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Phase II Study of S-1 and Irinotecan Plus Bevacizumab as Second-line Treatment for Patients With Metastatic Colorectal Cancer Resistant to the Fluoropyrimidine-oxaliplatin-cetuximab Regimen

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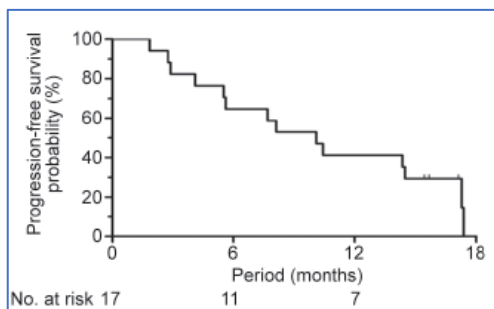


Figure 1. Progression-free survival (PFS) of S-1 and irinotecan plus bevacizumab as a second-line regimen (n=17). The 6-month PFS was 64.7% [95% confidence interval (CI)=41.99-87.43]. The median PFS was 10.1 months (95%CI=4.11-17.28). CI: Confidence interval; PFS: progression-free survival.

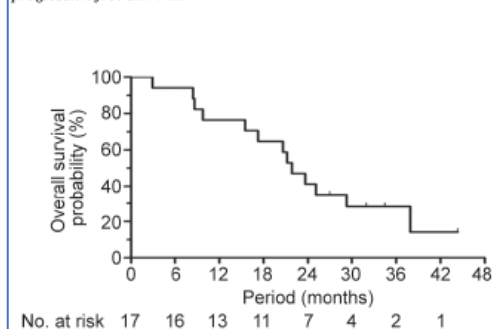


Figure 2. Overall survival (OS) of S-1 and irinotecan plus bevacizumab as a second-line regimen (n=17). The median OS was 21.8 months (95% confidence interval=9.79-37.91).

Table II. Response of patients to treatment.

Tumor response	N (%)
CR	0 (0)
PR	4 (23.5)
SD	11 (67.4)
PD	2 (11.8)
NE	0 (0)
RR	4 (23.5) [95%CI=6.81-49.90]
DCR	15 (88.2) [95%CI=63.56-98.54]

The response was assessed based on each investigator's data on the number of patients (%) (total, n=17) in each category. CR: Complete response; PR: partial response; SD: stable disease; PD: progressive disease; NE: not evaluated; RR: response rate; DCR: disease control rate; CI: confidence interval.

Table III. Adverse events according to the Common Terminology Criteria for Adverse Events.

Adverse events	All grades, N (%)	Grade ≥ 3, N (%)
Laboratory findings		
Neutropenia	15 (88.2)	5 (29.4)
Thrombocytopenia	8 (47.1)	0 (0.0)
Hemoglobin	12 (70.6)	2 (11.8)
Total bilirubin	9 (52.9)	1 (5.9)
AST	8 (47.1)	0 (0.0)
ALT	5 (29.4)	0 (0.0)
Creatinine	2 (11.8)	0 (0.0)
Proteinuria	6 (33.3)	0 (0.0)
INR	5 (29.4)	0 (0.0)
Clinical findings		
Stomatitis	7 (41.2)	1 (5.9)
Anorexia	10 (58.8)	2 (11.8)
Nausea	10 (58.8)	1 (5.9)
Vomiting	3 (17.6)	0 (0.0)
Diarrhea	8 (47.1)	2 (11.8)
Hyperpigmentation	7 (41.2)	-
Epistaxis	6 (35.3)	0 (0.0)
Hypertension	9 (52.9)	3 (17.6)
Fatigue	8 (47.1)	0 (0.0)