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Gemcitabine and vinorelbine in advanced breast cancer

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Keywords

Breast cancer, gemcitabine, vinorelbine

Introduction

The prognosis for advanced breast cancer remains poor. Most patients will relapse despite aggressive first-line therapy, and so effective and safe salvage chemotherapy regimens are required. Both GEM and VNR are new chemotherapy agents that display significant single-agent activity in patients with advanced breast cancer. Since both are well tolerated, act via different mechanisms and have similar administration schedules, testing them in combination seemed appropriate.

Aims

To test the feasibility, antitumour efficacy, and tolerability of the combination of GEM and VNR in patients with pretreated advanced breast cancer.

Comments

This early report of a small study suggests that the regimen of gemcitabine (GEM) and vinorelbine (VNR) is active and safe in pretreated women with advanced breast cancer. The activity was reasonable (48% response rate), but what was interesting was the low rates of grade 3 toxicity; in particular, thrombocytopaenia and anaemia (often a problem with GEM in previously treated patients) were not commonly seen. Unfortunately, details of dose-reductions, omitted doses etc were not provided, and these may have accounted for the low haematological toxicity seen. Many salvage therapies are available for patients with advanced breast cancer, the question being which ones have reasonable activity whilst causing the least degree of toxicity. The latter factor is crucially important in a patient population where cure is not an issue, but maintenance of quality of life is important. This is an interesting combination, utilising two of the newer chemotherapeutic agents available, and one that may

become of increasing importance if results of current adjuvant studies lead to increasing use of anthracyclines and taxanes. Larger trials with this combination are awaited with interest.

Methods

Women under the age of 70 with advanced breast cancer and with good performance status and organ function were eligible. The presence of cerebral metastases was an exclusion criterion. Patients were treated over cycles of 28 days, with gemcitabine 1000 mg/m^2 on days 1, 8 and 15 and with vinorelbine 25 mg/m^2 on days 1 and 8. Administration of up to 10 cycles was planned unless disease progressed or there was unacceptable toxicity. Patients were evaluated for response every two cycles and for toxicity every cycle.

Results

A total of 29 patients were treated (median age of 50); 25 of these had had adjuvant chemotherapy (the majority with an anthracycline-based regimen) and all patients had received first-line chemotherapy for advanced disease using a doxorubicin-paclitaxol regimen. The majority of patients had multiple sites of metastatic disease. Most common sites were bone (55%), lung (41%), and lymph nodes (41%). A total of 145 cycles of therapy were administered with a median number of cycles of 5 (range 3-10). The overall response rate was 14 out of 29 patients (48%) with three complete responses (CR) and 11 partial responses (PR). Seven patients developed progressive disease during treatment. The mean duration of response was 11+ (the mean duration will increase as this is a partial study and not all patients have relapsed) and 9.5+ months for CR and for PR, respectively. With a mean follow-up of 9.25 months, the median overall survival was not reached. The overall mean time-to-progression and overall survival were 6.8+ months and 9.2+ months, respectively. The treatment was well tolerated. The most common toxicity was grade 3 leucopaenia (48% of patients) but there were no episodes of neutropenic sepsis. Only three patients had grade 3 thrombocytopaenia.

Discussion

The combination of GEM and VNR appears to an active and well-tolerated regimen. The overall response rate of 48% is amongst the highest reported for second line therapy in previously treated advanced breast cancer, and the toxicities appear reasonable and manageable. Further and larger studies are required to confirm and extend these results.

References

1. Valenza R, Leonardi V, Gebbia V, Agostara B: Gemcitabine and vinorelbine in pretreated advanced breast cancer: a pilot study. Ann Oncol. 2000, 11: 495-496.