Patient Representatives Are a Must in Research

BY SHERRY BOSCHERT

FROM ANNALS OF THE RHEUMATIC DISEASES

New recommendations from the European League Against Rheumatism provide structure to the growing practice of including patient representatives in research projects.

The recommendations should be useful not only within the European League Against Rheumatism (EULAR) but also to other medical researchers, Maarten P. T. de Wit of Vrije Universiteit Medical Centre, Amsterdam, and his associates reported. EULAR convened a 16-member task force that crafted eight recommendations to promote inclusion of the patient perspective in EULAR-funded scientific research (Ann. Rheum. Dis. 2011[doi:10.1136/ard.2010.135129]).

Some previous reports suggest that the benefits of including patient representatives in research outweigh the drawbacks. Although including one or more patient representatives has become "usual practice" in EULAR scientific projects, the League's standardized procedures previously have not described how best to do this, the task force said.

They defined patient research partners as "persons with a relevant disease who operate as active research team members on an equal basis with professional researchers, adding the benefit of their experiential knowledge to any phase of the project." Including patient research partners can help prevent mismatches between patient preferences and the focus of research, lead to more patient-oriented research agendas, empower patients, and build trust between patient organizations and medical institutions, data suggest.

The task force of three rheumatologists, one rheumatologist/epidemiologist, two allied health professionals, two research organization representatives, and eight patient research partners from six countries reviewed the literature and met twice to develop the recommendations, which were then evaluated by 28 patient representatives and 53 health professionals.

First, the task force urged that clinical researchers and groups work with patient research partners when developing guidelines or recommendations, and that other researchers consider patient participation. Patients' experiential knowledge is important even for laboratory-based research, and researchers who do not include patient partners should justify that decision, they said.

Second, patient participation should be considered for all phases of a research project and is essential in the early stages of research when critical decisions about the protocol and project are made. If this recommendation is not followed, investigators should explain why when publishing results.

Third, each project should include at least two patient research partners. There's no solid evidence to support this, but it adds to the team's diversity and supports the patient partners, and provides a substitute if one patient is absent due to rheumatic illness. This recommendation also drew more support from patients in the group of experts, winning agreement from 26 patients (93%) compared with 36 professionals (68%).

Fourth, give potential patient research partners a clear description of the minimum requirements for the position and clarify the roles of the patient partners and the principal investigator.

Fifth, take into account the patient's communication skills, motivation, and attitude when selecting patient research partners. Having a critical but constructive and proactive attitude is ideal. Academic training is not necessary and a medical background might even be undesirable, though some familiarity with medical terminology helps. "Thinking like an outsider is crucial to provide experiential knowledge," the task force said.

Sixth, a good attitude, good communication, and good support from the principal investigator are crucial for the full participation of patient partners. These skills to create a safe and respectful environment for patient partners may not come naturally to researchers, who should learn these skills or get training.

Seventh, give patient partners the information and training they need to participate, including awareness of ethical issues such as confidentiality, privacy, and legislation.

Eighth, recognize the contributions of patient research partners, which is usually voluntary work.

The authors reported having no relevant conflicts of interest. ■

Bariatric Surgery Improved Knee OA, Metabolism

BY NASEEM S. MILLER

FROM ANNALS OF THE RHEUMATIC DISEASES

In obese patients with knee osteoarthritis, significant weight loss after bariatric surgery reduced pain and stiffness, decreased low-grade inflammation, and changed cartilage turnover, according to a study published in the journal.

In addition to the well-known relationship between obesity and onset of knee osteoarthritis (OA), several studies have now shown that the association goes beyond the increase in mechanical load on the tibiofemoral cartilage. "Adipose tissue may act as an endocrine organ, releasing several proinflammatory mediators and adipokines in blood that may participate in cartilage alteration in obese patients," according to Dr. Pascal Richette of Hôpital Lariboisière and coauthors. The authors added, "Trials that have assessed the efficacy of surgically induced massive weight loss on knee OA symptoms are scarce and have not specifically included patients with well-defined radiographic evidence of knee OA, as in our study" (Ann. Rheum. Dis. 2011;70:139-44).

