CONCLUSIONS: Many men with CPPS can reach a subjective cure, however having done so, the majority do not reach a CPSI score of 0. This group of "cured" patients is similar to our typical tertiary referral cohort in terms of age and phenotype but differs in having slightly lower starting CPSI pain scores.

Source of Funding: None

MP16-03

PELVIC-FLOOR BASED PHYSICAL THERAPY TREATMENT FOR CHRONIC ORCHALGIA

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INTRODUCTION AND OBJECTIVES: Chronic orchalgia is a common problem presenting to the urologist. Recent research and treatment has begun to focus on musculoskeletal dysfunction as a major contributor to this type of pelvic pain. We observed in our pelvic floor-based physical therapy (PFPT) program a reduction in patient reported pain following a comprehensive physical therapy treatment regimen. Here, we assess the clinically reported outcomes of patients in our center that presented with orchalgia who underwent physical therapy.

METHODS: A retrospective chart review was conducted on men presenting with a chief complaint of unilateral or bilateral orchalgia between January 2009 and April 2013 who were subsequently referred for PFPT. Referrals to physical therapy were made after evaluation ruled out pathologic etiologies for the orchalgia. Patients were evaluated and treated by our physical therapy team according to patient specific musculoskeletal impairments. Treatment included pelvic alignment exercises, therapeutic stretching and strengthening, manual therapy, modalities and EMG biofeedback. Following treatment, a global response measure was assessed based on patients' self-reports of pain reduction. Additionally, a follow-up phone survey was conducted to assess the perceived degree of pain at various intervals after completion of physical therapy.

RESULTS: We identified 61 patients that met inclusion criteria. After a mean 4.9 months of PFPT, 86.9% indicated their testicular pain was better, 13.1% reported no change and 0% reported worsening of their pain. Univariate analysis demonstrated that patient age, duration of symptoms, laterality and number of therapy sessions were not predictive of improvement following physical therapy. Thirty-two of the 61 patients participated in the follow up phone survey. Of these patients, 87.5 % reported a sustained improvement in their testicular pain, at an average of 7 months after completion of physical therapy.

CONCLUSIONS: Physical therapy represents a reasonable treatment option for many patients suffering from testicular pain. Symptom improvement was achieved in a large majority of our patients following PFPT and the results appear to be durable. Larger studies with longer follow up are needed.

Source of Funding: none

MP16-04

IMMUNOSTIMULATION IN CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME (CP/CPPS). A ONE-YEAR PROSPECTIVE, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

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INTRODUCTION AND OBJECTIVES: Inflammation/ immunological dysfunction are discussed etiological causes of chronic prostatitis/ chronic pelvic pain syndrome (CP/CPPS). OM-89 is an orally immunostimulating agent. We performed a phase 3 multicentre, randomized, double-blind, placebo controlled long term (12 months) study with OM-89 produced with a different lysis process in patients with moderate to severe CP/CPPS type II and III.

METHODS: Patients were randomised to placebo or OM-89. Primary efficacy variable was difference of responders at end of treatment (month 9) in patients receiving placebo versus OM-89.

RESULTS: 203 patients were screened, 185 (90% of CP/CPPS type IIIb) enrolled in 30 centres. 94 were randomized to OM-89, 91 to placebo. All 185 patients (47.8±8.4 years) were included in Safety Set (SS), 181 in Full Analysis (FAS), 155 in Per Protocol Set (PPS). Baseline NIH-CPSI score was 23.0±3.8 (OM-89) and 21.8±3.8 (placebo). At primary efficacy endpoint (month 9), 67.0% (PPS 72.7%) of OM-89 and 64.0% (PPS 64.1%) of placebo group were responders in the FAS [FAS: OR 1.20, $p=0.563$; PPS: $p=0.154$]. The mean relative decrease in NIH-CPSI was 40.5% and 43.4% in the FAS. Treatment related adverse events were low: 8.5% with OM-89 and 5.5% with placebo. Because of small numbers no conclusion could be drawn regarding the potential benefit of OM-89 in CP/CPPS type II and IIIa.

CONCLUSIONS: This placebo-controlled study evaluating OM-89 in patients with CP/CPPS showed a significant and long-lasting (12 months) favourable response with OM-89, but also with placebo. OM-89 was safe and well tolerated.

