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DISCUSSION FOLLOWING DR. PONTARI'S PRESENTATION

Scott I. Zeitlin, MD (Los Angeles, California): Is there a length of time to which you would limit the use of pentosan polysulfate?

Michel Pontari, MD (Philadelphia, Pennsylvania): There is probably a significant placebo effect, but at 3 months, those effects tend to decrease, as occurred in the saw palmetto trial done by Dr. Steve Kaplan.[1] In terms of doing a study, I think you take it up to 3 months. Clinically, I do not have an answer for that question. My patients are given it for several months.

Anthony J. Schaeffer, MD (Chicago, Illinois): How do the researchers using pentosan for interstitial cystitis interpret the data?

Dr. Pontari: The longer you use it, the more benefit you may have, with patients getting better out to 3 years.

J. Curtis Nickel, MD (Kingston, Ontario, Canada): In our prospective study in interstitial cystitis patients, there was a continued response out to 38 weeks, which did not plateau. There was no dose effect. There was no difference between 300 mg and 900 mg.[2]

Dr. Pontari: So if you are going to use pentosan polysulfate, it sounds like 100 mg tid might be as good as 300 mg tid.

John N. Krieger, MD (Seattle, Washington): You told us about inflammation and anti-inflammatory therapy, and rofecoxib is an anti-inflammatory agent. Can you interpret the results of that study in terms of who had evidence of white blood cells and who did not?

Dr. Nickel: We tried. The numbers are too small: 50 patients in either group. It was a pilot study, and the interpretation of the results depends on how you define your categories. The categories IIIA and IIIB can use different cut points, 10 white blood cells, 5 white blood cells. Different categorizations got different numbers, and that is why we did not pursue it. The study was too underpowered to allow a subanalysis.[3]

Dr. Zeitlin: Are you going to repeat the study for different protocols?

Dr. Nickel: The problem was that we might have used the wrong endpoint. We used the National Institutes of Health/Chronic Prostatitis Symptom Index (NIH-CPSI). Merck & Co., Inc., the study sponsor, initially interpreted the study as only mildly supportive. But subsequently we have done 4 or 5 more studies in other therapies, and this treatment has come up with some of the best results. Every study shows that the NIH-CPSI is not emerging to be as sensitive a test as we had

hoped it to be in differentiating quality-of-life issues. Global assessments or percentage response seems to be better.

Dr. Schaeffer: Isn't that begging the question? How do you know what the right assessment is? You are saying this is the right assessment because it proves your hypothesis.

Dr. Nickel: No. The global assessment for disease responsiveness is accepted by the regulatory authorities. The patients tell you that they are significantly better, moderately better, mildly better, or no better.

Dr. Pontari: Have we looked enough at the subsets of the CPSI? Have we broken it down to analyze just the pain, just the voiding, or just the quality-of-life domain?

Dr. Nickel: Yes. If you look at the quality-of-life scores, they have the most spectacular improvement rate. Of course, the 3 quality-of-life questions do in fact correlate with the subjective global assessments. The patient indicates that he is delighted or pleased with where he is right then, but he may not mark the pain and voiding symptoms as significantly decreased.

Dr. Schaeffer: What do we want to conclude about the role of inflammation in the prostate? It sounds as if all we can say at the present time is that it is unknown. Some people may have inflammation as the cause of their symptoms. Would you use the word inflammation if you had high white blood cell counts?

Daniel A. Shoskes, MD (Weston, Florida): No. Leukocytosis would be the proper term.

Dr. Schaeffer: Don't you call it an inflammatory response?

Dr. Shoskes: It is an inflammatory marker. I think what we have learned about inflammation in prostatitis to date is that cell counts do not correlate with any of the symptoms that we find nor with treatment response. However, there is preliminary evidence that a number of other inflammatory markers may be predictive of treatment response. Inflammation as measured by a simple white blood cell count does not seem to correlate either with diagnosis or stratification for treatment.

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