, A little = 1, Some = 2, A lot = 3. Maximum total score is 21

	Degree of Improvement			
Question	None	A Little	Some	A Lot
Ability to relax your mind				
Ability to relax your body				
Ability to relax muscles of your pelvic floor				
Control over your symptoms				
Understanding of your symptoms and ability to cope				
Sense of well-being				
Quality of your relationships				

Total score at first query (median Q1, Q3) = 13 (10, 17), N = 50 patients. Total score at second query = 14 (13, 17), N = 24 patients.

REFERENCES

1. Stav K, Dwyer PL and Roberts L: Pudendal neuralgia. Fact or Fiction? Obstet Gynecol Surv 2009; **64:** 190.
2. Fall M, Baranowski AP, Elneil S et al: EAU guidelines on chronic pelvic pain. Eur Urol 2010; **57:** 35.
3. Planken E, Voorham-van der Zalm PJ, Lycklama à Nijeholt AA et al: Chronic testicular pain as a symptom of pelvic floor dysfunction. J Urol 2010; **183:** 177.
4. Baranowski AP, Abrams P, Berger RE et al: Urogenital pain–time to accept a new approach to phenotyping and, as a consequence, management. Eur Urol 2008; **53:** 33.
5. Shoskes DA, Nickel JC, Dolinga R et al: Clinical phenotyping of patients with chronic prostatitis/chronic pelvic pain syndrome and correlation with symptom severity. Urology 2009; **73:** 538.
6. Potts JM and O'Dougherty E: Pelvic floor physical therapy for patients with prostatitis. Curr Urol Rep 2000; **1:** 155.
7. Anderson RU, Wise D, Sawyer T et al: Integration of myofascial trigger point release and paradoxical relaxation training treatment of chronic pelvic pain in men. J Urol 2005; **174:** 155.
8. Berger RE, Ciol MA, Rothman I et al: Pelvic tenderness is not limited to the prostate in chronic prostatitis/chronic pelvic pain syndrome (CPPS) type IIIA and IIIB: comparison of men with and without CP/CPPS. BMC Urol 2007; **7:** 17.
9. Shoskes DA, Berger R, Elmi A et al: Muscle tenderness in men with chronic prostatitis/chronic pelvic pain syndrome: the Chronic Prostatitis Cohort Study. J Urol 2008; **179:** 556.
10. Anderson RU, Sawyer T, Wise D et al: Painful myofascial trigger points and pain sites in men with chronic prostatitis/chronic pelvic pain syndrome. J Urol 2009; **182:** 2753.
11. FitzGerald MP, Anderson RU, Potts J et al: Randomized multicenter feasibility trial of myofascial physical therapy for the treatment of urological chronic pelvic pain syndromes. J Urol 2009; **182:** 570.
12. Shoskes DA, Nickel JC and Kattan MW: Phenotypically directed multimodal therapy for chronic prostatitis/chronic pelvic pain syndrome: a prospective study using UPOINT. Urology 2010; **75:** 1249.
13. Anderson RU, Wise D, Sawyer T et al: Sexual dysfunction in men with chronic prostatitis/chronic pelvic pain syndrome: improvement after trigger point release and paradoxical relaxation training. J Urol 2006; **176:** 1534.
14. Wise D and Anderson RU: A Headache in the Pelvis: A New Understanding and Treatment for Prostatitis and Chronic Pelvic Pain Syndromes, 6th ed. Occidental, California: National Center for Pelvic Pain Research 2010.
15. Litwin MS, McNaughton-Collins M, Fowler FJ Jr et al: The National Institutes of Health chronic prostatitis symptom index: development and val-

idation of a new outcome measure. J Urol 1999; **162:** 369.

16. Wolfe F, Smythe HA, Yunus MB et al: The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia. Report of the Multicenter Criteria Committee. Arthritis Rheum 1990; **33:** 160.
17. Clemens JQ, Nadler RB, Schaeffer AJ et al: Biofeedback, pelvic floor reeducation, and bladder training for male chronic pelvic pain syndrome. Urology 2000; **56:** 951.
18. Weiss JM: Pelvic floor myofascial trigger points: manual therapy for interstitial cystitis and the urgency-frequency syndrome. J Urol 2001; **166:** 2226.
19. Oyama IA, Rejba A, Lukban JC et al: Modified Thele massage as therapeutic intervention for female patients with interstitial cystitis and high-tone pelvic floor dysfunction. Urology 2004; **64:** 862.
20. Cornel EB, van Haarst EP, Schaarsberg RW et al: The effect of biofeedback physical therapy in men with Chronic Pelvic Pain Syndrome Type III. Eur Urol 2005; **47:** 607.
21. Anderson RU, Orenberg EK, Chan CA et al: Psychometric profiles and hypothalamic-pituitary-adrenal axis function in men with chronic prostatitis/chronic pelvic pain syndrome. J Urol 2008; **179:** 956.
22. Nickel JC, Mullins C and Tripp DA: Development of an evidence-based cognitive behavioral treatment program for men with chronic prostatitis/chronic pelvic pain syndrome. World J Urol 2008; **26:** 167.
23. Shoskes DA, Zeitlin SI, Shahed A et al: Quercitin in men with category III chronic prostatitis: a preliminary prospective, double-blind, placebo-controlled trial. Urology 1999; **54:** 960.
24. Wagenlehner FM, Schneider H, Ludwig M et al: A pollen extract (Cernilton) in patients with inflammatory chronic prostatitis-chronic pelvic pain syndrome: a multicentre, randomised, prospective, double-blind, placebo-controlled phase 3 study. Eur Urol 2009; **56:** 544.
25. Kabay S, Kabay SC, Yucel M et al: Efficacy of posterior tibial nerve stimulation in category IIIB chronic prostatitis/chronic pelvic pain: a sham-controlled comparative study. Urol Int 2009; **83:** 33.
26. Zimmermann R, Cumpanas A, Miclea F et al: Extracorporeal shock wave therapy for the treatment of chronic pelvic pain syndrome in males: a randomized, double-blind, placebo-controlled study. Eur Urol 2009; **56:** 418.
27. Tugcu V, Tas S, Eren G et al: Effectiveness of acupuncture in patients with category IIIB chronic pelvic pain syndrome: a report of 97 patients. Pain Med 2010; **11:** 518.