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Poliovirus therapy shows survival benefit in early patients

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An early group of patients who received a modified form of the poliovirus to treat recurrent glioblastoma brain tumors showed survival improvement over historical controls, according to researchers at the Preston Robert Tisch Brain Tumor Center at Duke Health.

The findings, which have not been peer reviewed, were presented at the American Society of Clinical Oncology annual meeting in Chicago (ASCO abstract #2061).

"At the first five dose levels used in the study, infusion of the modified poliovirus therapy appears to have had about a two-month survival advantage when compared to similar, non-study patients treated at our clinic," said Annick Desjardins, M.D., associate professor of neurology at Duke and the lead author on the abstract. "Notably, a higher proportion of poliovirus patients were alive at 24 and 36 months."

The poliovirus, which has been modified to eliminate any harmful effects, is attracted to certain receptors that are in abundance on cancer cells. The modified virus homes in on tumor cells, infecting them and igniting an additional immune response.

Desjardins and colleagues reported results of the first 15 patients in the phase one study. Among this early group, the dosage of the therapy was escalated on the premise that increasing the amount of the drug could show greater benefits.

The dose-escalation part of the trial began in May, 2012. Five different doses at increasingly higher levels were tested: one patient at dose level one; seven at dose level two; one at level three; two at level four; and four at level five.

For comparison, the researchers identified 124 patients who had not received the poliovirus therapy, but were closely matched for age, gender, functional level, prior number of progressions, steroid dosage at enrollment, and failure under the standard care using bevacizumab.

As of January, 2016, the median survival of patients who underwent one of the initial five levels of poliovirus therapy was 12.6 months, compared to 10.5 months for the non-study patients. About 20 percent of this group of poliovirus patients were alive at 24 months versus 13.7 percent of the non-study patients.

"This phase of the study helped us identify an optimum dose, which was even lower than the initial dose we used for the first patient," Desjardins said. "It turned out that escalating the dosage, much like what is done with chemotherapy drugs, was not the best strategy for the poliovirus therapy. We predict that patients treated at the optimal dose, called dose level minus one, will have a greater increase in survival than those who underwent the higher doses."

The researchers began testing the lower, optimal dose in October, 2014. This May, after reviewing data of the patients treated on dose levels 1-5 and the first patients treated on dose level minus 1, the FDA granted the poliovirus therapy "breakthrough therapy designation" to speed research.

Provided by Duke University