Source of Funding: Vifor Pharma/OM Pharma

MP16-05

EVIPROSTAT HAS AN IDENTICAL EFFECT COMPARED TO POLLEN EXTRACT (CERNILTON) IN PATIENTS WITH CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME: A RANDOMIZED, PROSPECTIVE STUDY

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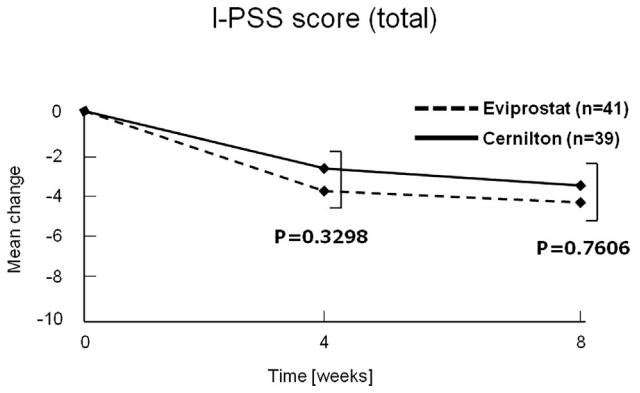
INTRODUCTION AND OBJECTIVES: Previously reported results of a prospective, randomized placebo-controlled study showed that the pollen extract (Cernilton) significantly improved total symptoms, pain, and quality of life in patients with inflammatory prostatitis/chronic pelvic pain syndrome (CP/CPPS) without severe side effects (Wagenlehner FM et al, Eur Urol, 2009). A phytotherapeutic agent, Eviprostat, is reportedly effective in a rat model of nonbacterial prostatitis (Sugimoto M et al, Prostate, 2011). The aim of the present study was to compare the efficacy and safety of Eviprostat to that of the pollen extract in the management of CP/CPPS.

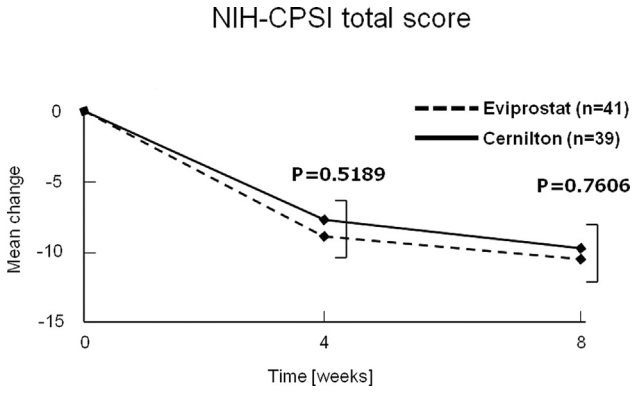
METHODS: The patients with category III CP/CPPS were randomized to receive either oral capsules of Eviprostat (two capsules, q 8 h) or the pollen extract (two capsules, q 8 h) for 8 weeks. The primary endpoint of the study was symptomatic improvement in the NIH Chronic Prostatitis Symptom Index (NIH-CPSI). Participants were evaluated using the NIH-CPSI and the International Prostate Symptom Score (IPSS) at baseline and after 4 and 8 weeks.

RESULTS: In the intention-to-treat analysis, 100 men were randomly allocated to Eviprostat ($n = 50$) or the pollen extract ($n = 50$). Response (defined as a decrease in the NIH-CPSI total score by at least 25%) in the Eviprostat group and the pollen extract group was 88.2% and 78.1%, respectively. There was no significant difference in the total, pain, urinary, and quality of life (QOL) scores of the NIH-CPSI. between the two groups at 8 weeks. This was also the case with the total, voiding, and storage symptoms of the IPSS. There were no adverse events observed in any patients in this study.

CONCLUSIONS: Both the pollen extract and Eviprostat significantly reduced the symptoms of category III CP/CPPS without any

adverse events. Eviprostat has an identical effect on category III CP/CPPS compared the pollen extract.





