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ACUPUNCTURE AMELIORATES SYMPTOMS IN MEN WITH CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME

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ABSTRACT

Objectives. To determine in a pilot study whether acupuncture improved pain, voiding symptoms, and the quality of life of men with chronic prostatitis/chronic pelvic pain syndrome.

Methods. Men diagnosed with chronic prostatitis/chronic pelvic pain syndrome (National Institutes of Health [NIH] criteria) who were refractory to standard therapy (antibiotics, alpha-blockers, anti-inflammatories, phytotherapy) were referred for acupuncture therapy. The treatment protocol involved three sets of acupuncture points totaling 30 points (8 points were electrically stimulated) given alternatively twice weekly for 6 weeks. The patients completed the NIH Chronic Prostatitis Symptom Index (CPSI) at baseline and the CPSI and subjective global assessment at 6 weeks (end of treatment), 12 weeks, and at least 6 months after the baseline assessment.

Results. Twelve men underwent a minimum of 6 weeks of acupuncture treatment. The average follow-up (from baseline) was 33 weeks (range 24 to 52). A significant decrease occurred in total NIH-CPSI (28.2 to 8.5), NIH-CPSI pain (14.1 to 4.8), NIH-CPSI urinary (5.2 to 1.3), and NIH-CPSI quality-of-life (8.8 to 2.3) scores after an average of 33 weeks of follow-up. Ten patients (83%) had a sustained greater than 50% decrease in NIH-CPSI at final visit (average 33 weeks). Ten patients (83%) reported marked improvement on the subjective global assessment at 12 weeks. At an average of 33 weeks, 8 patients (67%) had sustained marked improvement on subjective global assessment evaluation. No adverse events were reported in this pilot study.

Conclusions. Acupuncture appears to be a safe, effective, and durable treatment in improving symptoms in, and the quality of life of, men with chronic prostatitis/chronic pelvic pain syndrome refractory to treatment. A larger controlled study is required to confirm these encouraging initial results. UROLOGY **61:** 1156–1159, 2003. © 2003 Elsevier Inc.

Many men with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) fail to experience significant amelioration of their symptoms with conventional therapy. Traditional, but for the most part unvalidated, therapies for CP/CPPS include antibiotics, alpha-blockers, anti-inflammatory agents, phytotherapy, and other medical agents.[1] These medical therapies targeted at the "initiators" of chronic prostatitis (infection, inflammation, dysfunctional voiding, etc.), appear to be more effective in the early stages of the pathogenic disease cascade.[1] Ongoing research and expert consensus suggests that the end stage of CP/CPPS may be a neuropathic pain syndrome. The chronic pain, persistent inflammation, voiding symptoms, and sexual disturbances may be neurogenically mediated by upregulation of the local pelvic/perineal afferent sensory nervous system and "wind-up" within the spinal cord and central nervous system.[1,2] If this hypothesis is true, neuromodulatory therapies may provide amelioration of symptoms of CP/CPPS.

Acupuncture, an important component of the traditional Chinese system of medicine, is perhaps one of the oldest standardized neuromodulatory therapies available. The World Health Organization's recommendation of 1979 (WHA 44.34) that urged conventional medical scientists to study and exploit the possibilities of acupuncture has never been taken up by the Western urological community. The U.S. Food and Drug Administration took

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TABLE I. ***Mean CPSI total scores at baseline, 6 weeks (end of therapy), 12 weeks, and long-term follow-up (average 33 weeks)***

NIH-CPSI	Baseline	6 wk	12 wk	33 wk (range 24–52)
Total	28.2 ± 4.8	8.5 ± 5.1	7.8 ± 5.4	8.5 ± 8.6
Pain	14.1 ± 2.2	4.2 ± 2.9	3.6 ± 2.8	4.8 ± 5.2
Urinary	5.2 ± 2.5	1.7 ± 2.3	1.8 ± 2.2	1.3 ± 1.9
QoL	8.8 ± 2.3	2.7 ± 2.6	2.3 ± 1.8	2.3 ± 2.6

KEY: CPSI = Chronic Prostatitis Symptom Index; NIH = National Institutes of Health; QoL = quality-of-life.
All 12 men who started therapy were assessed for each of the follow-up visits.

acupuncture needles off its list of experimental medical devices in 1996 and endorsed the study of acupuncture as a treatment method for a number of medical problems. Many anecdotal reports and a number of uncontrolled studies[3–7] have suggested that acupuncture therapy may benefit men who have symptoms of chronic prostatitis. We undertook a pilot study to determine whether acupuncture improves the pain, voiding symptoms, and quality of life in men with CP/CPPS.

