Rapid Rituximab Infusion May Be Practical

BY DIANA MAHONEY
FROM THE ANNUAL MEETING OF THE CANADIAN RHEUMATOLOGY ASSOCIATION

CANCUN, MEXICO – An accelerated rituximab infusion for rheumatoid arthritis is safe and well tolerated in the community setting, a study has shown.

Moreover, the rapid infusion protocol “optimizes resources in busy rheumatology practices,” Dr. Rafat Faraawi said at the meeting.

As a chimeric monoclonal antibody, rituximab (Rituxan) is often associated with infusion toxicities, particularly during the initial 30-120 minutes of the first infusion, said Dr. Faraawi, a rheumatologist at St. Mary’s General Hospital in Kitchener, Ont.

To minimize the potential for infusion-related events, the drug manufacturers recommend that it be infused slowly, over the course of 4-5 hours – a long duration that is highly resource intensive, particularly in this era of intense competition for “chair time” and nursing attention, he said.

Small pilot studies in the oncology setting have shown that rapid rituximab infusion protocol was safe and well tolerated among patients with rheumatoid arthritis.

Data Source: A 10-patient prospective, open-label study designed to assess the practicality of a rapid-infusion protocol for rituximab in RA patients in a single community setting.

Disclosures: Dr. Faraawi reported that he had no relevant financial disclosures.
imib infusion protocols of 60-90 minutes can be administered safely without increasing the risk of infusion-related reactions.

To evaluate the practicality, safety, and tolerability of an accelerated-infusion protocol in the rheumatology setting, Dr. Farawa and his colleagues recruited 10 patients who were prescribed rituximab for their rheumatoid arthritis to participate in the study. The patients were randomized to one of five protocols: two courses of 1,000 mg infusions given 2 weeks apart. The first infusion followed the recommended 225-minute infusion schedule, while the subsequent infusions were administered over a period of 120 minutes as follows: 100 mg over 0-30 minutes; 200 mg over 30-60 minutes; 300 mg over 60-90 minutes; and 400 mg over 90-120 minutes, he said.

Prior to the infusions, patients were pretreated with 1,000 mg acetaminophen, 50 mg diphenhydramine, and 100 mg intravenous methylprednisolone. Vital signs were recorded before the first infusion (at 15, 30, 60, and 120 minutes), said Dr. Farawa.

The mean age and disease duration of the 10 patients was 50.6 years and 11.4 years, and the mean disease activity score at the first rituximab infusion was 5.9, he reported.

At the time of the presentation, a total of 40 infusions had been delivered: 30 of which followed the accelerated-infusion protocol, said Dr. Farawa.

“To date, the rapid infusion of rituximab has been well tolerated by all of the patients, with only one mild infusion reaction, who was resolved during the infusion,” he said. “In that case, the patient had refused premedication before the third infusion and experienced itching in her throat and ears, sore shoulders, and tremors, all of which resolved following treatment with intravenous diphenhydramine and methylprednisolone and oral acetaminophen.” The patient premedicated prior to subsequent infusions and had no further reactions, Dr. Farawa said.

Based on the positive findings of this small study, “rapid rituximab infusion is a practical option in a community setting,” he said.

“All of the patients were satisfied with the short infusion duration, it was safe and well tolerated, and it optimized patient, nurse, and physician time.”

CYMBALTA® (duloxetine hydrochloride) Delayed-Release Capsules
Brief Summary: Consult the package insert for complete prescribing information.

WASHINGTON: SYMPTOMATIC AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicide ideation and behavior (suicidal thoughts and behavior) in children, adolescents, and young adults in short-term trials of major depressive disorder (MDD) and other psychiatric disorders. The efficacy of CYMBALTA was established in four short-term trials and one maintenance trial in adults.

Generalized Anxiety Disorder—CYMBALTA is indicated for the treatment of generalized anxiety disorder (GAD). The efficacy of CYMBALTA was established in three short-term trials and one maintenance trial in adults.

Diabetic Peripheral Neuropathic Pain—CYMBALTA is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy.

Fibromyalgia—CYMBALTA is indicated for the management of fibromyalgia (FM).

Chronic Musculoskeletal Pain—CYMBALTA is indicated for the management of chronic musculoskeletal pain.

This has been established in studies in patients with chronic low back pain (CLBP) and chronic pain due to osteoarthritis.

CONTRAINDICATIONS: Monamine Oxidase Inhibitors—Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs. These interactions may include hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and, rarely, death due to extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued serotonin-reuptake inhibitors and are then started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome (see Warnings and Precautions).

Uncontrolled Narrow-Angle Glaucoma—In clinical trials, CYMBALTA use was associated with increased IOP in patients. Therefore, its use should be avoided in patients with uncontrolled narrow-angle glaucoma (see Warnings and Precautions).

WARNINGS AND PRECAUTIONS: Clinical Worsening and Suicide Risk—Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depressive symptoms and the emergence of suicidality, including ideation or behavior, either early or at any time during treatment with CYMBALTA. Patients with suicidal ideation or behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with cyproheptadine compared to placebo in adults aged 65 and older. There was a statistically significant increase in Obtained in trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 8 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in children with MDD, OCD, or other psychiatric disorders totaling 25-64 1 fewer case ≥65 6 fewer cases the 10 patients was 50.6 years and 11.4 minutes, said Dr. Farawa. At the time of the presentation, a total of 40 infusions had been delivered: 30 of which followed the accelerated-infusion protocol, said Dr. Farawa. “To date, the rapid infusion of rituximab has been well tolerated by all of the patients, with only one mild infusion reaction, who was resolved during the infusion,” he said. “In that case, the patient had refused premedication before the third infusion and experienced itching in her throat and ears, sore shoulders, and tremors, all of which resolved following treatment with intravenous diphenhydramine and methylprednisolone and oral acetaminophen.” The patient premedicated prior to subsequent infusions and had no further reactions, Dr. Farawa said.

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### TABLE 1

<table>
<thead>
<tr>
<th>Drug Placebo Difference</th>
<th>Number of Cases of Suicidality per 1000 Patients Treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;8</td>
<td>14 additional cases</td>
</tr>
<tr>
<td>8-24</td>
<td>5 additional cases</td>
</tr>
<tr>
<td>25-65</td>
<td>1 fewer case</td>
</tr>
<tr>
<td>&gt;65</td>
<td>6 fewer cases</td>
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### ATHRITIS

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Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)–like Reactions...