Perioperative chemotherapy with FOLFOX4 and surgery versus surgery alone for resectable liver metastases from colorectal cancer (EORTC Intergroup trial 40983): a randomised controlled trial

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Summary
Background Surgical resection alone is regarded as the standard of care for patients with liver metastases from colorectal cancer, but relapse is common. We assessed the combination of perioperative chemotherapy and surgery compared with surgery alone for patients with initially resectable liver metastases from colorectal cancer. Methods This parallel-group study reports the trial's final data for progression-free survival for a protocol unspecified interim time-point, while overall survival is still being monitored. 364 patients with histologically proven colorectal cancer and up to four liver metastases were randomly assigned to either six cycles of FOLFOX4 before and six cycles after surgery or to surgery alone (182 in perioperative chemotherapy group vs 182 in surgery group). Patients were centrally randomised by minimisation, adjusting for centre and risk score. The primary objective was to detect a hazard ratio (HR) of 0·71 or less for progression-free survival. Primary analysis was by intention to treat. Analyses were repeated for all eligible (171 vs 171) and resected patients (151 vs 152). This trial is registered with ClinicalTrials.gov, number NCT00006479. Findings In the perioperative chemotherapy group, 151 (83%) patients were resected after a median of six (range 1–6) preoperative cycles and 115 (63%) patients received a median six (1–8) postoperative cycles. 152 (84%) patients were resected in the surgery group. The absolute increase in rate of progression-free survival at 3 years was 7·3% (from 28·1% [95·66% CI 21·3–35·5] to 35·4% [28·1–42·7]; HR 0·79 [0·62–1·02]; p=0·058) in randomised patients; 8·1% (from 28·1% [21·2–36·6] to 36·2% [28·7–43·8]; HR 0·77 [0·60–1·00]; p=0·041) in eligible patients; and 9·2% (from 33·2% [25·3–41·2] to 42·4% [34·0–50·5]; HR 0·73 [0·55–0·97]; p=0·025) in patients undergoing resection. 139 patients died (64 in perioperative chemotherapy group vs 75 in surgery group). Reversible postoperative complications occurred more often after chemotherapy than after surgery (40/159 [25%] vs 27/170 [16%]; p=0·04). After surgery we recorded two deaths in the surgery alone group and one in the perioperative chemotherapy group. Interpretation Perioperative chemotherapy with FOLFOX4 is compatible with major liver surgery and reduces the risk of events of progression-free survival in eligible and resected patients.

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