

Fluorouracil (FU), Levamisole (LEV) and Interferon Alpha 2c (IFN) Adjuvant Therapy for Colon Cancer: First Report of a Prospective Randomized Trial of the ABCSG.

Sub-category:

Gastrointestinal Cancer

Category:

Gastrointestinal Cancer

Meeting:

2000 ASCO Annual Meeting

Abstract No:

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Abstract:

Based on the results of Moertel et al. (N.Engl.J.Med. 1990), FU/LEV was established as standard adjuvant therapy for colon cancer, although the value of LEV in this regimen remained uncertain. Simultaneously, other investigators demonstrated promising phase II data for FU/IFN in metastatic colorectal cancer. In 1991, the Austrian Colorectal Cancer Study Group (ABCSG) initiated a 2x2 prospectively randomized trial to evaluate the use of LEV and/or IFN in combination with FU. The main statistical endpoints were disease-free survival (DFS) and overall survival (OS) at 5 and 10 years, respectively. The following drug regimens were applied in 4 study arms: (i) FU + LEV + IFN intravenous injection daily x 5 (then weekly beginning day 29 for 48 additional weeks); (ii) FU + LEV + IFN intravenous injection q 2 weeks for 52 weeks; (iii) FU + IFN 3.5 mio units sc weekly x 3 for 52 weeks; (iv) FU + LEV + IFN intravenous injection q 2 weeks for 52 weeks. After recruitment of a planned 600 patients (pts), the study was closed in 1999. The median follow-up time is 5.5 years. Updated results and toxicity data will be presented. Pts with LEV show a significantly shorter DFS (p = .0036). OS survival for pts receiving LEV is not statistically different (p = .0936). Treatment with IFN influence OS (p = .4941) and DFS (p = .5896), respectively. Prognostic factors for DFS in multivariate analysis were treatment with LEV, nodal status and tumor stage, and were grading, sex and tumor stage for OS, respectively. Treatment-related side effects were infrequent and generally mild, although more pronounced for IFN regimens. Though premature, these data confirm that LEV is not a promising component for adjuvant therapy for colon cancer, but may even have a negative impact on outcome. For IFN, no effect has been demonstrated. Furthermore, these early results suggest that FU alone, given as bolus intravenous injection weekly, may be at least as effective as FU plus LEV and/or IFN.

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