## Pediatric Rheumatology: Interest Grows in India

BY DOUG BRUNK

amilies looking for a board-certified pediatric rheumatologist in India—which has a population of more than billion—are unlikely to find one.

"The official count is zero," Dr. Thomas J.A. Lehman said in an interview. "They don't have any training programs for pediatric rheumatologists in India. They have a few physicians who practice pediatric rheumatology, but there is no formal training program. When you talk to physicians in India, they tell you 'we're doing pediatric rheumatology, but we all started out as pediatricians. Somebody sent us an interesting rheumatology case and we're trying to learn pediatric rheumatology as we go along."

In October 2009, Dr. Lehman, chief of the division of pediatric rheumatology at the Hospital for Special Surgery in New

York, spent 1 week as a volunteer guest lecturer at the annual meeting of the Indian Pediatric Rheumatology Association in Nagpur, India, which is in the country's centrally located state of Maharashtra. Also volunteering to teach at this meeting were fellow pediatric rheumatologists Dr. Charles H. Spencer from Columbus, Ohio, Dr. Angelo Ravelli from Genoa, Italy, and Dr. Tadej Avcin from Ljubljana, Slovenia. Almost 200 pediatricians and a handful of adult rheumatologists assembled at a hotel conference center, eager to learn about the state of pediatric rheumatology in a country coping with spotty infrastructure and poverty.

Dr. Nandini Babhulkar of the department of pediatrics at the Indira Gandhi Medical College and Mayo General Hospital, Nagpur, organized the conference. In his interview, Dr. Lehman extended his congratulations for her excellent job in bringing pediatricians and



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pediatric rheumatologists from the United States and Europe together with physicians from India to advance the care of children with rheumatic diseases.

The attendees were "mostly in their 30s and 40s, physicians working to be the pediatric rheumatologists of this generation for their country," Dr. Lehman said.

Physicians in India see many cases of juvenile idiopathic arthritis, but lupus and scleroderma are especially common. "That's probably due to genetics," said Dr. Lehman, who is one of about 280 board-certified pediatric rheumatologists in the United States. "Different populations have different backgrounds."

Topics he talked about during the meeting included recognizing and understanding common rheumatic diseases of childhood, working with physicians in other specialties in the care of patients, "and reinforcing how to take care of people when they don't have access to the newest drugs. They have nonsteroidal anti-inflammatory drugs, methotrexate, and steroids. The biologicals are available in India, but many patients can't afford them."

"In a country with few pediatric rheumatologists, the best long-term results will come from steps that minimize the need for doctor visits and long-term medication," he said.

"At present, too much emphasis is being placed on expensive medications that suppress chronic inflammation and too little on finding the cure. Drugs that suppress inflammation need to be continued indefinitely with repeated doctor visits and monitoring. We don't have the ability to cure any of the rheumatic diseases yet, but that's where our emphasis must be."

During a discussion at the meeting about the risk of tuberculosis compli-

cating immunosuppressive therapy, he learned that most physicians in India "often assume that the patient needs to be treated for TB, because TB is so rampant there."

In spite of such obstacles, Dr. Lehman said that he returned home from the meeting inspired. "There are many children in India with rheumatic disease."

"They're short on drugs and they're short on financing for the more expensive drugs. But this was a group of interested and enthusiastic physicians who are working hard on getting pediatric rheumatology established in that country. I'll be going back in the future to do more teaching. They need it, and I'm glad to help out."

Dr. Lehman said his expenses were paid by the division of pediatric rheumatology at the Hospital for Special Surgery in New York.

## **Obesity Speeds Spinal Aging**

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The investigators excluded from the study patients with trauma and scoliosis, as well as those with genetic, metabolic, and developmental conditions associated with predisposition to spinal abnormalities.

With these findings in otherwise healthy teens with back pain, "we have another link in the chain of the end-organ damage that can result from obesity. From a public health perspective, I think that's significant," Dr. Burns said at the press briefing.

Press briefing moderator Dr. Deborah Levine, a professor at Harvard Medical School, Boston, said the findings are worrisome and emphasize the need to stem the rising tide of pediatric obesity in America.

Dr. Levine did, however, question whether the study criteria might have over-represented children with severe back pain, since MRI is not typically performed for this indication in children.

Dr. Burns responded that the reasons prompting patients to go to the ER and receive an MRI were not entirely clear, but that severity

of pain might have been the case for many of the MRIs.

The study also included 40 adolescents without back pain, and 8 (20%) of these patients had an abnormal MRI. Among these 8 patients, abnormal MRIs were observed in 6 adolescents with a BMI greater than the 85th percentile and in 2 with a BMI less than the 85th percentile, a difference that was not statistically significant, Dr. Burns said.

The findings do not support routine use of MRI in children with back pain, he added.

A prospective study is needed in children with obesity, not necessarily with back pain, to determine the longitudinal effects of obesity and whether lumbar disease is as common in adolescents as it is in adults

He noted that back pain accounted for just 0.4% of pediatric ED visits in one study (Clin. Pediatr. 1999;38:401-6).

**Disclosures:** The investigators disclosed no relevant conflicts of interest

## So Far, No Safety Signals Are Seen in Data on Abatacept, Adalimumab for JIA

BY ELIZABETH MECHCATIE

ROCKVILLE, MD. — Follow-up study of two biologics approved to treat juvenile idiopathic arthritis has not identified any new safety signals in pediatric patients that have not been previously identified in adults, a Food and Drug Administration official reported at a Dec. 8 committee meeting.

The FDA's Pediatric Advisory Committee heard updates from the agency on post-marketing safety data on abatacept, a selective T-cell costimulation modulator approved to treat JIA in children aged 6 years and older, and adalimumab, a tumor necrosis factor (TNF) blocker approved for treating JIA in children aged 4-17 years.

Abatacept, administered intravenously, is marketed as Orencia by Bristol-Myers Squibb Co. The company is conducting a 10-year pediatric safety study and is required by the FDA to establish a registry of 500 JIA patients who are treated with abatacept. The patients will be monitored for malignancies, other autoimmune diseases, and serious infections for 3 years. Between December 2005 and July 2009, there were seven reports of adverse events in children aged 7-16 years who were treated with abatacept, including one case of multiple scle-

rosis in a 14-year-old and lymphoma in a 16-year-old, which are listed in the label.

Adalimumab, administered subcutaneously, is marketed as Humira by Abbott Laboratories. Postmarketing requirements include conducting a 10-year safety study of the drug in 800 JIA patients aged 4-17 years.

In pediatric patients treated for at least 3 years, adverse events were similar in frequency and type to those reported in adults. But rates of hypersensitivity reactions and development of antibodies to adalimumab were higher among pediatric patients.

In August, the FDA reported an ongoing safety review, which suggested that pediatric patients who were treated with TNF blockers were at increased risk for lymphomas and other malignancies, including types rarely seen in children. A statement on this risk was added to the labels of all TNF blockers.

Since approval, 109 serious adverse events were reported in pediatric patients who were treated with adalimumab, of which 37 were cases of exposure in utero. There were two malignancies (lymphomas reported in a 16-year-old and a 10-year-old). Both patients had been on long-term treatment with other immunosuppressants, including other products associated with an increased malignancy risk.