일반연제 8

Randomized Trial of Docetaxel Plus Cisplatin (DC) Versus Etoposide Plus Cisplatin (EC) in Locally Advanced, Recurrent, or Metastatic Non-Small Cell Lung Cancer (NSCLC)

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Background: The aim of this study was to compare DC and EC regimens in terms of response rate, safety profile, and overall survival (OS).

Materials and Methods: From April 2000 to March 2002, 78 patients with locally advanced (LA, Stage IIIB), recurrent (R), or metastatic (M) NSCLC were recruited. Eligibility criteria included: age ≥18 years, pathologically confirmed NSCLC, no prior chemotherapy, Karnofsky performance score (KPS) ≥80%, measurable disease, no brain or leptomeningeal metastasis, and signed informed consent.

Patients

	DC	EC
n	40	38
Median age (years)	64.5	59.0
Adeno./Squamous	47.5%/50%	50%/48.7%
LA/M/Local R	50%/47.5%/2.5%	42.1%/57.9%/0%
Prior RT/Surgery (n)	1/2	0/4
KPS	80	80

DC treatment consisted of 75 mg/m^2 of both agents given on day 1, every 3 weeks for 6 cycles. EC treatment consisted of 75 mg/m^2 of cisplatin on day 1, and 100 mg/m^2 of etoposide on days 13, every 3 weeks for 6 cycles.

Results: Thirty-four patients from the DC arm and 33 patients from the EC arm were included in the efficacy analysis. The overall response rate (complete response and partial response) was 44.1% in the DC arm and 21.2% in the EC arm (p=0.023). The median time to progression (TTP) was 180 days with DC and 81 days with EC (p=0.1192). Median OS in the EC arm was 315 days, and had not yet been reached in the DC arm (p=0.0745) until Sep. 2002. Adverse events NCI grade 3 occurred in 32 patients (19 DC/13 EC): neutropenia without fever 4 (10.5%)/6 (15.8%); febrile neutropenia 3 (7.9%)/0; sepsis 1 (2.6%)/0; infection 1 (2.6%)/0; nausea 2 (5.3%)/4 (10.5%); diarrhea 2 (5.3%)/1 (2.6%); fatigue 3 (7.9%)/0, alopecia 6 (15.8%)/6 (15.8%).

Conclusion: DC offers superior response rates over EC and shows a trend in improved median survival in chemotherapy-nave patients with locally advanced (Stage IIIB), recurrent, or metastatic NSCLC. There was no significant difference in TTP between groups and both regimens were well tolerated.