Interim Data Show Longer Survival in Glioma

Fluorescence guidance using 5-ALA uptake may improve surgeons' identification of tumors.

BY ALICIA AULT
Contributing Writer

NEW ORLEANS — Fluorescence-guided surgery with 5-aminolevulinic acid appears to increase progression-free survival in malignant glioma, according to interim results of a multicenter study conducted in Germany, Walter Stummer, M.D., reported at the annual meeting of the American Association of Neurological Surgeons.

Participants in an ongoing study are being randomized to receive 20 mg/kg of 5-aminolevulinic acid (5-ALA) with fluorescence-guided surgery or conventional microsurgery, aided by white light. The German manufacturer Medac GmbH, which makes 5-ALA, designed the study with the researchers. Eighteen centers are participating in the ALA-Glioma Study Group, said Dr. Stummer, of the University of Düsseldorf, a participating center.

This study addresses a basic 'controversy in neurosurgery on whether maximal cytoreductive therapy of malignant gliomas is of benefit to patients.'

5-ALA causes the accumulation of fluorescent porphyrins in malignant gliomas, which may help surgeons better identify and resect tumors intraoperatively. It is not approved for this use in the United States.

Dr. Stummer reported on the first 270 patients in an intent-to-treat population. (A total of 350 will be in the final analysis.) All patients were given an MRI preoperatively, during surgery, and on days 103, day 7, week 6, and every 3 months after surgery.

The cumulative 6-month progression-free survival rate was 41% for the 5-ALA group, compared with 21% for the control group. The 5-ALA patients had a median survival of 15.2 months, compared with 13.5 months for patients in the control group; however, the trial was not powered to show any difference in overall survival.

Sixty-five percent of postoperative MRIs done on the 5-ALA patients were devoid of residual contrast-enhancing tumor, compared with 36% in the control group ($P < .001$). "This study addresses the basic controversy in neurosurgery on whether maximal cytoreductive therapy of malignant gliomas is of benefit to patients," said Dr. Stummer in a statement.

Results of the study "demonstrate that fluorescence guidance using 5-ALA enhances resections of malignant gliomas, and that enhanced resections are beneficial by translating into longer progression-free survival," Dr. Stummer added.

In discussing the study at the meeting, Peter Black, M.D., chief of neurosurgical oncology at Dana-Farber Cancer Institute in Boston, said it provided class I evidence of improved survival.

The study also demonstrated a successful collaboration by the 18 centers, he said.

But, noted Dr. Black, since 5-ALA is not yet approved for this use in the United States, there is still a continuing need for other therapies. ■