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REDUCTION IN SYMPTOMS IS ASSOCIATED WITH IMPROVED SEXUAL FUNCTIONING AND SLEEP IN PATIENTS WITH INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME

Hypothesis / aims of study
Interstitial cystitis/painful bladder syndrome (IC/PBS) is a chronic, debilitating condition that negatively impacts quality of life. Symptoms of IC/PBS include urgency, frequency, bladder pain and nocturia. The purpose of this analysis was to examine the relationship between symptom reduction, sexual functioning and sleep in patients with IC/PBS.

Study design, materials and methods
Retrospective analyses were conducted in a subset of 128 patients treated with 300 mg/day pentosan polysulfate sodium (PPS - FDA approved dose), from a 32-week U.S. multi-center, randomized, double-blind, parallel group study of 380 IC/PBS patients treated with PPS 300 mg/day, 600 mg/day, or 900 mg/day [1]. IC/PBS diagnosis was determined by either a history of IC/PBS symptoms (bladder pain, urgency, frequency and nocturia) for $\geq$6 months or a positive cystoscopic examination (petechial hemorrhages, glomerulations, and/or Hunner's ulcers) combined with bladder pain and urgency. Patient-rated outcome measures included the O'Leary-Sant Interstitial Cystitis Symptom Index (ICSI), Medical Outcomes Study (MOS) Sexual Functioning and MOS Sleep scales [2]. Treatment responders were defined using three definitions: 1) $\geq$30% reduction in ICSI from baseline to study endpoint; 2) $\geq$4 point reduction in ICSI from baseline to study endpoint; and 3) $\geq$30% or $\geq$4 point reduction in ICSI from baseline to study endpoint. Higher scores on the MOS scales reflect better functioning. An intent-to-treat last-observation-carried forward analysis was performed.

Results
Compared to non-responders, patients achieving a $\geq$30% reduction in ICSI had a mean change in MOS Sexual Functioning score of 19.2 $\pm$ 34.5 vs. 0.0 $\pm$ 28.7 (p=0.0023), respectively. Compared to non-responders, patients achieving a $\geq$30% reduction in ICSI had a mean change in MOS Sleep score of 11.8 $\pm$ 22.4 vs. 1.6 $\pm$ 15.7 (p=0.0055). Consistent results were found when examining the other treatment response criteria with MOS Sexual Functioning or MOS Sleep. At the end of study, among all patients, mean change in MOS Sexual Functioning and MOS Sleep scale scores from baseline were 8.9 $\pm$ 32.9 (p=0.0054) and 6.0 $\pm$ 19.3 (p=0.0011), respectively. Patients treated with PPS showed statistically significant improvement in ICSI, MOS Sexual Functioning and MOS Sleep scores over time at weeks 8, 16, 24 and 32. Reduction in ICSI score was moderately correlated with improvement in MOS Sexual Functioning (r=-0.35; p=0.0002) and MOS Sleep (r=-0.33; p=0.0003) scores from baseline to study endpoint.

Interpretation of results
Reduction in symptoms of IC/PBS was associated with improvement in the patient-reported outcomes of sexual functioning and sleep. Significant improvement in IC/PBS symptoms, sexual functioning and sleep were observed over time in PPS-treated patients.

Concluding message
IC/PBS patients treated with PPS experience significant improvement in IC/PBS symptoms which positively impacts sexual functioning and sleep.

References
1. Randomized, double-blind, dose-ranging study of pentosan polysulfate sodium for interstitial cystitis. Urology 2005; 65: 654-658.
2. Psychometric validation of the O'Leary-Sant Interstitial Cystitis Symptom Index in a clinical trial of pentosan polysulfate sodium. Urology 2001 (Suppl 6A): 62-66.

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the Queen's University IRB (#UROL-048-98) and followed the Declaration of Helsinki Informed consent was obtained from the patients.