Tailored Tx Proves Successful for Fibromyalgia

BY BRUCE JANCIN

FROM THE ANNUAL EUROPEAN CONGRESS OF RHEUMATOLOGY

ROME — A tailored combination of cognitive-behavioral therapy and physical exercise training has achieved the largest treatment benefit ever reported for fibromyalgia in a randomized, place-bo-controlled clinical trial.

The durability of the results was particularly impressive. The large improvements in psychological and physical functioning that were documented at the end of the 8-week treatment program were maintained at the 6-month follow-up, Saskia van Koulil said.

The success of this customized treatment approach hinged upon a two-stage screening process. First, patients who have had their fibromyalgia for fewer than 5 years and were at high risk of long-term dysfunction were selected because prior studies indicated that such individuals tend to have better treatment outcomes in general.

Within this group of high-risk patients, specific cognitive-behavioral patterns seemed to drive their fibromyalgia pain and disability. It is possible to screen for these patterns of thought and behavior. One school of thought among clinical psychologists, including Ms. van Koulil, holds that there are two main patterns: pain avoidance and pain persistence. The treatment programs for the two are quite different, explained Ms. van Koulil of St. Radboud University Medical Center in Nijmegen, the Netherlands.

The high treatment success rate in this randomized trial validated this concept of the pain-avoidance and pain-persistence fibromyalgia subtypes, she said.

In her experience, close to two-thirds of patients with fibromyalgia of fewer than 5 years' duration have a high-risk profile. This is characterized by high levels of anxiety and/or negative mood on standard measures of distress, worse physical functioning, greater impact of fibromyalgia on daily life, and obvious maladaptive cognitive-behavioral patterns such as high levels of helplessness and worrying. This high-level psychological distress is an indicator of treat-

ment motivation, Ms. van Koulil said.

In the randomized trial, 158 high-risk fibromyalgia patients (95% of whom were women) were evaluated with a brief screening instrument for pain-avoidance behavior. Those with a high score were assigned to the pain-avoidance treatment group or a wait-list control arm, whereas patients with a low score were randomized to the pain-per-

sistence group or the control arm.

pain-The avoidance subtype of fibromyalgia is often marked by fear of pain, hypervigilance, catastrophizing, and zealous avoidance of pain. The painpersistence subtype is marked by an overactive lifestyle and low levels of pain avoidance.

These highly self-demanding

patients tend to ignore pain, ignore their physical limits, and display high levels of task persistence. Both subtypes end up via different routes at the same place, which is marked by functional disability, psychologic distress, fatigue, and chronic pain. The pain-persistence group, however, tends to be more physically fit.

Of study participants, 53% were categorized as pain avoidant; 47% were classified in the pain-persistence group.

Patients in both active-treatment arms received 16 twice-weekly treatment sessions in eight-patient groups, each session 4 hours in length, plus homework assignments. The first half of each session was devoted to cognitive-behavioral therapy (CBT), the second half to exercise training. Each exercise session included aerobic exercises, either strength or flexibility training, and relaxation techniques. The patient's significant other attended the 3rd, 9th, and 15th sessions. A booster session was held 3 months after

completion of the 8-week program.

The CBT was delivered by therapists with experience in CBT for fibromyalgia and other rheumatologic conditions. Therapy was guided by a written manual. The exercise training was provided by physical therapists.

The pain-avoidance treatment regimen was tailored toward achieving increased daily activities, reduced fear of



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pain and pain-avoidance behaviors through titrated exposure, and a gradual gain in physical condition. The emphasis in the pain-persistence group was on learning to improve pacing and regulation of activities of daily life and physical exercise, along with altering pain-persistence cognitions.

Five of the six primary outcome end points in the study were changes from baseline in pain, fatigue, functional disability, negative mood, and anxiety as measured on the Impact of Rheumatic Diseases on General Health and Lifestyle scale, which is derived from the Arthritis Impact Measurement Scales. The sixth outcome measure was change in the impact of fibromyalgia on daily life, as assessed by the 10-item Fibromyalgia Impact Questionnaire (FIQ).