Source of Funding: none

MP16-06

CLINICAL EFFICACY OF ROXITHROMYCIN IN MEN WITH CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME IN COMPARISON WITH CIPROFLOXACIN AND ACECLOFENAC: A PROSPECTIVE, RANDOMIZED, MULTICENTER PILOT TRIAL

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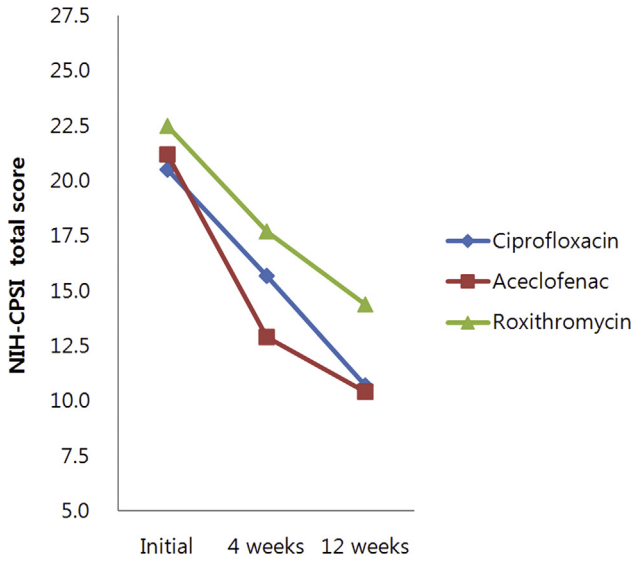
INTRODUCTION AND OBJECTIVES: Roxithromycin is effective in the treatment of intracellular organisms, including chlamydia and mycoplasma, and exhibits anti-inflammatory and immunomodulatory effects on respiratory diseases. To explore the potential therapeutic benefit of roxithromycin in chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), this study compared the effect of roxithromycin with ciprofloxacin and aceclofenac.

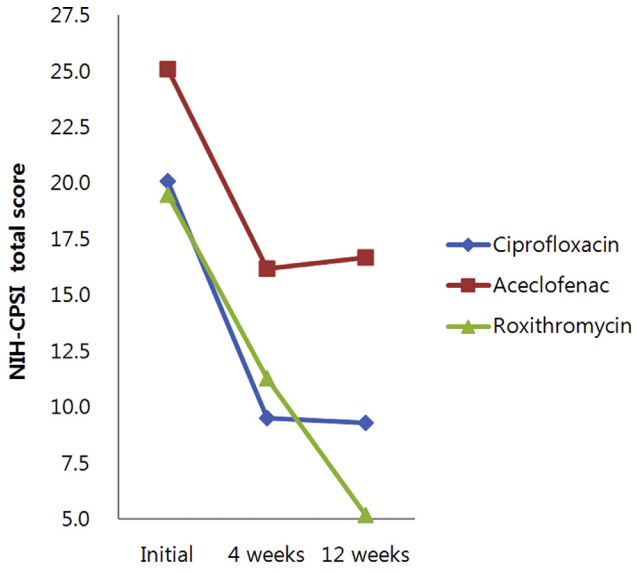
METHODS: A total of 75 patients with CP/CPPS were randomized to three groups in open-label: group 1, ciprofloxacin; group 2, aceclofenac; and group 3, roxithromycin. The patients were treated for 4 weeks and were subsequently followed for 12 weeks. Changes from baseline in the total and domain scores of the NIH Chronic Prostatitis Symptom Index (NIH-CPSI) were evaluated.

RESULTS: The NIH-CPSI score decreased in the roxithromycin, ciprofloxacin, and aceclofenac groups to a similar degree. The NIH-CPSI initial and 12-week total scores were 20.3 and 10.0, respectively, in group 1; 23.6 and 14.3, respectively, in group 2; and 21.1 and 9.8, respectively, in group 3. The three treatment arms did not differ significantly with respect to the efficiency of treatment ($p > 0.05$). Compared to patients in groups 1 and 2, group 3 patients with Category IIIb disease exhibited favorable results upon follow-up 12 weeks after treatment. The International Prostate Symptom Score (IPSS), uroflowmetry, and post void residual volume were equivalent between the groups.

CONCLUSIONS: Roxithromycin exhibits similar or favorable effects on the improvement of CP/CPPS compared to ciprofloxacin and aceclofenac. Roxithromycin could be used as a new therapeutic agent for CP/CPPS. Further study of the immunomodulatory action of roxithromycin in CP/CPPS is required.



(A) Category IIIa



(B) Category IIIb

Source of Funding: None