The authors studied 44 obese patients (36 women) with a baseline body mass index of 50.7 before surgery and moderate to severe knee OA. The patients underwent laparoscopic Roux-en-Y gastric bypass surgery or laparoscopic adjustable gastric banding. Patient data were collected before and 6 months after the surgery. At 6 months, patients had a 20% drop from baseline BMIs. Their VAS (visual acuity scores) decreased from 50 mm to 24.5 mm and their scores on the WOMAC (Western Ontario MacMaster) Questionnaire improved.

Significant decreases were seen in average serum levels of interleukin-6 (IL-6), which declined by 26%, and of high-sensitivity C-reactive protein (hsCRP), which dropped 46%. Also, weight loss was associated with changes in adipokine levels: Mean serum leptin concentration was decreased by 48% and serum level of adiponectin was increased by 21%, the authors reported.

The average serum level of procollagen type II N-terminal propeptide (PIIANP), a marker of cartilage synthesis, rose 32%, while the serum level of cartilage oligomeric matrix protein (COMP) decreased by 36%. "These results are the first to suggest a benefit of weight loss on both cartilage anabolism and catabolism," the authors wrote.

The researchers found a significant correlation between IL-6 level and WOMAC Questionnaire scores as well as between urinary type II collagen helical peptide (helix-II) and hsCRP. Variation in COMP concentration was significantly correlated with changes in VAS pain scores and WOMAC stiffness score, the authors wrote, adding, "Our findings extend the results of recent work showing a significant association of IL-6 circulating levels and the prevalence and incidence of knee OA." ■

Oral Apixaban Halved VTE Rate After Joint Replacement

BY HEIDI SPLETE

FROM THE ANNUAL MEETING OF THE AMERICAN SOCIETY OF HEMATOLOGY

ORLANDO – Oral apixaban reduced the incidence of major venous thromboembolism after joint replacement surgery by approximately half compared with enoxaparin, with no increased risk of bleeding, investigators have reported.

Of approximately 7,000 patients who underwent thromboprophylaxis after surgery, major VTE occurred in 0.68% of those who had received apixaban, compared with 1.50% who had been given enoxaparin. This was a significant difference, Gary E. Raskob, Ph.D., said.

HEIDI SPLETE/ELSEVIER GLOBAL MEDICAL NEWS

To see an interview with Dr. Gary E. Raskob, go to www.rheumatologynews.com.

Prevention of major venous thromboembolism is "a significant issue in health care in the United States," where the number of knee and hip replacements is expected to increase, said Dr. Raskob, dean of the College of Public Health at the University of Oklahoma Health Sciences Center in Oklahoma City. To provide more precise estimates of the incidence of major VTE and safety outcomes, the researchers combined data from two phase III, randomized, double-blind trials of patients who had undergone knee (ADVANCE-2 study) or hip (ADVANCE-3) replacement. A total of 8,464 were randomized to apixaban, a novel orally administered factor Xa inhibitor (4,236 patients), or enoxaparin (4,228 patients).

Efficacy results related to VTE were based on 3,394 patients in each group. Major VTE occurred in 23 patients in the apixaban group (0.68%), vs. 51 patients in the enoxaparin group (1.50%).

Bleeding results were based on 4,174 apixaban patients and 4,228 enoxaparin patients. Major bleeding occurred in 31 patients in the apixaban group and 32 in the enoxaparin group (0.74% vs. 0.77%). Major bleeding at the surgical site occurred in 26 in the apixaban group and 27 in the enoxaparin group.

Dr. Raskob has financial relationships with Bristol-Meyers Squibb, Pfizer, Bayer, Johnson & Johnson, Sanofi Aventis, and Daiichi Sankyo. ■