Table 1. Patient's Characteristics

Characteristics		No.
No. of patients		25
Cycles of treatment	Total	117
	Average	4.68
	Range	2-10
Age in year	Average	46.9
	Range	30-65
Performance status	0	1
	1	10
	2	14
Site of metastases	Liver	8
	Lung	15
	Liver/lung	1
	Lymph nodes	15
	Bone	15
Prior adjuvant chemotherapy	Yes	25
	No	0

30-65) years. All of them had definite evidence of metastatic breast cancer and had received complete courses of anthracycline-containing agents (6 courses of FAC with fluorouracil 500 mg/m^2, adriamycin 50 mg/m^2 and cyclophosphamide 500 mg/m^2) as adjuvant chemotherapy for at least one year before applying paclitaxel.

All patients who were eligible for this study had to fulfill all of the following criteria: histological proof of metastatic breast cancer; measurable disease, unless subsequent progression was documented; and age between 18 and 70 years and a life expectancy of more than 3 months. Prior adjuvant chemotherapy is necessary with anthracycline-containing regimens but must be at least one year before entering this study. All patients were required to have an ECOG performance status of 2 or less and to have adequate hematopoietic function as evidenced by a leukocyte count of > 4,000/uL and a platelet count of > 100,000/uL.

A liver panel that included serum alkaline phosphatase, albumin, globulin, total and direct bilirubin, lactic dehydrogenase (LDH), alanine aminotransferase (ALT), aspartate aminotransferase (AST), sodium, potassium, and creatinine, was obtained for all patients before chemotherapy was initiated. For patients who received intermittent chemotherapy, this liver panel was obtained 2 weeks after completion of each chemotherapy cycle. In accordance with the protocol, for patients who received continuous treatment, the liver panel was also obtained every 4 weeks. During the post-treatment period, the liver panel was tested at monthly intervals for 6 months and every 2-6 months thereafter. If clinically indicated, AST, ALT, PT, and bilirubin levels were also determined at other times during the chemotherapy cycles. Liver dysfunction was defined as serum aminotransferase levels above the upper level of normal (ULN) and elevated bilirubin of more than 3 mg/dL.

Patients had to provide written informed consent before chemotherapy was given, and the Institutional Review Board at Taipei-Veterans General Hospital approved all aspects of this study.

Treatment

The chemotherapy regimen utilized single agent of paclitaxel (Anzatax, Faulding, Australia) at a dose of 175 mg/m^2 over a 3-h infusion, and the treatment was repeated every 3 weeks. All patients were pretreated with 20 mg hydrocortisone intravenously 1 h before paclitaxel administration, 20 mg allermin intravenously 30 min and 150 mg cimetidine intravenously 20 min before each treatment. For prevention of vomiting, all patients received ondansetron as antiemetic treatment.

Response Criteria

Response was evaluated using criteria of the Eastern Cooperative Oncology Group (ECOG). Complete response (CR) was defined as complete disappearance of all known lesions documented by 2 separate observations at least 4 weeks apart and with the appearance of no new lesions. Partial response (PR) required at least a 50% reduction in the cross-sectional area of the indicator lesion (or sum of areas if there was more than one indication lesion), again documented by two separate observations at least 4 weeks apart, with no individual lesion growing and no new lesions appearing. Stable disease (SD) was defined as less than 50% reduction or less than 25% increase in the sum of cross-sectional areas of all measurable lesions, with the appearance of no new lesions for at least 4 weeks. Patients were considered to have progressive disease