557

CEFUROXIME AXETIL VS. CEFTRIAXONE AND BOTH COMBINATION IN TREATMENT OF CHRONIC BACTERIAL PROSTATITIS: A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND TRIAL

Drasa K.[1], Tartari F.[2]

[1]Central Polyclinic, Dept. of Urology, Tirana, Albania, [2]Mother Tereza Hospital, Dept. of Urology, Tirana, Albania

Introduction & Objectives: Oral and parenteral cephalosporins is a good choice to treat patient, documented with Chronic Bacterial Prostatitis (CBP). The purpose of this study is to compare the action efficiency of Cefuroxime axetil (oral cephalosporin, broad spectrum, group 2) with Ceftriaxone (parenteral cephalosporin, 3rd generation group 3a), and both combination in the treatment of men with CBP.

Material & Methods: A total of 123 patients with a clinical diagnosis of CBP and current laboratory evidence of infection were randomized to receive 10-30 days oral and parenteral cephalosporins. They were separated in three different groups with 41 patients in each group. First group (n=41) cefuroxime axetil 500 mg. twice daily (b.i.d)for 10 days and continue once daily (o.d.) for 10 days in the evening, at bedtime. Second group (n=41) ceftriaxone 1gm, parenteral b.i.d. for 10 days. Third group (n=41) ceftriaxone 1gm, parenteral b.i.d. for 10 days then cefuroxime axetile 500 mg b.i.d. for 10 days and continue cefuroxime axetil o.d. for 10 days in the evening, at bedtime. All the cases in three groups during their treatment have been taken Lenycist (a natyral italian liquid with cranberry) that have four action: A strong antinflamatory and antibacterial action, works as diuretic agent also preventing the bacterial adhesion to the bladder wall. All patients were evaluated with the Meares-Stamey test and the validated with chronic bacterial prostatitis symptoms index (CBPSI) at baseline and one week after therapy completion. Patients with microbiological eradication were evaluated for recurrent infection with the Meares-Stamey test, 6 months after therapy completion. The primary end points was microbiologic eradication. The secondary was clinical improvement, assessed by reduction in the CBPSI, recurrent infection rate after 6 months and safety.

Results: The microbiologic eradication rate was: first group 68.29% (n= 28), second group 75.6% (n= 31) and third group 85.36% (n=35). At the end of the treatment the clinical improvement based on the CBPSI was a small difference between the first and the second group, but for the third group was maximally reduce of the CBPSI. The Meares-Stamey test after 6 months results positive: First group 13 cases; Second group 10 cases and the third group 6 cases.

Conclusions: The cause of CBP may be a defect in the prostate, that lets bacteria collection in the urinary tract. This study tell that combination of cefuroxime axetil with ceftriaxone have a greater tendency than the other cephalosporins to penetrate within both bacteria and phagocytic cells. The present results suggest that treatment in 3rd group (both combination) is reflected by a trend to resolution of subjective symptoms. Insure you that can arrive a great achievement with this treatment in the cure of patients with CBP.

558

SERENOA REPENS ASSOCIATED WITH URTICA DIOICA (PROSTAMEV®), CURCUMIN AND QUERCITIN (FLOGMEV®) EXTRACTS ARE ABLE TO IMPROVE EFFICACY OF PRULIFLOXACIN IN BACTERIAL PROSTATITIS PATIENTS: RESULTS FROM A PROSPECTIVE AND RANDOMIZED STUDY

Cai T.[1], Mazzoli S.[2], Mondaini N.[1], Bartoletti R.[1]

[1]Santa Maria Annunziata Hospital, University of Florence, Dept. of Urology, Bagno a Ripoli, Italy, [2]Santa Maria Annunziata Hospital, University of Florence, Sexually Transmitted Diseases Centre, Bagno a Ripoli, Italy

Introduction & Objectives: The use of phytotherapy to alleviate the symptoms related to Chronic Bacterial Prostatitis (CBP) is, nowadays, increasing, due to several reasons, such as typically low side-effect profiles and costs, a high level of acceptance by patients and, unfortunately, a high rate of inefficacy of standard treatments with subsequent patient and physician disappointment. We report the results of a prospective and randomized study in order to evaluate therapeutic effect of Serenoa repens, Urtica dioica (PROSTAMEV®), Quercitin and Curcumin (FLOGMEV®) extracts associated with prulifloxacin in patients affected by chronic bacterial prostatitis.

Material & Methods: From a whole population of 284 patients, 143 affected by CBP (NIH class II prostatitis) were, enrolled. All patients underwent prulifloxacin 600 mg daily for 14 days, in accordance with antibiogram results. Patients were split into two groups: Group A – prulifloxacin associated with PROSTAMEV® and FLOGMEV®, Group B – only antibiotic therapy. Microbiological and clinical efficacies were tested by two follow-up visits at 1 and 6 months, respectively. Quality of life (QoL) was measured by using NIH-CPSI and IPSS questionnaires.

Results: 106 out of 143 were assigned to Group A, 37 out of 143 to Group B. One month after treatment, 89.6% of patients who had undergone prulifloxacin associated with PROSTAMEV® and FLOGMEV® did not report symptoms related to CBP, while 27% of patients who had undergone antibiotic therapy alone were recurrence-free (p

Conclusions: The association between Serenoa repens, Urtica dioica (PROSTAMEV®), Quercitin and Curcumin (FLOGMEV®) extracts is able to improve clinical efficacy of prulifloxacin in patients affected by CBP.

