アジュバント療法としてのベバシズマブは有益でない（Abstract #: LBA4）

標準アジュバント化学療法へのベバシズマブの追加は早期結腸がんの無病生存率を改善しない

Adding bevacizumab to standard adjuvant chemotherapy does not improve disease-free survival for early-stage colon cancer

Phase IIIトライアルの結果、標準アジュバント化学療法にベバシズマブを追加しても局所進行結腸がんの無病生存率を改善しないことが示された。このスタディは2,710人の患者を組み入れ、標準アジュバント化学療法を6ヵ月間受ける群またはベバシズマブと組み合わせたアジュバント化学療法を6ヵ月間施行した後にベバシズマブ投与を6ヵ月間行う群に無作為に割り付けた。対象者は全員ステージIIまたはIIIの結腸がん患者で、先に手術で腫瘍を除去された。経過観察期間中央値3年間の後、がんを有さず生存していたのはベバシズマブ群患者で77.4%であったのに対しコントロール群におけるその割合は75.5%であり、その差は統計学的に有意ではなかった。両群ともに想定外の副作用はなく、ベバシズマブによる毒性は忍容できるものであった。第45回American Society of Clinical Oncology学会で発表されたこのスタディは、アジュバント療法としてベバシズマブを使用した結果を報告した初めてのものである。

Full Text

The results of a randomized, phase III trial have found that adding bevacizumab to standard adjuvant chemotherapy did not improve disease-free survival in early-stage colon cancer.

This was the first study to report results on the use of bevacizumab as an adjuvant treatment. The antibody, which targets the vascular endothelial growth factor (VEGF) receptor, is currently approved in the United States for metastatic colorectal, breast, and lung cancers, and other trials are ongoing to evaluate it as an adjuvant treatment for a variety of solid tumors.

The current study enrolled 2,710 patients who were randomized to receive six months of standard adjuvant chemotherapy or six months of adjuvant chemotherapy combined with bevacizumab plus an additional six months of bevacizumab after the chemotherapy had ended. All patients in the study had stage II or stage III disease and first had surgery to remove their tumors. After a median follow-up of three years, the investigators found that 77.4 percent of patients in the experimental group (bevacizumab) were alive and free of disease, compared with 75.5 percent of patients in the control group, a difference that was not statistically significant. There were no unexpected side effects in either arm and the toxicities from bevacizumab were well tolerated.

"One interesting effect was that during the year that patients were receiving bevacizumab we saw a benefit in disease-free survival that subsequently diminished when follow-up was completed," said Norman Wolmark, M.D., chairman of the Department of Human Oncology at Allegheny General Hospital and the study's lead author. "Our overall conclusion is that bevacizumab was not effective as an adjuvant treatment for early-stage colon cancer, but the transient benefit we saw in patients who received bevacizumab illustrates that we have more to learn about how this reagent works, and we need to design more clinical trials to determine how it can be used most effectively."

The trial was conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP) group, chaired by Dr. Wolmark, and was funded by the National Cancer Institute.

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