MATERIAL AND METHODS

PATIENTS

To be eligible to participate in this study, men had to have a clinical diagnosis of CP/CPPS (category III) according to the National Institutes of Health (NIH) consensus criteria.[8] The CP/CPPS of patients had to be refractory (patient unsatisfied with clinical response) to standard conventional therapy (antibiotics, alpha-blockers, anti-inflammatory agents, phytotherapy). The inclusion/exclusion criteria were compatible (except that patients treated with antibiotics and/or alpha-blockers were included in this reported study) with that recently reported by the NIH-Chronic Prostatitis Collaborative Research Network for clinical trials in CPPS.[9] Patients had to express a willingness to undergo 6 weeks of acupuncture therapy. Patient eligibility and informed consent were completed by one of us (J.C.N., Queen's University Prostatitis Research Clinic, Kingston, Ontario, Canada).

TREATMENT PROTOCOL

Three sets of acupuncture points were given alternatively twice weekly for 20 minutes for 6 weeks by one of us (R.C., Mississauga, Ontario, Canada):

First set of points (uniting the divergent meridian of kidney and bladder)
- BL10, BL23, BL28, BL40, K10
- K1 and BL67, all bilateral

Second set of points
- CV4, CV3
- M-CA-17 (bilateral stimulate ilioinguinal and iliohypogastric nerve)
- All four points were electrically stimulated at 5 HZ, constant mode
- SP6

Third set of points (bilateral points)
- BL23 (sympathetic)
- BL54 (L4, L5, S1, S2)
- BL35 (pelvic plexus and levator ani)
- BL54 and BL35 electrically stimulated at 20 HZ (constant mode) using 3-in. needles (for BL35 points, the direction of the needle should be 30° sagittal and 30° horizontal to the depth of 1.5 to 2 in. to avoid puncturing the rectum
- BL39 and SP6

Although not relevant to this study (exclusion criteria would exclude these men), bladder 35 points should not be used if the patient has had radiotherapy to the pelvis or multiple pelvic operations or is taking anticoagulant agents.

FOLLOW-UP

The NIH Chronic Prostatitis Symptom Index (CPSI)[10] was completed by each patient at baseline (start of therapy, day 0) and 6 weeks, 12 weeks, and at least 6 months (long-term follow-up) after the baseline assessment. A standard subjective global assessment (SGA)[11] was completed at 6 weeks, 12 weeks, and at least 6 months after the baseline assessment.

STATISTICAL ANALYSIS

The mean values of the total CPSI, pain subscore, urinary subscore, and quality of life subscore at 6 and 12 weeks and at long-term follow-up were compared to the baseline values (analysis of variance Tukey test). Significance was assigned at $P < 0.05$ compared with baseline. Responders were predefined as patients who had experienced a more than 50% decrease in the total CPSI score. The degree of subjective improvement was assessed at 6 and 12 weeks and at long-term follow-up compared with the baseline values using the SGA. A responder was defined as a patient who reported marked improvement in the SGA (more than 75% improvement). The responder analysis (CPSI and SGA) data was treated descriptively.

RESULTS

Twelve men who met the inclusion/exclusion criteria for the study underwent a minimum of 6 weeks of acupuncture treatments by December 2001. The average age was 42.4 years (range 26 to 57), and the duration of symptoms was 33 months (range 6 to 54). All participants were followed up for an average of 33 weeks (range 24 to 52 weeks).

A statistically significant decrease occurred in the mean total CPSI score (28.2 to 8.5), CPSI pain subscore (14.1 to 4.8), CPSI urinary subscore (5.2 to 1.3), and CPSI quality-of-life subscore (8.8 to 2.3) an average of 33 weeks after the baseline assessment. The CPSI total scores and subscores for baseline, 6 weeks, 12 weeks, and long-term follow-up are shown in Table I.

At end of therapy (6 weeks), 92% (11 of 12) of men were NIH-CPSI responders (more than 50% decrease from baseline total NIH-CPSI score), and 83% (10 of 12) were SGA responders (marked improvement or more than 75% subjective global improvement from baseline). At 12 weeks, the response rate was unchanged (92% and 83%, respectively, for NIH-CPSI and SGA responders). This response rate was sustained up to the long-term follow-up visit (average 33 weeks); 10 (83%) of the 12 patients had experienced more than a 50% decrease in total NIH-CPSI score, and 8 (67%) of the 12 patients continued to report a marked improvement in the SGA.

None of the patients reported any adverse events or problems with acupuncture therapy.

