

Preoperative versus postoperative docetaxel–cisplatin–fluorouracil (TCF) chemotherapy in locally advanced resectable gastric carcinoma: 10-year follow-up of the SAKK 43/99 phase III trial[†]

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Background: Fluorouracil-based adjuvant chemotherapy in gastric cancer has been reported to be effective by several meta-analyses. Perioperative chemotherapy in locally advanced resectable gastric cancer (RGC) has been reported improving survival by two large randomized trials and recent meta-analyses but the role of neoadjuvant chemotherapy and optimal regimen remains to be determined. We compared a neoadjuvant with adjuvant docetaxel-based regimen in a prospective randomized phase III trial, of which we present the 10-year follow-up data.

Patients and methods: Patients with cT3–4 anyN M0 or anyT cN1–3 M0 gastric carcinoma, staged with endoscopic ultrasound, computed tomography, bone scan, and laparoscopy, were assigned to receive four 21-day/cycles of docetaxel 75 mg/m² day 1, cisplatin 75 mg/m² day 1, and fluorouracil 300 mg/m²/day over days 1–14, either before (arm A) or after (arm B) gastrectomy. Event-free survival was the primary end point, whereas secondary end points included overall survival, toxicity, down-staging, pathological response, quality of life, and feasibility of adjuvant chemotherapy.

Results: This trial was activated in November 1999 and closed in November 2005 due to insufficient accrual. Of the 70 enrolled patients, 69 were randomized, 34 to arm A and 35 to arm B. No difference in EFS (2.5 years in both arms) or OS (4.3 versus 3.7 years, in arms A and B, respectively) was found. A higher dose intensity of chemotherapy was observed in arm A and more frequent chemotherapy-related serious adverse events occurred in arm B. Surgery was safe after preoperative chemotherapy. A 12% pathological complete response was observed in arm A.

Conclusion: Docetaxel/cisplatin/fluorouracil chemotherapy is promising in preoperative setting of locally advanced RGC. The early stopping could mask the real effectiveness of neoadjuvant treatment. However, the complete pathological tumour responses, feasibility, and safe surgery warrant further investigation of a taxane-based regimen in the preoperative setting.

Key words: gastric cancer, docetaxel, TCF, chemotherapy, neoadjuvant, preoperative

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