THALIDOMIDE AS THERAPY FOR THE CHRONIC PELVIC PAIN SYNDROME (CPPS)

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INTRODUCTION & OBJECTIVES: Many reports suggested that chronic abacterial Type 3A prostatitis may have an autoimmune origin with an abnormal reaction of the prostate parenchyma to some bacteria such as Chlamydia Tracomatis or Mycoplasmata, which are hard to detect. Abnormal levels of several cytokines (IL2, IL6, IL8, IL10 and TNFα) in sperm have been linked with prostatic autoimmunity. Cytokine modulating drugs include INFLIXIMAB, ETANERCEPT and THALIDOMIDE, the first two of which are associated with severe side effects. As thalidomide is not associated with serious side effects in men we decided to assess the efficacy of oral thalidomide therapy as therapy for suspected autoimmune chronic prostatitis in a double-blind randomised trial.

MATERIAL & METHODS: Thirty patients aged between 18 and 65 years old were recruited to the study which was approved by the Perugia University Ethics Committee. Inclusion criteria were chronic abacterial prostatitis associated with abnormal sperm cytokine levels (IL2, 6, 8, 10 and TNFα) as measured by a commercial Kit Quanti Flow. Exclusion criteria were signs of peripheral neuropathy and blood concentrations of bilirubin, and other liver function indices three times higher than normal. Patients were randomised to two groups of 15. After signing a detailed informed consent form, all patients underwent the NIH Chronic Prostatitis Symptom Score (NIH-CPSI) was assessed in all. Patients in group A received oral Thalidomide (100 mg/daily) for 4 weeks, which was increased to 200 mg/daily during the following 8 weeks of treatment. Patients in group B were given placebo which was administered in the same modality. At 4, 12 and 16 weeks follow-up, cytokines were measured in sperm and the NIH-CPSI score was assessed again in both groups. Data analysis was performed using the Mann-Whitney test to compare the NIH-CPS scores and cytokine levels in Group A vs. Group B at baseline and at 4, 12, 16 weeks follow-up. Statistical significance was set at $p<0.05$.

RESULTS: *Baseline*: The median NIH-CPSI score was 34 in Group A and 36 in Group B. Median IL2 level was 220 in both groups. Median IL6 was 260 in group A and 95 in Group B. Median IL8 was >2.000 in both groups and mean IL10 was <3.9 in both groups. Median TNFα was 12 in group A and 8 in Group B.
After thalidomide therapy: Median NIH-CPSI scores were not significantly different in the two groups at 4, 12 and 16 weeks follow up. In patients in Group A all cytokine levels were significantly reduced at 4, 8 and 12 weeks follow up as compared to baseline levels. No significant differences were observed in Group B. Side effects: 2 patients (1 in Group A and 1 in group B) developed signs of peripheral neuropathy and were excluded from the study.

CONCLUSIONS: This double-blind randomised study shows that at the administered dose Thalidomide does not provide relief of symptoms associated with CPPS, despite a significant reduction in cytokine levels in sperm.

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