

ASSOCIATION BETWEEN SYMPTOM REDUCTION AND SATISFACTION WITH PENTOSAN POLYSULFATE SODIUM IN PATIENTS WITH INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME

Hypothesis / aims of study

To evaluate the relationship between symptom reduction and satisfaction with pentosan polysulfate sodium (PPS) therapy in patients with interstitial cystitis/painful bladder syndrome (IC/PBS).

Study design, materials and methods

Retrospective analyses were conducted in a subset of 128 patients treated with 300 mg/day 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 ≥ 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) [2] and a patient satisfaction questionnaire. Treatment responders were defined using three definitions: 1) $\geq 30\%$ reduction in ICSI from baseline to study endpoint; 2) ≥ 4 point reduction in ICSI from baseline to study endpoint; and 3) $\geq 30\%$ or ≥ 4 point reduction in ICSI from baseline to study endpoint. An intent-to-treat last-observation-carried forward analysis was performed.

Results

Compared to non-responders, patients achieving a $\geq 30\%$ reduction in ICSI were 7.2 (95% CI: 2.82-18.42) times more likely to be pleased with PPS study medication for IC/PBS symptoms, 8.34 (95% CI: 3.26-21.34) times more likely to have benefited from PPS study medication for IC/PBS symptoms, 2.71 (95% CI: 1.03-7.12) times more likely to recommend PPS study medication for IC/PBS symptoms to someone else with the same condition, and 5.36 (95% CI: 1.78-16.17) times more likely to say that PPS study medication provides better relief, given their experience with other IC/PBS treatments. Consistent results were found when examining the other treatment response criteria. Among all patients, over 70% stated that they would recommend PPS therapy for IC/PBS symptoms to someone else with the condition (70.3%, 74.8%, 73.3%, 75% at weeks 8, 16, 24, and 32, respectively).

Interpretation of results

Clinically meaningful reduction in IC/PBS symptoms was associated with significantly higher patient satisfaction. Over 70% of patients in this study would recommend PPS therapy for IC/PBS symptoms to someone else with the same condition.

Concluding message

Treatment response and patient satisfaction are important clinical outcomes to consider in the management of patients with IC/PBS.

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; 57 (Suppl 6A): 62-66.

FUNDING: Ortho Women's Health & Urology

DISCLOSURES: Consultant for Ortho Women's Health & Urology; J&J employee

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.