Framingham Approach Needed in Back Pain

BY MIRIAM E. TUCKER

FROM THE WORKSHOP ON DECONSTRUCTING BACK PAIN

ROCKVILLE, MD. — Chronic back pain is an enormously heterogenous and common disorder that might better be examined in observational "Framingham-like studies" than in randomized, controlled clinical trials.

The recommendation was proposed by several presenters at the workshop sponsored by the National Center for Complementary and Alternative Medicine (NCCAM), a division of the National Institutes of Health.

"I think this is the right time to be talking about this problem. The NIH has certainly been urged by our leader, Dr. Francis Collins, to worry about research of relevance to health policy, and I can't think of a single issue that has as much resonance or potential implications for health policy as this one," NCCAM director Josephine Briggs said.

Dr. Briggs also noted, "This is not my area, but as I've learned more about back pain over the last year, I have been absolutely blown away by the magnitude of this problem and the enormous clinical difficulties in bringing relief to most patients suffering from chronic back pain .... This is a totally pervasive, a huge driver of health costs, and frankly, I think a problem for which we only have a small number of satisfactory clinical solutions, so I think it's incredibly important that we talk about it."

There was agreement among participants that chronic back pain is not simply a multifaceted biological problem, but also a psychosocial one. And as such, there is little correlation between physical findings on imaging or other studies and the degree to which a patient perceives pain or experiences functional impairment. Participants also generally agreed that current treatments, including opioids and surgical approaches, are ineffective in a large proportion of patients and have been associated with harm as well.

The extensive heterogeneity in causes, presentations, and functional impact of chronic back pain has made it impossible to compare studies on the problem and determine the extent to which results from any given study can be extrapolated to another, speakers agreed.

Indeed, even the most commonly used definition of "chronic"—pain lasting longer than 3 or 6 months—is limiting in that it doesn't account for other parameters such as pain intensity, associated psychological dysfunction, or degree of functional impairment, noted Michael Von Korff, Sc.D., senior investigator at Group Health Research Institute, Seattle.

He described an alternative "prognostic risk score" that would not only classify patients with back pain but would also help to determine their probability of future clinically significant back pain. The score, derived from a study of 1,213 primary care back pain patients, utilizes measurements of degrees of pain intensity, interference with activities, persistence, number of pain sites, and depression to define risk levels corresponding to a 50% and an 80% probability of future clinically significant pain (Pain 2005;117:304-13).

Such an "empirically grounded" approach, he said, could help distinguish patients at low risk who could be managed conservatively from those at greater risk for whom intervention could be initiated early, rather than waiting for the passage of time until they meet the "chronic" criteria. Moreover, "it avoids labeling patients as hopeless, with immutable back pain, when change for the better is always possible and often likely."

William Maixner, D.D.S., Ph.D., professor and director of the Center for Neurosensory Disorders at the University of North Carolina School of Dentistry, Chapel Hill, said that a study he's heading in patients with temporomandibular joint (TMJ) disorders could also serve as a model for studying chronic back pain.

The 7-year Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA), funded by the National Institute of Dental and Craniofacial Research (NIDCR), is the first-ever large, prospective clinical study in the field of chronic pain. Begun in 2005, it enrolled 3,276 initially pain-free adults, and is following them with the aim of identifying underlying pathophysiological, psychological, and genetic risk factors that predict who will go on to develop TMJ disorders.

Michele Crites Battié, Ph.D., of the University of Alberta, Edmonton, called into question whether the outcome measures that have been used so far in back pain studies are actually the most relevant and appropriate for ascertaining clinically meaningful treatment effects. For example, should studies assess mean changes in intervention versus control groups, or measure the difference in percent achieving a clinically meaningful threshold? And beyond that, is the data point being measured one that is meaningful to the patient?

Dr. Gary Franklin, a research professor in environmental and occupational health sciences at the University of Washington, Seattle, said the Food and Drug Administration uses only pain as a primary outcome measure for drug trials, with function and quality of life as secondary outcomes.

