Infections, Dr. Revankar said. Bronchopulmonary mycoses are characterized by the presence of allergic mucin and it seems to be a virulence factor, he said. Melanin is the right moment to intervene in these high-risk patients. But we do know that randomized controlled trials are needed, and this will require an ongoing effort from a large group of clinicians in order to succeed,” Dr. Hardalo said. She disclosed that she owns stock in Schering Plough.

In a second study, 600 patients with acute myelogenous leukemia or myelodysplastic syndrome received the same dose of posaconazole or fluconazole, 400 mg once a day, or itraconazole, 200 mg twice a day. The number of cases of invasive fungal infection and invasive aspergillosis were “virtually the same” as in the other study: 2% and 1% for posaconazole, and 8% and 7% for the other azoles, Dr. Hardalo said.

There were 49 deaths among patients receiving posaconazole and 67 among patients receiving the other azoles. Five deaths in the posaconazole group were fungal related, as were 16 in the other azole groups. These differences were statistically significant. Moreover, fungemia was statistically more common in the itraconazole group than in the posaconazole group. Nevertheless, significant fungemia benefit was seen among neutropenic patients, she said.

Because posaconazole is an oral drug, concern has been expressed about its absorption by patients with gastrointestinal dysfunction related to graft-versus-host disease. In this experience, patients with neutropenia and mucositis didn’t absorb the drug as well as healthy volunteers, but tissue levels were adequate for preventing infections, Dr. Hardalo said.

“We still have a lot of questions. We still don’t know what is the best treatment for aspergillosis or for zygomycosis. We don’t know what is the right moment to intervene in these high-risk patients. But we do know that randomized controlled trials are needed, and this will require an ongoing effort from a large group of clinicians in order to succeed,” Dr. Hardalo said. She disclosed that she owns stock in Schering Plough.

Invasive fungal infections have emerged as a potentially lethal complication for immunosuppressed patients, and some of the pathogens involved are resistant to standard antifungal therapy. Posaconazole is a broad-spectrum agent with activity against Aspergillus, Fusarium, Coccidioides, Candida, pigmented and hyaline molds, and the Zygomycetes, she said at a meeting on fungal infections sponsored by Lamedex.

Previously, the drug had been used primarily as salvage therapy for patients with invasive aspergillosis, with about 40% of patients responding. “In salvage therapy you will see at best a 40% response rate with any antifungal,” said Dr. Hardalo, senior director of antifungal clinical and medical research, Schering Plough Research Institute, Kenilworth, N.J.

Studies performed in the 1990s suggested the potential benefit of prophylaxis against invasive fungal infections in high-risk patients. Current prophylaxis options include fluconazole and micafungin for patients undergoing hematopoietic stem cell transplantation, and itraconazole (in Europe only) for the prevention of fungal infections during prolonged neutropenia.

Posaconazole now has been evaluated in a multicenter, double-blind study that included 600 patients who had undergone allo- genic stem cell transplantation and had graft-versus-host disease. They were randomized to receive either posaconazole 200 mg three times daily, or fluconazole 400 mg/day, for 16 weeks. The incidence of invasive fungal infections and invasive aspergillosis were 2% and 3%, respectively, in the posaconazole group vs. 8% and 6% in the fluconazole group. A total of 64 patients in the posaconazole group died, as did 84 in the fluconazole group. This difference was not significant. However, only 10% of patients on posaconazole died from fungal causes, which was significantly fewer than the 12 patients with fungal-related deaths in the fluconazole group.

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