COMMENT

Acupuncture has been used by practitioners of traditional Chinese medicine to treat a variety of illnesses for more than 2000 years. Traditional Chinese medicine diagnoses differ from Western medicine, to some extent, by the priorities in physical examination and history taking. The practitioners' observation of the pulse and tongue, as well as a thorough patient interview, to assess the body's balance of yin and yang (hot or cold properties) for evaluating the deficiency or excess patterns of disease, and for determining the state of the body's internal organs and channels is required before a series of acupuncture points are selected. Initially, acupuncture is believed to improve the balance of yin and yang, to harmonize the deficient or excess condition, and to nourish the organ or channel involved in the disease process. Inserting needles along "meridians" was believed to promote the flow of energy through the body, thereby restoring the balance.

Numerous studies have shown that acupuncture is effective in the treatment of various types of pain.[12,13] Contemporary research suggests that the effects of acupuncture are brought about by a complicated phenomenon involving many neuropeptides and neurotransmitters.[14,15] The effects may be mediated by met-enkephalin, beta-endorphin, dynorphin,[15–17] serotonin,[18] and/or noradrenaline[19,20] at the spinal cord, midbrain, hypothalamus, and pituitary levels. This neuromodulation is believed to inhibit transmission of pain, as well as to normalize the function of various midbrain nuclei in micturition control and sensory processing. Acupuncture is also believed to neuromodulate upregulation and "wind-up" within the peripheral and central nervous systems.

Our pilot study of 12 men with treatment-refractory CP/CPPS demonstrated significant amelioration of chronic prostatitis-related symptoms. A significant improvement in the average CPSI total score, as well as the separate domains of pain, urinary, and quality-of-life scores, was observed at the end of treatment (6 weeks) and 6 weeks after treatment (12 weeks). More than 90% of patients experienced a greater than 50% decrease in the NIH-CPSI score at 12 weeks. More than 80% of patients noted a marked improvement on the SGA (patient perceived at least a 75% improvement in subjective symptoms compared with baseline). The improvement in CPSI and SGA seen at 6 and 12 weeks was durable (average follow-up of 33 weeks, range 24 to 52).

A number of other studies published in non-urologic and non-Western journals have also suggested that prostatitis may be effectively treated with acupuncture. Yuting[3] treated 360 cases of prostatitis with acupuncture and a number of combinations of traditional Chinese medicine. He reported that 89% were cured, 10% had improvement, and only 1% failed treatment. Katai[4] described the use of electroacupuncture therapy in 100 patients diagnosed with nonbacterial prostatitis or prostatodynia. He reported an 85% improvement of subjective symptoms, decreased leukocyte counts in the expressed prostatic secretions in 65% of the patients, and amelioration of prostate tenderness in 82% of the patients. Ikeuchi and Iguchi[5] administered electroacupuncture to 17 patients with prostatodynia and reported excellent results in 30% and moderate results in 70%. Chen *et al.*[6] and Ge *et al.*[7] reported similar results. To our knowledge, no study (including our own pilot study) has used a sham or placebo arm. Placebo-controlled studies are difficult to design and implement in acupuncture trials,[21] and perhaps an active comparator would provide a credible alternative.

CONCLUSIONS

This pilot study assessing the potential benefits of acupuncture in patients with CP/CPPS included men with an NIH-defined clinical diagnosis of CPPS, standardized inclusion/exclusion criteria, and follow-up using validated outcome parameters. However, the study group was small, uncontrolled, and was not compared with a placebo/sham or active comparator treatment group. Despite these limitations, however, the results of the study suggest that acupuncture appears to be a safe and potentially effective treatment in improving the symptoms and quality of life of men clinically diagnosed with CP/CPPS. The results of this pilot study justify a prospective controlled multicenter study to confirm these very encouraging initial results.

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EDITORIAL COMMENT

Acupuncture has been used in traditional Chinese medicine for more than 2000 years. Several groups have studied this therapy for the treatment of chronic prostatitis in China and Japan. None of the studies were placebo or sham controlled. This paper describes the use of acupuncture in 12 men with CP/CPPS in an uncontrolled trial. After a minimum of 6 weeks of acupuncture, 11 of 12 were deemed responders, with an overall decrease in total NIH-CPSI, NIH-CPSI pain, NIH-CPSI urinary, and NIH-CPSI QoL scores.

This study showed that these difficult-to-treat patients with CP/CPPS could benefit from acupuncture therapy. However, it was a small uncontrolled pilot study; therefore, the true benefit, if any, of this procedure over placebo/sham interventions is uncertain. The authors are to be commended for attempting this initial assessment of acupuncture for CP/CPPS in North America. No conclusions can be drawn from this study except that acupuncture should be studied in a controlled trial for CP/CPPS.

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