

RESULTS OF TAXOL THERAPY FOR RECURRENT OVARIAN CANCER

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Several years ago, a new chemotherapeutic agent made the headlines of major newspapers around the world. It was because of great promise for ovarian cancer - a difficult-to-treat disease - and the scarcity of the hoped for breakthrough drug - that a brohaha erupted.

The drug - Taxol or generically known as Paclitaxel - was initially found in the bark of the Western Yew tree and could only be obtained in small amounts. More recently, the drug was synthesized and is currently available in any needed quantities.

At first, there were lotteries with the winners being selected to participate in research studies. Now Maurie Markman has published a report of women treated with that agent for recurrent ovarian cancer.

For entrance into the study, it was necessary for patients to have ovarian cancer unsuccessfully treated by three prior chemotherapy regimens and specifically have tumor that was resistant to Cis-platin treatment. What was considered resistance to Cis-platin? It was progressive or persistent disease after having received a regimen consisting of Cis-platin-containing therapy.

Patients with other malignancies, active infection or serious medical diseases as well as myocardial infarctions, heart disease, heart failure were excluded from the study.

The medicine - Taxol - was given to patients in doses of 135 mg/m² intravenously over 24 hours and was repeated every three to four weeks. Dose by "m²" means the amount of chemotherapy was given in proportion to the body surface area in meters squared. This is common way to compensate for different sized patients. Complete response was defined as no evidence of cancer and a return to normal of all tests. Partial response was said to be greater than 50% reduction in the amount of cancer and stable disease was said to be no significant change in the amount of cancer. Progressive disease was called new areas of cancer or greater than 25% increase in pre-treatment areas.

One-hundred and three women with ovarian cancer entered this study. The treatment was said to be generally well tolerated. The major side effect was lowering of the white blood counts. Platelet counts were not greatly adversely affected and, as well, vomiting was mild. There were five treatment-related deaths caused by infection, heart disease or respiratory-related problems.

Of the 103 patients, only 46 were evaluable for analysis. Two patients had complete responses. There were no partial responses in the group.

Unfortunately, the majority of women treated were not evaluable. That is, the physicians could not determine the response to therapy. Of the 103 women, the median survival time was 8 months, with a two year survival rate of 18%. Ten patients are still alive at median follow-up of 37 months from the start of Taxol therapy.

The authors stated "The overall objective response rate to Paclitaxel observed in this single institution experience with Cis-platin refractory ovarian cancer was disappointing, although not surprising." The authors went on to write that "Few patients will achieve major objective responses in this clinical setting, although when they occur, the responses can provide significant short-term palliation of symptoms."

"The prolonged survival of a subset of patients with Cis-platin refractory heavily pretreated ovarian cancer is of interest. Was this survival the result of anti-neoplastic effects of Paclitaxel or simply the natural history of disease in this clinical setting?"

"The prolonged survival observed in a substantial minority of individuals with progressive Cis-platin refractory ovarian cancer observed in this study emphasizes once again the extremely heterogeneous natural history of this malignancy. It is important to note at this point in time we do not know if this interesting survival curve observed in the subset of patients reflects the effects of treatment or simply the unique biology of tumor in this small group of individuals. Unfortunately, we also do not know of any long-term survival data for comparable well-studied group of patients treated with alternative strategies to which these data can be compared."

This evaluation of ovarian cancer patients treated with Taxol is important. It is a chapter in medicine as much as in the publicity of a new agent and how it stirred the media and public. Taxol certainly has a role in the care of cancer patients. That role is still being defined.