

新たな微小管阻害薬は週1回のパクリタキセルと変わらない (Abstract # CRA1002)

局所進行または転移性乳がん治療において新たなより高価な薬剤は標準的な週1回のパクリタキセル投与と変わらない

Newer, more costly drugs no better than standard weekly paclitaxel for locally advanced or metastatic breast cancer

第48回American Society of Clinical Oncology学会で発表された第3相無作為化トライアルの結果、局所進行または転移性乳がんに対するファーストライン治療として、新たなより高価な2つの薬剤であるnab-パクリタキセルおよびixabepiloneの週1回投与はいずれも標準的な週1回のパクリタキセル投与よりも優れてはいないことが明らかにされた。さらに、この条件下ではパクリタキセルを使用した方がixabepiloneよりも無増悪生存期間 (PFS) が長く、nab-パクリタキセルよりも毒性が少ないようであった。スタディには799人の患者を組み入れ、これらの3つの治療法のいずれかを受ける群に無作為に割り付けた。PFS中央値はパクリタキセル投与群で10.6か月、nab-パクリタキセル群で9.2か月であり、ixabepilone群で7.6か月であった。週1回のixabepilone投与はパクリタキセルよりも有意に有効性が低く、nab-パクリタキセルもまたパクリタキセルよりも優れてはいなかった。感覚神経障害 (パクリタキセル群16% 対 治験薬群25%) を含むグレード3または4の非血液毒性もまたパクリタキセル群において最も少なかった。グレード3または4の血液毒性はixabepilone群で最も少なく、nab-パクリタキセル群で最も多く (12% 対 51%)、それと比較してパクリタキセル群では21%であった。実際問題として、多くの患者は週1回のパクリタキセル投与により、副作用は少なく低コストで (新たな治験薬を投与された患者と) 同等に軽快することがこの結果から示唆された。

Full Text

A phase III randomized trial presented at the American Society of Clinical Oncology's 48th Annual Meeting found that weekly administration of either of two newer and significantly more costly agents, nanoparticle albumin bound ("nab") paclitaxel and ixabepilone, was not superior to standard weekly dosing of paclitaxel as first-line therapy for locally advanced or metastatic breast cancer. Furthermore, paclitaxel appears to offer better progression-free survival (PFS) than ixabepilone and fewer toxicities than nab-paclitaxel in this setting.

In practical terms, the findings suggest that many patients could do equally well on weekly paclitaxel with fewer side effects and at lower cost.

"We wanted to know whether giving these newer microtubule agents when given on a weekly schedule would result in similar or superior effectiveness with improved toxicity profiles over the standard weekly paclitaxel regimen," said lead study author Hope S. Rugo, M.D., professor of medicine and director of breast oncology and clinical trials education at the University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center, San Francisco, CA. "This study demonstrates that we should not simply assume that newer drugs are always better than the standard therapies. In metastatic breast cancer, we are constantly examining and refining dosing schedules, testing new therapies, and looking closely at molecular characteristics of patients' tumors to find the right treatment for the right patient, with the fewest toxicities."

The study enrolled 799 patients who were randomized to receive one of the three therapies—paclitaxel, nab-paclitaxel or ixabepilone—on a weekly basis with each cycle consisting of three weeks of treatment followed by a one-week break. The majority of patients enrolled in this trial received bevacizumab.

Median PFS was 10.6 months for those receiving paclitaxel, 9.2 months for nab-paclitaxel, and 7.6 months for ixabepilone. Weekly ixabepilone was significantly less effective than paclitaxel, and nab-paclitaxel was also not superior to paclitaxel. Grade 3 or 4 non-hematologic toxicities were also lowest in the paclitaxel arm, including sensory neuropathy (16% versus 25% for both experimental arms). Grade 3 or 4 hematologic toxicities were lowest in the ixabepilone arm, and highest in the nab-paclitaxel arm (12% versus 51%), compared to paclitaxel (21%). Coupled with the lack of superiority for the newer agents, this suggests that eligible patients can be appropriately treated with paclitaxel using a weekly schedule. Paclitaxel, nab-paclitaxel and ixabepilone are approved by the Food and Drug Administration for metastatic breast cancer.

The study also was designed to look at specific biologic features to understand which patients might benefit the most from one or another of the therapies, and which patients are more susceptible to peripheral neuropathy, a painful side effect of treatment. Investigators await the outcome of these correlative studies in the hopes of better defining which patients might do better on different agents or using different dosing schedules. The newer agents may offer lower toxicity or improved efficacy for some patients, based on molecular characteristics of tumors, but further studies looking at pre-determined patient subsets would be needed.

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