

Phase II trial of S-1 monotherapy in elderly or frail patients with metastatic colorectal cancer

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Aims:

To evaluate S-1 monotherapy in previously untreated elderly or frail patients with metastatic colorectal cancer.

Materials and methods:

Elderly (70-85 years old) and frail (PS 2 and 65-69 years old) patients who were eligible for first-line treatment, were given S-1 (70 mg/m²) twice daily for 2 weeks followed by 1 week of rest.

Results:

A total of 48 patients were entered into this study. The overall response rate was 18.7%: 22.2% for frail patients and 17.9% for elderly patients. Median progression-free survival (PFS) and overall survival (OS) for all patients were 3.9 months (95% CI, 3.0 - 4.8) and 11.3 months (95% CI, 7.4 - 15.2). For frail patients, PFS was 1.4 (95% CI, 0.8 - 2.0) vs. 4.3 months (95% CI, 3.2 - 5.4) for the elderly; P=0.016. OS was 4.1 months (95% CI, 3.2 - 5.0) in frail patients and significantly longer at 13.1 months (95% CI, 9.5 - 16.7) for elderly patients (P=0.01). Toxicity was mild to moderate and only 29% of patients experienced grade 3 toxicity. There was no grade 4 toxicity and febrile neutropenia.

Conclusions:

S-1 monotherapy is well-tolerated and effective in elderly patients but suboptimal in frail patients. In terms of efficacy and toxicity, S-1 monotherapy could be considered as a therapeutic option for elderly patients with mCRC in the first-line setting.