Multiple myeloma patients experience high response rate with new 3-drug combination

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A new three-drug combination has shown in a phase 1/2 clinical trial that it is a "highly effective regimen" in the treatment of patients newly diagnosed with multiple myeloma, a cancer of white blood cells in bone marrow, say researchers from Dana-Farber Cancer Institute.

Partial responses or better were seen in all of the 66 patients treated with the drug combination in the multi-center study, with 74 percent having a "very good partial response rate" in the phase 2 population, reports Paul G. Richardson, MD, of Dana-Farber, who led the study. The rate of complete or "near complete" responses to the therapy was also encouraging at 54 percent.

Richardson will describe the results in an oral presentation at the American Society of Hematology's 51st annual meeting on Saturday, Dec. 5.

The regimen, known as RVD, combined the drugs Revlimid® (lenalidomide), Velcade® (bortezomib) and dexamethasone, which previously were found to be highly effective in multiple myeloma patients who had relapsed or no longer responded to first-line therapies.

Fifteen of the 35 newly diagnosed patients in the open-label phase 2 portion of the study subsequently underwent autologous (using their own blood-forming stem cells) transplants, a standard treatment for multiple myeloma "and did very well," says Richardson.

For the entire group, after a median 19.3 months of follow up, the median time-to-progression (TTP) of the disease, progression-free survival (PFS), and overall survival (OS) had not yet been reached, according to the presentation. The estimated TTP and PFS at one year are 76 percent, and the estimated one-year overall survival is 100 percent, the results showed.

An estimated 20,580 new cases of multiple myeloma will be diagnosed in 2009, according to the American Cancer Society, and 10,580 patients will die from the disease.

Richardson says it was "particularly exciting" to observe that the high response rate was not affected by the specific genetic characteristics of the patients' disease. Patients with so-called "adverse cytogenetics" are at higher risk for treatment failure and death, but in the current study the drug combination worked as well for them as it did in patients with more favorable cytogenetic features.

The toxic side effects of the treatment were "manageable," Richard says. The main adverse effect was peripheral neuropathy (numbness or pain in the extremities), which typically cleared up after dosages were lowered and the treatment was completed.

"Our conclusion is that this is a highly effective regimen for newly diagnosed multiple myeloma patients," says Richardson. "The combination has now gone into large phase 3 clinical trials, and we think it has the potential to be a new standard of treatment in multiple myeloma."

Source: Dana-Farber Cancer Institute