

tions, men seeking care in nonreferral centers, and other diverse populations. Moreover, although the CPCRN investigators worked to develop the best possible index of symptoms and impact for CPPS, further refinements may be necessary. As in all newly validated instruments, these issues will be resolved with greater experience in using the NIH-CPSI in populations of color, less affluence or education, and in those with low literacy.

The NIH-CPSI is likely to function best if adopted widely as a standard instrument in the evaluation of men with chronic prostatitis. With a uniformly accepted outcome measure, patients, clinicians, and researchers can begin speaking the same language when assessing the natural history of this disease and its response to various treatments.

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DISCUSSION FOLLOWING DR. LITWIN'S PRESENTATION

Anthony J. Schaeffer, MD (Chicago, Illinois): Is it axiomatic that a good index can be used to judge response to therapy or is that not a given?

Mark S. Litwin, MD, MPH (Los Angeles, California): I would say it is axiomatic that a good index should be able to judge response to therapy. If the disease under study is primarily manifested by symptoms, then in fact, symptoms ought to be the primary outcome measure, provided those symptoms are reliably and validly measured by the instrument.

J. Curtis Nickel, MD (Kingston, Ontario, Canada): We have now used this index in clinical trials in 540 patients outside the first Chronic Prostatitis Collaborative Research Network (CPCRN) trial. We have all of this raw data, and we are finding that this instrument may not be as responsive as we would like it to be. Patients tell us that they have significant improvement on a subjective global assessment, but the scores

of these same patients decrease only a couple of points on the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI), which statistically is not meaningful. If you use the impact on quality of life as a measure, the change with treatment can be phenomenal. When you compare it with the total score or pain score, the improvement seems really minimal. As new information becomes available from ongoing clinical trials, we will want to look at this responsiveness issue again and see how the NIH-CPSI scores correlate with the patients' own perception of global improvement.

Dr. Litwin: When we started, we did not yet have data on the responsiveness to change of the CPSI. When you do a study, you have to pick a primary outcome. I would disagree that we can just change the primary outcome at this point. The CPCRN study was powered to use total score, 0 to 43, adding all the domains, pain, urination, and quality of life together.

The total score is the primary outcome; however, there are some important secondary outcomes that are listed as the subscale scores. We may learn that it may not actually make sense to score the CPSI by simply adding all these things up. It may be that it is better to score the instrument by weighting the scores so that we multiply the importance of each domain versus the other. There are a variety of things that we can do and paradigms that we use, but it may be that the quality-of-life impact subscale is the most important scale.

Daniel A. Shoskes, MD (Weston, Florida): The most common criticism that I hear from my patients is the absence of questions specifically about erectile dysfunction. In listening to how this was developed, I wonder whether that might have been because we used older patients, and we were trying to discriminate between the effects of prostatitis and benign prostatic hyperplasia (BPH). If we look at this in an age-specific way, for a 73-year-old man, the erectile dysfunction is not going to be a big issue. For a 22-year-old man, that is often why

they are coming to the office. They have been worried about the pain, but it is the erectile dysfunction that has them scared. Might there be value in modifying a symptom index for the younger population that is not quite so discriminative from BPH, where BPH really is not in the picture?

Dr. Litwin: The short answer is "yes." That is why you have version 2, version 3, and version 5.1 of various instruments. With any symptom index there are 2 potential uses: as a diagnostic tool or as an outcome measure. This was primarily designed as an outcome measure and not a diagnostic tool.

Dr. Schaeffer: Yes, but Dr. Shoskes is saying that the relevant outcome measures might be different for a younger versus an older patient.

Dr. Litwin: It is not written in stone. It is version 1.0. We think it is pretty good, but part of the point of using it in future studies is to determine, over time, whether the data suggest that it needs to be tweaked or that it needs additions for other functions.