Several speakers questioned whether the randomized clinical trial, widely considered the "gold standard" type of study for the efficacy of drugs, is really the best type of trial to examine aspects of such a heterogenous problem as chronic back pain, and whether longitudinal observational "Framingham-like" study might be more appropriate to determine what happens to patients with chronic back pain over time.

In an interview, workshop cochair Dr. Partap Khalsa, program officer of the division of intramural research at NCCAM, noted that the best clinical guidelines currently available for managing chronic low back pain are those developed jointly by the American College of Physicians and the American Pain Society. They advise clinicians to conduct a focused history and physical to help determine etiology, and only perform diagnostic imaging in selected patients with severe or progressive neurologic deficits or in whom serious underlying conditions are suspected based on the history and physical exam (Ann. Intern. Med. 2007;147:478-91).

For the 80%-90% of patients with chronic back pain for whom no specific cause can be found, the guidelines advise that physicians educate patients about appropriate self-care and prescribe acetaminophen or nonsteroidal anti-inflammatory agents as first-line therapy. For patients in whom pain persists, nonpharmacologic approaches such as exercise and spinal manipulation may be tried, along with other "interdisciplinary" approaches such as acupuncture, massage therapy, yoga, cognitive-behavioral therapy, or progressive relaxation therapy. ■

Disclosures: *Dr. Khalsa and Dr. Briggs are government employees with no financial conflicts. Dr. von Korff said he received funding only from the NIH, and Dr. Franklin and Dr. Battié stated that they have no disclosures. Dr. Maixner is a cofounder, officer, and equity shareholder in Algynomics Inc.*

No Dose Effect Seen

NSAIDs *from page 1*

The patients were observed for a mean of 3.1 years. Their mean drug-exposure time was 2.5 years to conventional NSAIDs and 0.5 years to coxibs. At the congress, Dr. Möller reported on data from 1,657 patients.

At the start of annual observations, 20% of patients were taking NSAIDs and 18% were taking coxibs. By the end of the observation period, 18% of patients were still taking NSAIDs and 12% were still taking coxibs.

The median annual change in GFR in this most conservative analysis was 1.3 mL/min, and estimates were even less in additional longitudinal analyses for more than 4,000 patients. Neither start nor continuation of the NSAIDs altogether, or of the subgroup of coxibs or nonselective NSAIDs, significantly modified the clearance rates. Furthermore, no single NSAID was associated with worsening of GFR estimates in annual analyses.

"We did not find a dose effect, nor other modifications of renal function by NSAID except for patients with baseline grade IV renal insufficiency (clearance of less than 30 mL/min), who underwent accelerated loss of renal function," Dr. Möller said.

Only 2% of physicians who treat this cohort of patients reported prevalence of renal comorbidity. However, the researchers found that the true frequency of at least moderate renal insufficiency (defined as chronic kidney disease of stage 3 or higher) was about 18%. "Thus, rheumatologists did not much care about the existent renal condition, and prescribed NSAIDs irrespective of this objective relative contraindication in two-thirds of the patients," Dr. Möller noted.

NSAIDs "can still be estimated as valuable and safe drugs when used responsively. Many patients can be treated for years without any of the expected complications. If your patient is still suffering from unbearable pain despite appropriate disease-modifying therapy, it might be unethical not to treat him. In this situation, consider NSAIDs after careful evaluation of any potential risk, especially for gastrointestinal, cardiovascular, and renal complications. Measure or estimate the renal function by validated tools before starting NSAIDs. Do not use NSAIDs in [chronic kidney disease] stage 4 or 5, and control the kidney function in stage 3 after having started with NSAID therapy." ■

To watch a video interview of Dr. Möller, go to www.youtube.com/elsglobalmedicalnews and click on "Playlists." Then click on RHEUMATOLOGY NEWS.

VITALS

Major Finding: The median annual change in glomerular filtration rate among patients with RA who were taking NSAIDs was just 1.3 mL/min.

Data Source: A study of 1,657 patients enrolled in the Swiss RA Registry.

Disclosures: Dr. Möller said that he had no relevant conflicts to disclose.

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Dr. Burkhard Möller: Rheumatologists prescribed NSAIDs in many patients with at least moderate renal comorbidity.