

多発性骨髄腫に対する幹細胞移植は依然として望ましい治療法である (Abstract 8000)

新規薬剤時代においてもなお、多発性骨髄腫に対する自家幹細胞移植は重要である

Autologous stem cell transplant remains important for multiple myeloma even in novel agent era

2016年American Society of Clinical Oncology年次集会で発表された第III相試験の早期結果から、自家幹細胞移植 (ASCT) を実施された65歳未満の多発性骨髄腫患者は、新規薬剤を用いた化学療法のみ実施された患者に比べ、無増悪生存期間の長いことが示された。無増悪生存期間中央値にはまだ到達しなかったが、ASCTを実施された患者は、ボルテゾミブ-メルファラン-プレドニゾン治療のみで移植を受けなかった患者に比べ、進行が緩徐であった。疾患が未進行の患者では、ASCT群患者は移植を受けなかった患者に比べ、将来のいずれの時点においても進行リスクが24%低かった。

Full Text

Early findings from a phase III clinical trial showed that patients with multiple myeloma who received an autologous stem cell transplant (ASCT) survived longer without disease progression than those who received only chemotherapy using novel agents. This is the largest study reported to date aimed at comparing ASCT with a bortezomib-based regimen alone in patients younger than 65. The study was presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

ASCT is an intensive procedure in which a patient's blood-forming stem cells are harvested from the blood and stored. After treatment with high-dose chemotherapy, the stem cells are given back to the patient.

The proteasome inhibitor bortezomib has been incorporated into the standard treatments for patients with newly diagnosed multiple myeloma, whether or not they are able to undergo ASCT. For patients younger than 65, however, the continued need for ASCT has been debated in the era of novel agents, such as bortezomib (patients older than 65 are often unable to undergo ASCT).

"Our findings show that autologous stem cell transplant should remain the preferred treatment for patients with multiple myeloma age 65 and under," said lead study author Michele Cavo, MD, Head of the Seràgnoli Institute of Hematology at the University of Bologna. "While transplant-free treatment with novel agents remains an intriguing prospect, the reality is that stem cell transplant remains a powerful and proven approach, and with novel agents playing a supporting role, it is more effective than ever."

The randomized phase III study included 1,266 patients who were newly diagnosed with multiple myeloma. Following induction therapy with bortezomib-cyclophosphamide-dexamethasone, patients were randomly assigned to receive either bortezomib-melphalan-prednisone (VMP), or high-dose melphalan followed by single ASCT. (In treatment centers with a standard policy of performing double ASCTs, patients were randomly assigned to either VMP or single ASCT or double ASCT.)

In the second stage of the study, patients in both groups were randomly assigned to consolidation therapy with bortezomib-lenalidomide-dexamethasone or no consolidation therapy. All patients received maintenance therapy with lenalidomide until disease progression or intolerable toxicity. A planned interim analysis was performed in January 2016.

At the time of the analysis, median follow-up after the first treatment randomization was two years (23.9 months). While median progression-free survival was not yet reached, the data showed that patients who received stem cell transplants progressed more slowly than those who received VMP therapy without transplant. Among patients who had not yet experienced disease progression, those in the ASCT arm had a 24% lower risk of progressing at any future time point compared to those not receiving transplant.

The benefit of transplant was confirmed in a further multivariate analysis and was even greater among certain patients at high risk of early progression. Patients with advanced disease (according to International Staging System III) randomized to the ASCT arm had a 48% lower chance of progressing at the next analysis compared to those not receiving transplant; among patients with certain high-risk genetic factors, ASCT was associated with a 28% lower chance of future progression compared to VMP therapy without transplant. In comparison with patients who did not have a transplant, those receiving ASCT were also more likely to achieve a high quality response (at least 90% tumor cell mass reduction) to treatment (74% vs. 84%, respectively), which is an important indicator of longer survival.

Interim analysis of data related to the second randomization to consolidation therapy or no consolidation therapy is not yet complete. The study is ongoing, and future analyses will assess overall survival, toxicity and quality of life as well as other measures.

"Even in an age of novel therapies, proven approaches can retain their value. This study demonstrated that combining the best of both worlds – initial therapy with a novel agent followed by stem cell transplant – resulted in the best patient outcomes," said ASCO President Julie M. Vose, MD, MBA, FASCO, ASCO President.

This study received funding from the Haemato Oncology Foundation for Adults in the Netherlands (HOVON).

ASCO2016特集

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