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Paclitaxel and carboplatin as first-line chemotherapy combined with gefitinib (IRESSA) in patients with advanced breast cancer: a phase I/II study conducted by the Hellenic Cooperative Oncology Group.

Fountzilas G, Pectasides D, Kalogera-Fountzila A, Skarlos D, Kalofonos HP, Papadimitriou C, Bafaloukos D, Lambropoulos S, Papadopoulos S, Kourea H, Markopoulos C, Linardou H, Mavroudis D, Briasoulis E, Pavlidis N, Razis E, Kosmidis P, Gogas H.

Source

AHEPA Hospital, School of Medicine, Aristotle University of Thessaloniki, Nea Efkarpia, 56249 Thessaloniki, Greece. fountzil@med.auth.gr

Abstract

Paclitaxel (Taxol) and carboplatin are an effective combination regimen for treating advanced breast cancer. Gefitinib (IRESSA) is the first epidermal growth factor receptor tyrosine kinase inhibitor to be approved for cancer treatment. This multicenter phase II trial treated 68 patients with advanced breast cancer with paclitaxel (175 mg/m(2) over 3 h) and 3-weekly carboplatin (area under the curve of 6) for six cycles, and 250 mg/day gefitinib orally. Median age was 57 (range 35-77) years, patients had performance status 0 (69.1%), 1 (27.9%) 2 (2.9%), 82.4% of patients had visceral metastases and 63.2% had received adjuvant chemotherapy. Forty-eight (70.6%) patients completed six cycles of chemotherapy and 20 (29.4%) patients discontinued treatment (seven [10.3%] due to disease progression, seven [10.3%] due to toxicity, five [7.4%] withdrew consent and one [1.5%] died after the first cycle). Sixty-three (92.7%) patients were evaluable for response; nine (13.2%) had complete responses, 30 (44.1%) had partial responses, 21 (30.9%) had stable disease and three (4.4%) had disease progression. Grade 3/4 adverse events in > or =5% of patients except of alopecia, included neutropenia (17.7%), anemia (10.3%), diarrhea (7.4%), thrombocytopenia (5.9%) and peripheral neuropathy (5.9%). Of those tumor biopsies available for immunohistochemical analysis (n=60), 5.0% were positive and 35.0% negative for expression of all HER-family receptors. Comparable numbers of tumor biopsies were nuclear p27(kipl) positive and negative (39.7 and 42.7%, respectively), with the majority (72.1%) negative for cytoplasmic p27(kipl). The observed efficacy data in this study were similar to those reported for the combination of paclitaxel and carboplatin alone.