

Decreasing symptoms in interstitial cystitis patients: pentosan polysulfate vs. sacral neuromodulation

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Abstract. Objective: Oral pentosan polysulfate is the only FDA-approved drug for interstitial cystitis. Several studies have been conducted that show PPS will reduce IC symptoms. Sacral neuromodulation is a newer therapy for IC that has been FDA-approved in incontinent patients. Both therapies have studies documenting a reduction in IC symptoms, but no studies have compared these therapies to see which is more effective. **Methods:** An evidence-based systematic literature review was conducted using Pubmed, Medline, and Proquest nursing journals. Inclusion criteria were a peer-reviewed article, publish date of 1990 or later, level 1 or 2 evidence, were diagnosed with IC, and were only treated with either oral PPS or sacral neuromodulation during the study. Exclusion criteria were multiple therapies for IC or a non-IC diagnosis. **Results:** Three PPS studies fit all inclusion criteria. With successful treatment being defined as a 50% overall improvement in symptoms, studies had a success rate of 26-32%. Four studies fit the criteria for sacral neuromodulation. In these studies 40-94% of the patients had a 50% improvement in one or more IC symptom. **Conclusions:** PPS and sacral neuromodulation have both been shown to reduce IC symptoms. Sacral neuromodulation has been shown to have a higher rate of symptom relief in IC patients. Based on level 2 evidence, a Grade B recommendation can be made for sacral neuromodulation. This evidence was limited by sacral neuromodulation studies having only level 2 evidence, while PPS has level 1 evidence studies. More studies are needed for each of these therapies.

1. Introduction

Interstitial Cystitis (IC) is a clinical syndrome of unknown etiology, which has led to much debate over its diagnosis criteria and treatment regimens. Patients with IC present with urinary frequency and urgency, burning sensations while voiding, and pelvic pain. Many of these symptoms cause alterations in daily activities and a decrease in quality of life. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has developed diagnostic criteria to help aid in diagnosis. The NIDDK states that the patient must present with the above symptoms and upon examination, patients with IC have a negative urinalysis, have no signs of genitourinary infections, bladder cancer, or prostatitis, and have no history of radiation or tuberculosis cystitis. The definitive sign of an IC diagnosis is the presence of glomerulations or ulcers on the bladder wall found during a cystoscopic examination. [1]

Due to the lack of a definitive cause of IC the treatment for this condition is usually multi-modal. There is no definite cure for IC and the goal of treatment is to decrease the severity and frequency of the symptoms. Oral treatments have been used to try and reverse the proposed causes of the disease and reduce the painful symptoms. Intravesicular treatments have been used to attempt to coat and protect the lining of the bladder. A more invasive therapy is sacral neuromodulation in which a device stimulates sacral nerve roots in an effort to reduce symptoms.[2] This study will compare oral pentosan polysulfate (PPS) versus sacral neuromodulation to see which treatment is more effective in reducing IC symptoms.

2. Experiment, Results, Discussion, and Significance

The method of research is an evidence-based systematic literature review. The databases used in the review were PubMed, Medline, Proquest nursing journals and First Search from 1990 to present. Selected articles for review were based on level of evidence, journal type, and relevance to the topic. Inclusion criteria for the articles were a peer-reviewed article, a publish date of 1990 or later, subjects with a diagnosis of interstitial cystitis, and were only

treated with either oral pentosan polysulfate or sacral neuromodulation therapy during the study. Studies were excluded if subjects were treated with multiple therapies during the study or were not diagnosed with interstitial cystitis. Studies also had to meet the criteria of level 1 or level 2 evidence, which were defined using the Oxford Centre for EBM levels of evidence. Level 1 studies included randomized-controlled trials. Level 2 studies included systematic reviews of cohort.

The systematic literature review found 3 studies examining PPS therapy that fit all inclusion criteria. Two of these studies were of level 1 evidence and the third study was of level 2 evidence. The studies included a combined total of 355 patients. With successful treatment being defined as 50% overall improvement in symptoms, the two PPS studies with a positive correlation, a success rate of 26-32% was seen in the subjects.

Four studies fit the inclusion criteria for sacral neuromodulation. All studies were of level 2 evidence. The studies included a combined total of 110 patients. With successful treatment being defined as 50% improvement in one of more presenting IC symptoms, which is the criteria for permanent implantation; rates were found to be between 40-94% of the subjects. Comparison of the successful treatment percentages can be seen in Figure 1. Maximum relief is the highest percent of patients experiencing treatment success in a single study. Minimum relief is the lowest percent of patients experiencing treatment success in a single study.

Both treatments were found to reduce IC symptoms. Sacral neuromodulation had a greater rate of success among patients. This treatment also provides immediate relief in positive responders, while PPS can take up to 8 weeks to see a reduction in symptoms. Sacral neuromodulation has also been shown to reduce narcotic use by 36% in IC patients. [3] This systematic literature review demonstrated the efficacy of sacral neuromodulation in reducing IC symptoms.

3. Conclusions

Pentosan polysulfate and sacral neuromodulation have both been shown to reduce IC symptoms. PPS has a lower rate of symptom relief in IC patients. Due to slow onset of action, patients on PPS experience compliance issues and relapse of symptoms during treatment initiation. Sacral neuromodulation has been shown to have a higher rate of symptom relief in IC patients and demonstrates immediate symptom relief in positive responders. Upon review of the literature, a grade B recommendation can be made for sacral neuromodulation in the reduction of symptoms in IC patients. Grades of recommendation were defined by the Oxford Centre for EBM levels of evidence. A grade B recommendation is made when there are consistent Level 2 studies to support your conclusion. Sacral neuromodulation studies are limited by being a lower level of evidence than PPS studies. More studies are needed to further examine the effectiveness of these therapies in IC patients.

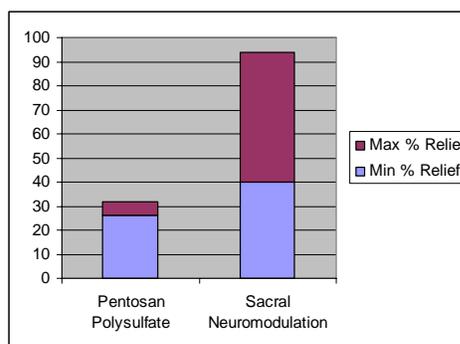


Fig. 1. Overall IC treatment success

[1] Gillenwater J, Wein A. Summary of the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases workshop on interstitial cystitis, National Institute of Health, Bethesda, Maryland, August 28-29, 1987. *Journal of Urology*. July 1987; 140:203-206.

[2] Chancellor MY, Yoshimura N. Treatment of interstitial cystitis. *Journal of Urology*. March 2004; 63:85-92.

[3] Peters K, Konstant D. Sacral neuromodulation decreases narcotic requirements in refractory interstitial cystitis. *British Journal of Urology International*. 2004; 93:777-779.