2つの乳がん化学療法レジメンが比較された（Abstract # CRA1008）

2つの一般的な術後補助化学療法レジメンは有効性では同等であるが副作用では差があった

Two common adjuvant chemotherapy regimens have comparable efficacy but differ in side effects

第49回American Society of Clinical Oncology年次集会で発表された第III相試験の結果、外科手術を施行された高リスクの早期乳がんに対する週1回低用量パクリタキセル術後補助化学療法は、標準用量の2週間に1回のレジメンと有効性は同等であったが副作用はかなり少なかったことが報告された。リンパ節転移陽性またはリンパ節転移陰性高リスクで手術可能な患者が、まずドキソルビシンおよびシクロホスファミドの異なる3つのレジメンのうちの1つを受けその後にパクリタキセルを用いた2つの異なるレジメンのいずれかを無作為に施行された。パクリタキセルのレジメンは標準用量投与をpegfilgrastim（遺伝子組換え型顆粒球コロニー刺激因子）のサポートを用いながら12週間にわたり2週間に1回施行する群か、または毎週1回の低用量投与を12週間行う群のいずれかであった。推定5年無増悪生存期間は週1回と2週間に1回のパクリタキセル群とで同等であった（それぞれ82%および81%）。これらの2つの投与計画は副作用の種類および重症度の点で異なっていた：2週に1回の投与スケジュールでは週1回投与よりもアレルギー反応（1.4%対0.6%）、筋および骨痛（11%対3%）が多かった。神経毒性の頻度もまた2週に1回の群で多かった（17%対10%）。

Full Text

A phase III study presented at the American Society of Clinical Oncology 2013 annual meeting reports that a lower dose, weekly regimen of adjuvant paclitaxel chemotherapy for higher-risk, early-stage breast cancer who have undergone surgery was comparable to the standard dose, biweekly regimen, but caused substantially fewer side effects. These findings may lead to more doctors utilizing the weekly schedule and an improvement in patients' quality of life, and potentially, cost savings. These findings may lead to more doctors utilizing the weekly schedule, which could also result in cost savings, as the every two weeks regimen requires additional supportive care, including growth factors (e.g., pegfilgrastim) to boost white blood cell production.

Paclitaxel is a long-standing component of breast cancer treatment. The drug is typically given to patients either weekly or every two weeks, at a higher dose. Both approaches are widely used in practice but until this study, there has not been a formal comparison of their efficacies.

"Our results suggest that either regimen will give a good outcome, but the weekly schedule seems to result in better quality of life for patients, causing less muscle and bone pain and allergic reactions," said lead study author G. Thomas Budd, M.D., a medical oncologist at the Cleveland Clinic in Cleveland, Ohio. "The findings provide assurance that women can choose the lower-dose therapy without sacrificing their chances of survival."

In this trial, patients with node-positive or high-risk node-negative operable breast cancer first received treatment with one of three different regimens of doxorubicin and cyclophosphamide and then received one of two different regimens of paclitaxel, in a randomized fashion. The paclitaxel regimens studied were 1) a standard-dose treatment given every two weeks for 12 weeks with pegfilgrastim support, or 2) a low-dose weekly regimen for 12 weeks. The results of the doxorubicin and cyclophosphamide treatment were reported at ASCO in 2011, and the results of a comparison of the two ways of giving paclitaxel were reported at this year's meeting.

The estimated five-year progression-free survival rates for weekly and every two weeks paclitaxel were equivalent - 82 percent and 81 percent, respectively. The two schedules differed in the type and severity of side effects: the every two-week schedule was associated with higher frequency of allergic reactions (1.4 percent vs. 0.6 percent), and muscle and bone pain (11 percent vs. 3 percent), compared to the weekly schedule. The frequency of neurologic toxicity, a common side effect involving numbness, tingling and pain of the fingers and toes, was also higher in the every two week regimen (17 percent vs. 10 percent), but this difference may have been smaller had the patients received only four cycles of every two weeks therapy (as is current practice) rather than six. (Six cycles of every two weeks regimen was selected in this study so that patients in both arms would be on treatment for 12 weeks).

"The current trial demonstrates that weekly paclitaxel dosing and every two weeks dosing were equally effective in preventing breast cancer progression. However, weekly dosing caused less toxicity, and should ultimately be associated with lower cost due to less use of granulocyte colony stimulating factor. While some oncologists have already been using the weekly schedule for adjuvant therapy, these results will motivate many doctors, including myself, to use weekly dosing," said Andrew D. Seidman, M.D., ASCO spokesperson and breast cancer expert.

A longer follow-up of patients enrolled in this study is planned, in addition to several ancillary studies using participants' tumor samples. Those studies will explore genetic factors that predict the likelihood of toxic side effects in individual patients treated with paclitaxel and effects of diet and exercise on treatment efficacy and side effects.

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