Adjuvant perioperative portal vein or peripheral intravenous chemotherapy for potentially curative colorectal cancer : long-term results of a randomized controlled trial

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BACKGROUND AND AIMS: The perioperative use of a single course adjuvant portal vein infusion chemotherapy in patients with potentially curable colorectal cancer has been shown to significantly improve overall survival but did not reduce the occurrence of liver metastases (SAKK 40/81) [Swiss Group for Clinical Cancer Research (SAKK) Lancet 345(8946):349-353, 1995]. The objective of the present prospective, three-arm randomized multicenter trial was to assess whether peripheral venous administration of adjuvant chemotherapy regimen based on 5-fluorouracil (5-FU) and mitomycin C decreases the occurrence of liver metastases as well as prolongs disease-free and overall survival. MATERIALS AND METHODS: Stages I-III colorectal cancer patients (n = 753) were randomized to receive either surgery alone (control arm), surgery plus postoperative portal venous infusion of 5-FU 500 mg/m(2) plus heparin given for 24 hours for seven consecutive days plus mitomycin C 10 mg/m(2) given on the first day (arm 2), or surgery and the same chemotherapy regimen administered by peripheral venous route (arm 3). RESULTS: The 5-year disease-free survival for the three treatment groups were 65% (control group), 60% (portal vein infusion, hazard ratio 1.18, p = 0.23), and 64% (intravenous infusion, hazard ratio 1.04, p = 0.76); the 5-year overall survival was 72% (control group), 69% (portal vein infusion, hazard ratio 1.21, p = 0.2), and 74% (intravenous infusion, hazard ratio 1.03, p = 0.86), respectively. A significant accumulation of early deaths were observed in the portal vein infusion group (p = 0.015). CONCLUSIONS: The present prospective randomized multicenter trial provides compelling evidence that short-term perioperative chemotherapy does not improve disease-free and overall survival in patients with potentially curative colorectal cancer. In contrary, the chemotherapy regimen administered in the present investigation seems to have potentially harmful effects, a finding which should be carefully considered in the planning of future trials. Postoperative short-term administration of 5-FU plus mitomycin C either through portal infusion or a central venous catheter is not recommended for routine use in patients with potentially curable colorectal cancer.
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