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## Open-label, multicenter, randomized phase III trial of adjuvant chemoradiation plus interferon Alfa-2b versus fluorouracil and folinic acid for patients with resected pancreatic adenocarcinoma.

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#### Abstract

**PURPOSE:** Adjuvant chemotherapy prolongs survival in patients with pancreatic cancer, but its benefit is limited. Long-term survival times of up to 44 months after adjuvant chemoradioimmunotherapy in phase II trials motivated the present study.

**PATIENTS AND METHODS:** Between 2004 and 2007, 132 R0/R1 resected patients received either fluorouracil (FU), cisplatin, and interferon alfa-2b (IFN  $\alpha$ -2b) plus radiotherapy followed by two cycles of FU (arm A, n=64) or six cycles of FU monotherapy (arm B, n=68). One hundred ten patients (arm A, n=53; arm B, n=57) received at least one dose of the study medication, and these patients composed the per-protocol (PP) population. Biomarkers were analyzed longitudinally for their predictive value.

**RESULTS:** Median survival for all randomly assigned patients was 26.5 months (95% CI, 21.6 to 39.5 months) in arm A and 28.5 months (95% CI, 20.4 to 38.6 months) in arm B. The hazard ratio was 1.04 (arm A v arm B: 95% CI, 0.66 to 1.53; P=.99). Median survival for the PP population was 32.1 months (95% CI, 22.8 to 42.2 months) in arm A and 28.5 months (95% CI, 19.5 to 38.6 months) in arm B (P=.49). Eighty-five percent of patients in arm A and 16% of patients in arm B experienced grade 3 or 4 toxicity. The quality of life was temporarily negatively affected in arm A.

**CONCLUSION:** The FU, cisplatin, and IFN  $\alpha$ -2b plus radiotherapy regimen did not improve the survival compared with FU monotherapy. Given the substantial adverse effects, this treatment can currently not be recommended. Nevertheless, the outcome in both arms represents the best survival, to our knowledge, ever reported for patients with resected pancreatic cancer in randomized controlled trials. Future studies will demonstrate whether immune response to IFN  $\alpha$ -2b challenge has a predictive value.

#### Comment in

Keys to personalized care in pancreatic oncology. [*J Clin Oncol.* 2012]

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