

Stem Cell Transplant Offers No Additional Benefit for Mantle Cell Lymphoma Patients in Deep Remission

Transplant recipients showed no difference in progression-free or overall survival compared with those on maintenance therapy alone.

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Patients with no detectable cancer after initial therapy for mantle cell lymphoma (MCL) did not experience any survival benefit from undergoing a stem cell transplant compared with maintenance therapy alone, according to findings presented during the [66th American Society of Hematology \(ASH\) Annual Meeting and Exposition](#).

The trial, called EA4151, was stopped early based on the results of an interim analysis conducted when the study had followed patients for a median of 2.7 years. According to researchers, the findings suggest that patients who test negative for minimal residual disease (MRD) with an ultra-high sensitivity blood test do not need to undergo a stem cell transplant or the high-dose chemotherapy regimen used to prepare for a transplant.

“I think these results will make physicians comfortable omitting the transplant in patients who are MRD-negative; in the current treatment landscape for MCL, we can achieve good outcomes for these patients without the high-dose chemotherapy and transplant,” said the study’s lead author, Timothy S. Fenske, MD, professor of medicine at Medical College of Wisconsin in Milwaukee. “For patients who remain MRD-positive following induction, we would consider offering transplant.”

MCL is a rare, aggressive blood cancer that develops in the mantle zone of the lymph nodes. It is most common in older adults. After initial chemotherapy, doctors often recommend that patients undergo high-dose chemotherapy followed by an autologous stem cell transplant (using healthy stem cells collected from the patient’s own bone marrow) to help reduce the level of residual lymphoma further. However, this practice is based on studies conducted before today’s newer, more effective chemotherapy, immune therapy, and targeted therapies were available. In addition to EA4151, one other recent randomized clinical trial assessed whether a stem cell transplant is still necessary in light of the improved efficacy of today’s induction and maintenance chemotherapy regimens.

“A stem cell transplant can be a hard process for patients to get through,” said Dr. Fenske, noting that the side effects can last for months, and the potential complications of the procedure can be especially risky for older people. “If we can avoid that piece and still have similar outcomes, that would really be a nice step forward.”

The trial enrolled 650 patients between 2017-2024 who were in their first remission after initial treatment for MCL. Participants had a median age of 60 years, 79% were male, and 92% were white. Researchers assessed each patient’s remission status using a PET/CT scan, a bone marrow biopsy, and a highly sensitive blood test. They then divided participants into three groups based on the test results: MRD-negative (no evidence of cancer), MRD-positive (evidence of cancer in one or more cells per million), or MRD-indeterminate (testing incomplete or evidence of cancer in greater than zero but less than one cell per million).

The 516 patients who tested MRD-negative were randomly assigned to receive either a stem cell transplant and three years of maintenance rituximab or three years of maintenance rituximab alone. The rest of the patients (MRD-positive and MRD-indeterminate) were assigned to receive a stem cell transplant and three years of maintenance rituximab.

At the time of the most recent interim analysis, researchers determined that there was no evidence that a difference would emerge between the randomized arms of the MRD-negative group. With a median follow-up of 2.7 years, the overall survival rate was 82.1% among those assigned to receive a stem cell transplant and 82.7% among those assigned to maintenance therapy alone. The rate of survival without disease progression was 76.6% among those assigned to receive a stem cell transplant and 77.4% among those assigned to maintenance therapy alone.

About one-quarter of participants who tested MRD-negative and were randomized to receive a stem cell transplant refused to undergo the transplant. The researchers conducted a separate analysis to compare outcomes among participants who received their assigned treatment regimen, and found the survival rates were still similar enough to conclude there was no difference between groups.

The researchers also found no differences in outcomes among the randomized groups based on patients’ MIPI-c levels (a prognostic index for MCL) or the intensity of the induction therapy patients had undergone to achieve their first remission. Overall and progression-free survival rates were also similar among participants who were MRD-positive or MRD-indeterminate and assigned to receive a stem cell transplant.

Based on the evidence from this trial, researchers said that patients who test MRD-negative can safely avoid a stem cell transplant – and the associated side effects and risks – since they are likely to see no additional survival benefit from undergoing the procedure. One difference between EA4151 and other trials is that there were no restrictions on the induction therapy regimen used to achieve the first remission. Researchers noted that this makes the results generalizable across different settings since it reflects the real-world variability in regimens used by different doctors and hospitals across the U.S.

Although the study stopped enrolling new patients, researchers will continue to follow participants for several more years to assess longer term survival. They also plan to study molecular markers to determine whether different subgroups of patients may receive more benefit from a stem cell transplant.

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