Benefit of the sequential administration of Docetaxel after standard FEC regimen for node-positive breast cancer: long-term follow-up results of the FNCLCC-PACS 01 trial

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Finding: The sequential regimen demonstrated significantly less long term cardiac events.

Objective: To evaluate the benefit of the sequential administration of docetaxel (D) following FEC100 among patients with node-positive, operable breast cancer.

Methods: A randomized trial comparing 6 cycles of FEC100 to 4 cycles of FEC100 followed by 3 cycles of Docetaxel (D). The primary endpoint was overall survival (OS).

Results: The study initially enrolled 2,001 patients, with a median follow-up of 8.9 years. The OS at 8 years was 78.0% with 6 cycles of FEC100 and 83.2% with 4 cycles of FEC100 followed by 3 cycles of D. A Cox-adjusted hazard ratio of 0.75 (95% CI: 0.61-0.92) was observed for the FEC100-3D regimen. This benefit was observed in patients with 1 to 3 positive nodes but not in patients with 4 or more positive nodes.

Conclusions: The sequential regimen of FEC100 followed by 3 cycles of D significantly improves DFS and OS in node-positive breast cancer patients. This benefit is observed for younger women but not for older women.

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