

Sequential adjuvant epirubicin-based and docetaxel chemotherapy for node-positive breast cancer patients: the FNCLCC PACS 01 Trial.

Roché H, Fumoleau P, Spielmann M, et al. *J Clin Oncol.* 2006;**24(36)**:5664-71.

Study overview: In the PACS01 trial, 1,999 women with early node-positive breast cancer were randomised to receive either six cycles of fluorouracil 500 mg/m², epirubicin 100 mg/m², and cyclophosphamide 500 mg/m² (FEC), or three cycles of the same FEC regimen followed by three cycles of docetaxel 100 mg/m² (FEC-D). Hormone-receptor-positive patients received tamoxifen for 5 years after chemotherapy.

Key findings: The FEC-D regimen significantly improved disease free survival (DFS); 5-year DFS rates were 78% for FEC-D versus 73% for FEC. Overall, patients treated with FEC-D showed an 18% reduction in the relative risk of relapse; this particularly benefited women aged ≥ 50 years, but was not found to benefit younger women. A similar improvement in overall survival (OS) was seen; 5-year OS rates were 91% for FEC-D versus 87% for FEC. OS was not analysed for patients aged 50 years and older in comparison with younger women. A similar proportion of serious adverse events occurred in both treatment groups (14% for FEC and 15% for FEC-D).

The incidence of severe chemotherapy-induced neutropenia was more frequent with FEC, whereas the incidence of febrile neutropenia was highest in the first cycle of docetaxel (cycle 4). Nausea and vomiting were more frequent with FEC, and stomatitis, oedema, and nail disorders were reported more frequently with FEC-D. After 5-years follow up, FEC-D was associated with significantly fewer cardiac events and less secondary leukaemia.

Conclusions: The authors concluded that sequential adjuvant chemotherapy with FEC-D significantly improved survival in node-positive breast cancer patients and demonstrated a favourable safety profile.

<http://www.ncbi.nlm.nih.gov/pubmed/17116941?dopt=Citation>