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Randomized Controlled Trial of Intraportal Chemotherapy Combined With Adjuvant Chemotherapy (mFOLFOX6) for Stage II and III Colon Cancer.

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Abstract

OBJECTIVES:

The optimal time to initiate adjuvant chemotherapy after surgery in patients with colon cancer is not clear. We investigated the benefit of combined intraportal chemotherapy administered during radical surgery with adjuvant chemotherapy for treating stage II and III colon cancer.

METHODS:

Patients were randomly assigned to OCTREE arm (intraportal chemotherapy plus mFOLFOX6) or a standard adjuvant chemotherapy arm (mFOLFOX6). The primary study endpoint was disease-free survival. The secondary endpoints included metastasis-free survival, overall survival, and safety.

RESULTS:

The intent-to-treat population comprised 237 patients. With a median follow-up of 44 months, the hazard ratio (OCTREE vs mFOLFOX6) was 0.66 (95% confidence interval, 0.43-0.90), a 34% risk reduction in favor of OCTREE (P=0.016). The 3-year disease-free survival rate was 85.2% for OCTREE and 75.6% for mFOLFOX6 alone (P=0.030). The 3-year metastasis-free survival rates were 87.6% for OCTREE and 78.0% for mFOLFOX6 (P=0.035). Patients had lower distant metastatic rate in the OCTREE arm (12.7% vs 22.7%; P=0.044), when compared with the mFOLFOX6 arm. The 3-year overall survival was no significant difference between 2 arms (P=0.178). Neutropenia occurred in 12.7% of the patients receiving OCTREE and in 2.5% of the patients receiving mFOLFOX6 (P=0.003) within 2 weeks of surgery, and grade 3 or 4 toxicity event was no difference between 2 regimens.

CONCLUSIONS:

Combination of intraoperative intraportal chemotherapy with mFOLFOX6 reduced the occurrence of distant metastases and improved disease-free survival in patients with stage II and stage III colon cancer.