

A randomized phase III study comparing three anthracycline-free taxane-based regimens, as first line chemotherapy, in metastatic breast cancer: a Hellenic Cooperative Oncology Group study.

[Fountzilas G](#), [Dafni U](#), [Dimopoulos MA](#), [Koutras A](#), [Skarlos D](#), [Papakostas P](#), [Gogas H](#), [Bafaloukos D](#), [Kalogera-Fountzila A](#), [Samantas E](#), [Briasoulis E](#), [Pectasides D](#), [Maniadakis N](#), [Matsiakou F](#), [Aravantinos G](#), [Papadimitriou C](#), [Karina M](#), [Christodoulou C](#), [Kosmidis P](#), [Kalofonos HP](#).

Source

Department of Medical Oncology, Papageorgiou Hospital, Aristotle University of Thessaloniki School of Medicine, Thessaloniki, Macedonia, Greece. fountzil@med.auth.gr

Abstract

BACKGROUND:

Effective anthracycline-free combinations need to be evaluated in metastatic breast cancer (MBC), due to the increased number of patients treated with anthracycline-based adjuvant chemotherapy.

PATIENTS AND METHODS:

Patients with MBC were randomized to paclitaxel and carboplatin (PCb) every 3 weeks or docetaxel and gemcitabine (GDoc) every 3 weeks or weekly paclitaxel (Pw). Trastuzumab was given to patients with HER-2 over-expressing tumors. The primary endpoint of the study was survival. Quality of life (QoL) and cost were assessed.

RESULTS:

Totally, 416 eligible patients entered the study. Median survival times were 29.9 months for PCb, 26.9 for GDoc and 41.0 for Pw ($P = 0.037$). According to multivariate analysis, adjuvant chemotherapy, >1 metastatic sites, lack of maintenance hormonal therapy, and worse performance status (PS) were significant adverse prognostic factors for survival, while Pw when compared to GDoc improved survival ($P = 0.03$), as well as when compared to PCb in the subgroup of patients with PS = 1 ($P = 0.01$, treatment by PS interaction $P = 0.03$). No significant differences in terms of time to progression were found. Severe myelotoxicity and mucositis were more frequent with GDoc, while severe neuropathy with PCb and Pw. QoL changes did not differ significantly between treatment groups, while cost analysis favored Pw.

CONCLUSIONS:

Pw appears to be the most preferable choice among the 3 anthracycline-free taxanes-based regimens tested in the present study.