Additions to standard multiple myeloma therapy do not appear to yield additional benefit

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Trial results being presented today during the 58th American Society of Hematology (ASH) Annual Meeting and Exposition in San Diego suggest two therapies that are often added to standard therapy in patients with multiple myeloma do not improve rates of progression-free survival compared with the current standard course of treatment alone. The study is the largest randomized controlled trial of post-transplant therapy for multiple myeloma ever conducted in the United States.

Multiple myeloma, a cancer of the plasma cells - cells that exist in the bone marrow that help fight infection - that is diagnosed in about 30,000 people per year in the United States. For physically fit individuals below age 70, standard care consists of three components: 1) A course of initial therapy with combinations of proteasome inhibitors, thalidomide analogues, corticosteroids and alkylating agents, then high doses of the chemotherapy drug melphalan to kill cancer cells, 2) transplantation of the patient's own hematopoietic stem cells (autoHCT) to help rebuild the immune system, and 3) ongoing treatment with the chemotherapy drug lenalidomide to prevent cancer from returning. Over the past decade, many doctors have added to this regimen either by incorporating an additional intensive three-drug course of chemotherapy after autoHCT (including the drugs dexamethasone and bortezomib in addition to lenalidomide), or by adding a second round of autoHCT.

"These results are very important because they answer a question that

has been ongoing and has not been compared head-to-head: 'Does the addition of these interventions result in a true advantage for these patients?'" said lead study author Edward A. Stadtmauer, MD, of the Abramson Cancer Center, University of Pennsylvania in Philadelphia. "The conclusion of this study, so far, is that the other interventions are not superior to initial melphalan therapy followed by a single autoHCT followed by lenalidomide maintenance."

The researchers, participating in a national collaborative effort of 54 centers, enrolled 758 patients and randomly assigned them to receive either standard care, standard care plus additional chemotherapy, or standard care plus a second round of autoHCT. With almost all patients nearing the end of follow-up, the study's Data and Safety Monitoring Board released the current results. The results showed no difference among the three groups in terms of the study's primary endpoint—38-month survival without disease progression, as indicated by intent-to-treat—with progression-free survival observed in 52 percent, 57 percent, and 56 percent of patients in each of the three treatment arms, respectively.

The final analysis and the analysis of secondary outcomes including quality of life indicators, the degree of disease response, and evidence of toxicity will be available after all patients have completed 38 months of follow-up.

"Despite remarkable advances in the therapy and outlook for patients with multiple myeloma over the last decade, ultimately many patients will have their disease progress. So, there's always room for improvement," said Dr. Stadtmauer. "New therapies and interventions need to be actively investigated to see how much they further benefit the early treatment of patients with myeloma; I believe that the results of this study suggest it would be reasonable to compare any new treatments to the standard therapy of melphalan followed by a single autoHCT

followed by lenalidomide maintenance."

The researchers will track patients in a follow-up study to assess long-term trends and outcomes.

More information: Edward A. Stadtmauer, MD, Abramson Cancer Center, University of Pennsylvania, Philadelphia, Pa. will present this study, titled "Comparison of Autologous Hematopoietic Cell Transplant (autoHCT), Bortezomib, Lenalidomide (Len) and Dexamethasone (RVD) Consolidation with Len Maintenance (ACM), Tandem AutoHCT with Len Maintenance (TAM) and AutoHCT with Len Maintenance (AM) for up-Front Treatment of Patients with Multiple Myeloma (MM): Primary Results from the Randomized Phase III Trial of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN 0702 - StaMINA Trial)," (LBA-1) during the late-breaking abstracts session on Tuesday, December 6 at 7:30 a.m. PST in Hall AB.

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