The results were striking: In all, 60% of patients in the tailored-therapy arms experienced a clinically significant reduction in the impact of fibromyalgia on daily life, compared with 24% of con-

trols. Of the tailored-therapy patients, 67% had a clinically significant improvement in the physical function domain combining pain, fatigue, and functional disability, compared with 33% of controls. And 62% of tailored-therapy patients demonstrated a clinically significant improvement in psychological function as reflected in reduced scores for negative mood and anxiety, compared with 33% of controls.

The size of the improvements in the various end points was consistently numerically greater in the pain-avoidance group than in the pain-persistence arm, but not statistically significantly so.

Ms. van Koulil said the treatment effect sizes achieved with a tailored approach in this study were much larger than those seen in prior published studies of various one-size-fits-all therapies.

Pain scores (which have a theoretical range of 6-25) went from a mean baseline of 20 in the pain-avoidance treatment arm to 16 at the end of treatment and 17 at 6 months of follow-up. In the pain-persistence arm, pain scores went from a baseline of 19 to 16, then 16 at follow-up. Pain scores were unchanged over time in the control arm.

The impact of fibromyalgia on daily life as assessed by the FIQ (with a theoretical range of 0-100 points) went from a baseline of 66 to 48 at the end of painavoidance therapy, with a modest rebound to 50 at 6 months of follow-up. In the pain-persistence treatment arm, scores improved from a baseline of 57 to 47 at treatment's end and 43 at follow-up. Again, scores were flat over time in the control arms.

The encouraging results are welcome because of the dearth of effective treatment options for fibromyalgia. Fibromyalgia has the highest associated financial costs of all chronic pain and rheumatologic conditions, and the disease's negative impact on daily life is often profound, Ms. van Koulil said.

Disclosures: The study was fimded by the Dutch Arthritis Association and the Netherlands Organization for Health Research. Ms. van Koulil reported having no conflicts of interest.

Osteoarthritis Patients Less Prone to Hip Fractures, Study Finds

BY BRUCE JANCIN

FROM THE ANNUAL EUROPEAN CONGRESS OF RHEUMATOLOGY

ROME — Osteoarthritis of the knee or hip might hurt like the dickens, but affected patients can take a measure of solace from new evidence that their ailment is associated with less hip fracture.

Preliminary results from a large Swedish population-based study show that an inverse relationship exists between knee or hip osteoarthritis (OA) and incident hip fracture. The OA patients had roughly a 15% lower-than-expected rate of the traumatic injury, Dr. Martin Englund reported at the meeting.

The study captured all 11,901 adult residents of the southernmost county of Sweden who had hip OA, as well as the 23,866 with knee OA.

During the study years of 2004-2007, there were 398 hip fractures among the knee OA group.

This was significantly fewer than the 470 hip fractures that

would have been expected based on age- and sex-standardized data from the general population of the county, which contains 1.1 million residents, he reported.

Similarly, there were 233 hip fractures in patients with OA of the hip, compared with an expected 271, noted Dr. Englund, who is affiliated with the department of orthopedics at Lund (Sweden) University and the clinical epidemiology research and training unit at Boston University.

This translates to an observed hip fracture rate in the knee OA group of 763/100,000 per year, compared with an expected rate of 900/100,000 per year.

The observed rate of hip fracture in patients with hip OA was 884/100,000 per year, compared with the expected rate of 1,028 hip fractures per 100,000 per year.

The mechanism responsible for this protective effect remains unclear, according to Dr. Englund, who noted that there are some reports of increased bone

mineral density in patients who have hip OA. More frequent obesity among OA patients may possibly also protect against fracture when patients fall—through the extra "padding" in the hip.

Disclosures: Dr. Englund reported having no conflicts of interest. The study was funded by the Swedish Research Council, the Swedish Social Insurance Agency, the Lund University Faculty of Medicine, and Region Skåne, Sweden.