559

LONG TERM EFFICACY OF CERNILTON IN PATIENTS WITH CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME TYPE NIH IIIA

Wagenlehner F.M.E.[1], Schneider H.[2], Ludwig M.[3], Horstmann A.[4], Schnitker J.[5], Weidner W.[1]

[1]Justus-Liebig-University, Dept. of Urology and Pediatric Urology, Giessen, Germany, [2]Clinic Braunfels, Dept. of Neurology, Braunfels, Germany, [3]Urologische Praxis, Praxis Keitz Et Al., Marburg, Germany, [4]Strathmann Ag Co., Hamburg, Germany, [5]Institute For Applied Statistics Ltd., Bielefeld, Germany

Introduction & Objectives: To assess safety and efficacy of Cernilton, a rye-grass pollen extract versus placebo in men with category IIIA chronic prostatitis / chronic pelvic pain syndrome (CP/CPPS).

Material & Methods: Multicenter, randomized, prospective, double-blind, placebo controlled clinical phase III study. Patients were randomized to Cernilton or placebo for 12 weeks. In the subsequent open follow up period of another 12 weeks all patients received Cernilton. Patients were evaluated by Meares and Stamey 4-glass test and the NIH-CPSI at baseline and after 12 and 24 weeks.

Results: A total of 93 patients completed the follow up period (Cernilton to Cernilton, n=48; placebo to Cernilton, n=45) up to 24 weeks as the primary efficacy cohort. The pain, quality of life domains and the total NIH-CPSI score improved significantly at week 12 in the Cernilton group versus placebo and continued to improve at week 24 in both groups. The latter effects were more pronounced in patients with cross-over from placebo to Cernilton from week 12 on. Urinary symptoms improved moderately, but not significantly in both groups. Leucocytes in the post massage urine improved significantly in both groups at week 12 and continued to improve at week 24 in both groups, with a more pronounced effect in the Cernilton to Cernilton group. Adverse events were minor in all patients.

Conclusions: Cernilton compared to placebo significantly improved total symptoms, pain and quality of life and reduced leucocytes in the post massage urine in patients with CP/CPPS IIIA without severe side effects up to 24 weeks. Cernilton can therefore be recommended for patients with CP/CPPS for long term treatment.

560

EFFICACY AND SAFETY OF POLLEN EXTRACT OF SEVERAL DIFFERENT PLANTS (CERNILTON) IN PATIENTS WITH CHRONIC ABACTERIAL PROSTATITIS

Apolikhin O.I., Sivkov A.V., Oshepkov V.N., Keshishev N.G., Bedretdinova D.A.

Research Institute of Urology, Dept. of Innovations, Moscow, Russia

Introduction & Objectives: In 2008 comparative clinical randomized trial was conducted to investigate efficacy and safety of two doses of pollen extract of several different plants (Cernilton) in patients with chronic abacterial prostatitis.

Material & Methods: 48 male patients (age: 18-50 years) with confirmed chronic abacterial prostatitis were randomized into two groups; I group (25 patients) took 2 tablets 3 times per day, II group (23 patients) took 1 tablet 3 times per day. The patients were treated for 3 months and followed up for a further 6 mo. The results were analyzed comparatively with NIH-CPSI, symptom frequency scale, linear scale, Sex-4, I-PSS, QoL, results of clinical blood and urine analysis, bacteriological and microscopical analysis of secretion of prostate, urodynamics examination (Qmax, Vres), ultrasound examination (prostate volume, residual urine volume).

Results: The NIH-CPSI six-month total score was lower on 18% ($p<0,001$) in I group than in II one. Comparing initial and 6-month score of subjective sensations in I group it decreased on 57% in I group ($p<0,001$; in II group on 48% ($p<0,001$). The linear scale total score on 3rd visit lowered on 80% ($p<0,001$) in I group and on 71% ($p<0,001$) in II group. The symptom frequency scale score in I group decreased on last visit on 50% ($p<0,001$), in II group on 33% ($p<0,001$). After treatment statistically significant increase was observed in both groups, but most evident in I group than in II one ($p=0,003$). The scale Sex-4 total score there is decrease in I group of 23% ($p=0,22$), and in II – 13%($p=0,44$), but results are not significant. The QoL total score decreased on last visit in I group to 63% ($p<0,001$), in II group on 60% ($p<0,001$). In microscopical analysis we found decrease of leucocytes, that showed diminution of inflammation, most evident in I group (on 38%, $p=0,093$). Before treatment results of urodynamics and ultrasound examination were almost normal and after treatment we don't get any significant changes in both groups.

Conclusions: The pollen extract of several different plants (Cernilton) in patients with chronic abacterial prostatitis showed significant anti-inflammatory effect which maintains for 3 months. Comparing two regimen two tablets 3 times per day showed better clinical effect. Both regimens are safe. Intensity of symptoms and inflammation decreases significantly, normalization of clinical aspects was approved. This compound of pollen extract is effective and safe medication for treatment of chronic abacterial prostatitis.