

# Enhancement of the Efficacy of Chemotherapy with Oxaliplatin Plus 5-Fluorouracil by Pretreatment with IL-2 Subcutaneous Immunotherapy in Metastatic Colorectal Cancer Patients with Lymphocytopenia Prior to Therapy

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## Abstract

The present study was carried out to evaluate the influence of a short-period IL-2 administration on the efficacy of chemotherapy in metastatic colorectal cancer patients with pretreatment lymphocytopenia, which was defined as a lymphocyte count of less than 1500/mm<sup>3</sup>. The study included 144 consecutive metastatic colorectal cancer patients, who underwent chemotherapy with oxaliplatin plus 5-fluorouracil. Lymphocytopenia was seen in 41/144 (28%) patients, who were randomized to receive chemotherapy alone or chemotherapy after a prechemoimmunotherapy with IL-2 (3 MIU twice/day for 3 consecutive days), whereas patients with a normal pretreatment lymphocyte count received only chemotherapy. A normalization of the lymphocyte number was achieved in 12/19 lymphocytopenic patients pretreated with IL-2. The objective tumor regression rate achieved in patients with a normal lymphocyte count prior to chemotherapy was significantly higher compared to that obtained in lymphocytopenic patients treated with chemotherapy alone (54/103 vs. 3/22,  $p < 0.01$ ), whereas no significant difference occurred between patients with normal lymphocyte count and lymphocytopenic patients pretreated with IL-2 (54/103 vs. 8/19). This study confirms that pretreatment lymphocytopenia is associated with reduced efficacy of chemotherapy in metastatic colorectal cancer patients. Moreover, it suggests that pretreatment with IL-2 before the onset of chemotherapy may enhance the efficacy of chemotherapy in lymphocytopenic patients. Therefore, the administration of IL-2 before the onset of chemotherapy to improve the immune status of cancer patients may be considered as a new chemoimmunotherapeutic combination, which may be recommended in the treatment of advanced cancer patients, particularly in those with cancer-related immune alterations.