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Pancreas

Preoperative Chemoradiotherapy versus Immediate Surgery for Resectable and Borderline Resectable Pancreatic Cancer: Results of the Dutch Randomised Phase III PREOPANC Trial.

Versteijne E, Suker M, Groothuis K, Akkermans-Vogelaar JM, Besselink MG, Bonsing BA, Buijsen J, Busch OR, Creemers GM, van Dam RM, Eskens FALM, Festen S, de Groot JWB, Groot Koerkamp B, de Hingh IH, Homs MYV, van Hooft JE, Kerver ED, Luelmo SAC, Neelis KJ, Nuyttens J, Paardekooper GMRM, Patijn GA, van der Sangen MJC, de Vos-Geelen J, Wilmink JW, Zwinderman AH, Punt CJ, van Eijck CH, van Tienhoven G; Dutch Pancreatic Cancer Group.

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PURPOSE:

Preoperative chemoradiotherapy may improve the radical resection rate for resectable or borderline resectable pancreatic cancer, but the overall benefit is unproven.

PATIENTS AND METHODS:

In this randomised phase III trial in 16 centres, patients with resectable or borderline resectable pancreatic cancer were randomly assigned to receive preoperative chemoradiotherapy, which consisted of three courses of gemcitabine, the second combined with 15×2.4 Gy radiotherapy, followed by surgery and four courses of adjuvant gemcitabine; or to immediate surgery and six courses of adjuvant gemcitabine. The primary end-point was overall survival by intention to treat.

RESULTS:

Between April 2013 and July 2017, 246 eligible patients were randomly assigned; 119 were assigned to preoperative chemoradiotherapy and 127 to immediate surgery. Median overall survival by intention to treat was 16.0 months with preoperative chemoradiotherapy and 14.3 months with immediate surgery (hazard ratio, 0.78; 95% CI, 0.58 to 1.05; $P = .096$). The resection rate was 61% and 72% ($P = .058$). The R0 resection rate was 71% (51 of 72) in patients who received preoperative chemoradiotherapy and 40% (37 of 92) in patients assigned to immediate surgery ($P < .001$). Preoperative chemoradiotherapy was associated with significantly better disease-free survival and locoregional failure-free interval as well as with significantly lower rates of pathologic lymph nodes, perineural invasion, and venous invasion. Survival analysis of patients who underwent tumour resection and started adjuvant chemotherapy showed improved survival with preoperative chemoradiotherapy (35.2 v 19.8 months; $P = .029$). The proportion of patients who suffered serious adverse events was 52% versus 41% ($P = .096$).

CONCLUSION:

Preoperative chemoradiotherapy for resectable or borderline resectable pancreatic cancer did not show a significant overall survival benefit. Although the outcomes of the secondary end-points and predefined subgroup analyses suggest an advantage of the neoadjuvant approach, additional evidence is required.