PAIN

Tailoring treatment of chronic pelvic pain

The first high-quality trials of the pollen extract Cernilton and extracorporeal shock wave therapy (ESWT) have shown that these interventions effectively alleviate symptoms of the chronic pelvic pain syndrome (CPPS). Study enrollment was restricted to specific subgroups of male CPPS patients. This heterogeneity-limiting design feature probably contributed to the positive study outcomes.

Chronic prostatitis/CPPS is an extremely heterogeneous condition. This is reflected in the standard NIH classification schema, which comprises five subcategories. Frustratingly little is known about the causes and, despite testing of a plethora of interventions, an effective treatment is still lacking.

In many trials, participants have been drawn from the entire spectrum of NIH subgroups (acute and chronic, bacterial and nonbacterial, inflammatory and noninflammatory). This approach probably decreases the likelihood of detecting treatment effects. Now, two European teams have targeted specific subgroups of CPPS sufferers, and emerged with highly promising trial results.

Wolfgang Weidner initiated the first placebo-controlled study of the pollen extract Cernilton. Containing carbohydrates, fats, amino acids, vitamins and minerals, this extract has been used widely for the past 20 years, but no stringently-conducted trials had been performed. Weidner and co-workers analyzed data from almost 140 men treated at one of 34 urology clinics in Germany. Including only those with NIH category IIIA (inflammatory) CPPS, the study has confirmed the findings of previous noncomparative clinical investigations.

After 12 weeks of oral Cernilton therapy, marked improvements in pain and quality of life were reported. Improvements in these domains of the NIH Chronic Prostatitis Symptom Index were also observed in the placebo group, but to a significantly lesser degree. Trends toward superior outcomes in the active arm were also noted for micturition-related and sexuality-related symptoms. Oral pollen treatment was well tolerated.

Lead author Florian Wagenlehner highlights the importance of duration of medication administration, noting that "symptomatic relief in patients with CPPS [often becomes apparent] only after 6 weeks of treatment". This is true of many systemic therapies used in CPPS. Could a more-direct intervention strategy deliver equivalent benefits in a shorter amount of time?

Following up on the promising results of a small feasibility study, Reinhold Zimmermann and colleagues have conducted the first-ever placebo-controlled, double-blind trial of ESWT in CPPS. Enrollment was restricted to men with disease categorized as NIH IIIB (noninflammatory); 60 were included.

Each week for 4 weeks, 30 randomly allocated participants received ESWT. 3,000 low-energy pulses were delivered perineally via a standard device during each session. Careful design of the sham treatment ensured patient blinding. The same ESWT device, fitted with shock-wave-absorbing material, was used. No anesthesia was administered in either group, and outcomes assessors were blinded to allocation.

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Several key clinical parameters improved continuously in the 8-week period following the final ESWT session. There were improvements of 50%, 16% and 10% in patient-reported scores for pain, prostatic symptoms, and erectile function, respectively. These changes were statistically significant, both in comparison to baseline values and to outcomes in the placebo group. Interestingly, and in contrast to the generally noted occurrence of profound placebo effects, sham treatment was not associated with any improvement.

This unusual result was noted by the authors of an Editorial that accompanied the Zimmermann *et al.* paper in a recent issue of *European Urology*. Despite the doubt it casts on the efficacy of randomization, the editorialists praise the trialists for their impressive data and well-designed study. An "outpatient procedure that is anesthesia free, that lacks side-effects, and that can be easily repeated" might prove to be the 'magic bullet' needed to target the intractable problem of CPPS.

Why, then, are urologists not as interested as patients in this new therapy? Zimmermann, who has received requests for ESWT from CPPS sufferers all over the world, postulates that the urological community is used to shock waves being associated exclusively with stone disease and 'destructive' intent. Our "colleagues [will] have to realize that ESWT [can] work at a completely different—and lower—level of energy".

Suzanne J. Farley

Original articles Zimmermann, R. *et al.* Extracorporeal shock wave therapy for the treatment of chronic pelvic pain syndrome in males: a randomised, double-blind, placebo controlled study. *Eur. Urol.* doi:10.1016/j.eururo.2009.03.043
Wagenlehner, F. M. E. *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.* doi:10.1016/j.eururo.2009.05.046

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