

Chronic Back Pain Examined at NIH Workshop

BY MIRIAM E. TUCKER

FROM THE WORKSHOP ON DECONSTRUCTING BACK PAIN

ROCKVILLE, MD. — Chronic back pain is an enormously heterogeneous 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.

With seven thematic panels and 23 speakers, the meeting included lively discussions about optimal approaches for studying a problem that affects one in four adults and costs the health care system billions of dollars annually, and for which research thus far has not yielded the kinds of interventions that can help the majority of affected patients.

“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 Dr. Josephine Briggs said.

Dr. Briggs, who was originally trained in internal medicine and nephrology, 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 totally pervasive, a huge driver of health costs.”

There was agreement among participants that chronic back pain is not simply a multifaceted biological problem, but also a psychosocial one. 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 many patients and have been associated with harm as well.

Several speakers pointed out that the extensive heterogeneity in causes, presentations, and functional impact of chronic back pain has made it difficult to define “case-ness,” which in turn makes it impossible to compare studies on the problem and determine the extent to which results from any given study can be extrapolated to another.

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.”

Indeed, noted Dr. Gary Franklin, a research professor in environmental and occupational health sciences at the University of Washington, Seattle, 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. “The FDA needs to consider using a composite measure,” he commented.

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 heterogeneous 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 NSAIDs 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.

A main goal of the workshop, Dr. Khalsa said, was to move beyond those measures to design approaches that can prevent chronic pain in the first place. “It’s much better to be able to do something when the patient first walks in the door to identify and predict—and hopefully prevent—a long-term chronic, debilitating problem.”

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 stated that he has no disclosures.

Moderate RA Not Treated Aggressively in Older Patients

BY SARA FREEMAN

FROM THE ANNUAL MEETING OF THE BRITISH SOCIETY FOR RHEUMATOLOGY

BIRMINGHAM, ENGLAND — Elderly patients with rheumatoid arthritis are treated less intensively than their younger counterparts, despite experiencing similar levels of disease activity.

Data from a cross-sectional study that was conducted at two centers in the United Kingdom show that for every 10-year increase in age, the chance of an RA patient’s receiving more intensive treatment is reduced by approximately 22%.

“Unfortunately, the elderly population is not well represented in clinical studies,” said Dr. Margaret H.Y. Ma, a clinical research fellow at King’s College Hospital in London.

“In routine clinical practice, we see a much larger proportion of elderly patients, and it is unclear currently how well we treat this population,” Dr. Ma said.

The incidence and prevalence of RA increases with age, and it is in the elderly (aged 65 years and older) that disease-related disabilities usually have the greatest impact. Therefore, the aim of the study was to examine the effects of age and other variables on the treatment of RA.

VITALS

Major Finding: For every 10-year increase in age, the chance of a patient with RA receiving more intensive treatment reduces by approximately 22%.

Data Source: Repeat cross-sectional study of 290 patients with RA.

Disclosures: Dr. Ma and Dr. Deighton had no conflicts of interest to declare.

Dr. Ma reported that the study, performed in 2009-2010 and involving 290 participants, was a repeat of a similar investigation that was performed in 2007-2008 and involved 236 people. The original and repeat cohorts of patients were similar in terms of age (58 and 59 years, respectively), sex (79% vs. 81% female), and ethnicity (70% vs. 72% white; 20% vs. 19% Afro-Caribbean). Treatment

plans also were similar between the cohorts (80% vs. 81% taking disease-modifying antirheumatic drugs [DMARDs]; 11% vs. 11% taking steroids; 15% vs. 17% taking biologics).

Patients in the repeat study, however, were more likely to have longer disease duration (10 years vs. 8.3 years), as well as a lower 28-joint disease activity score, or DAS28 (4.1 vs. 3.78), than did those who took part in the original study.

Both studies showed that there was a significant effect of age and disease activity on the chances that patients would be given more intensive therapy. While older patients were less likely to receive treatment increases (odds ratio, 0.83 in the original study and 0.82 in the repeat study), higher disease activity was associated with more intensive therapy (OR, 2.15 and 2.39, respectively).

Adjustment for possible confounding factors revealed that age and disease activity were the only determinants of treatment changes.

In the 2009-2010 cohort, the percentage of patients aged 65 years and older on DMARDs, steroids, and biologics was 77%, 11%, and 11%, whereas the

percentage of those younger than 65 years who took these drugs was 83%, 19%, and 19%.

“What stuck us the most was the comparison of disease activity,” Dr. Ma said. When they compared patients aged 65 years or older vs. those younger than 65 years, they found that there were no differences in disease activity, with both age groups exhibiting a similar spectrum of disease activity in both the original and repeat studies. However, for the same DAS28, elderly patients were less likely than younger patients to receive an increase in therapy if they had more moderate disease, Dr. Ma reported.

“It is interesting because in patients that have got very active disease, then it seems that, irrespective of their age, we are more likely to try to treat their disease more aggressively,” Dr. Chris Deighton, consultant rheumatologist at the Derbyshire Royal Infirmary, Derby, England, commented.

“If they have got moderate disease, then there is probably more of a negotiation that takes place” between the patient and physician, Dr. Deighton added.