Tocilizumab Shows Efficacy for Systemic JIA

These data are proof of the principle that many patients seem to benefit from blocking IL-6.

BY MITCHEL L. ZOLER
FROM THE ANNUAL EUROPEAN CONGRESS OF RHEUMATOLOGY

Rome — Patients with systemic juvenile idiopathic arthritis who were treated with the interleukin-6 inhibitor drug tocilizumab produced strong responses in a randomized, multicenter, placebo-controlled trial.

After 12 weeks of treatment in the 112-patient study, the children in the tocilizumab arm had response rates that significantly surpassed those of patients in the placebo arm, Dr. Fabrizio De Benedetti said at the annual European Congress of Rheumatology (see table).

In addition, the response rates were "still going up" at 12 weeks. "I hope that the 1-year data will show even better benefit," Dr. De Benedetti said in an interview.

"A wealth of body of evidence suggests that IL-6 (interleukin)-6 drives systemic JIA. These data are a proof of principle that the majority of patients appear to benefit from blocking IL-6," said Dr. De Benedetti, a rheumatologist at Bambino Gesù Pediatric Hospital here.

"In our experience, tocilizumab is a dramatically beneficial drug," commented Dr. Taunton Southwood, professor of pediatric rheumatology at the University of Birmingham (England), who was not involved in the study.

The new study in children and adolescents with systemic JIA was sponsored by Roche, which markets tocilizumab (Actemra).

The trial enrolled patients aged 2-17 years who had been diagnosed with systemic JIA for at least 6 months at several centers worldwide.

The average age of the 112 enrolled patients was 10 years, and they had been diagnosed for a median of 5 years. The researchers randomized 75 patients to tocilizumab and 37 to placebo. Patients who weighed less than 30 kg received 12 mg/kg tocilizumab as an intravenous infusion every 2 weeks; patients who weighed 30 kg or more received 8 mg/kg on the same schedule. Seventeen patients in the placebo group (46%) and 72 patients in the tocilizumab group (96%) completed all 12 weeks of treatment.

The study’s primary end point was the fraction of patients who achieved an ACR50 response and had no fever at 12 weeks, calculated on an intention to treat basis.

"We tested a different dosing regimen from adults [who receive the drug every 4 weeks], because the disease is different and the pharmacokinetics of the drug is different compared with adults," Dr. De Benedetti said.

The primary end point occurred in 24% of the placebo patients and 91% of those in the tocilizumab arm, a statistically significant difference.

Patients Achieving Response Level After 12 Weeks

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<thead>
<tr>
<th>Tocilizumab (n = 75)</th>
<th>Placebo (n = 37)</th>
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<tbody>
<tr>
<td>ACR30</td>
<td>91%*</td>
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<tr>
<td>ACR50</td>
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<td>ACR70</td>
<td>71%*</td>
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*Statistically significant difference between tocilizumab and placebo

**Major Finding:** Patients with systemic juvenile idiopathic arthritis randomized to biweekly infusions of tocilizumab for 12 weeks had an 91% rate of an ACR30 response and no fever, compared with a 24% rate of this primary end point in patients randomized to placebo.

**Data Source:** A multicenter, randomized, placebo-controlled trial of intravenous tocilizumab in 112 patients with systemic juvenile idiopathic arthritis.

**Disclosures:** Dr. De Benedetti said that he has been a consultant to and has received research funding from Roche.

How to Deliver Bad News to Parents of Pediatric Patients

BY DOUG BRUNK
FROM A MEETING ON CRITICAL CARE MEDICINE SPONSORED BY THE UNIVERSITY OF CALIFORNIA, SAN DIEGO

San Diego — Delivering devastating news about a pediatric patient to loved ones is arguably one of the toughest parts of a physician’s job. According to one pediatric social worker, a lot of physicians struggle with how to present such difficult information and to do so with just the right compassion.

“It’s unpleasant because you don’t want to take away hope from the family,” Jill Farabelli said during the meeting.

“Families are never prepared, and doctors are equally unprepared. They know the medical information, but how to deal with the emotional part of it is really tough.”

Ms. Farabelli, a social worker for the pediatric intensive care unit at Rady Children’s Hospital, San Diego, offered the following tips for communicating with families of pediatric patients during difficult times:

► Be upfront about the diagnosis or prognosis. Parents “want and need to know what’s going on with their child, whether it’s good news or bad news,” she said.

“The other day a family came in whose child was in crisis. The doctor kept beating around the bush about the information that he wanted to give the parents. The dad finally said, ‘Just tell me how it is. Give me the details.’”

Ms. Farabelli emphasized that a physician’s communication skills “play a crucial role in how families cope.” Most families, she continued, pay close attention to how physicians act toward them, “their body language, their attitude, whether they seem that they want to be there, and whether they seem that they care.”

► Use a quiet, comfortable place to deliver the news. “On a trauma unit, that may not be possible, but be prepared with the medical information,” she said. Review the medical chart and know what your options are. Consult with specialty services before giving the medical information to families, if applicable.

“Often it happens that doctors don’t communicate with one another, and they give conflicting information to the family,” Ms. Farabelli said. “The family gets very confused because everyone’s saying something different.”

► Prepare yourself from an emotional standpoint. Consider meeting with social workers before you meet with the family, “to know the right words to say, or to discuss background on the family,” she advised. “When you’re working with a family that’s in a trauma situation, no one really knows that family; no one’s had the chance to build a relationship. But when you’re working with kids who are in critical care for months at a time or chronically ill patients, that’s when that information can come in handy.”

► Allow for uninterrupted time. It might not be possible to turn off pagers, but they can be silenced while you meet with the patient’s loved ones.

“Many times I’ve had crucial conversations with families with pagers going wild,” Ms. Farabelli said. “It really takes away from the parents’ ability to focus on the information that’s being given to them, and it’s distracting to the doctors for being able to answer questions or to give diagnosis and prognoses.”

► Know the names of the family members who are present. When you are delivering bad news, it helps if both parents can be present. “There are times when a child may be brought into the trauma unit, and the mom is there and the dad is a couple of hours away,” she said.

“It’s important that, when possible, both parents hear the same information at the same time.”

After you’ve delivered the news, ask family members to tell you their understanding of the information. Often, they don’t digest it all at first. “Medical jargon is hard to understand for a lot of families,” she said.

“Also, if you tell them something ultimately devastating, they are probably not going to process the rest of what you have to say, so you might have to ease into it.”

► Use touch when appropriate. Sometimes parents “will grab your hand or need to hug you” for consolation, she said. Be aware of personal preferences and be sensitive to cultural differences.

► Allow time for questions. “Tears are appropriate, “as is silence,” Ms. Farabelli said. “Sometimes you don’t know what to say. You may cry. Sometimes you cannot help but be touched or overwhelmed by what a family is going through. ‘After the news is given, how do you support the family?’

“Hush, hug, and hang out. ‘Your presence means so much to these families.’”

Ms. Farabelli said she had no relevant conflict to disclose.