BIWEEKLY DOCETAXEL-CISPLATIN IN CHEMONAÏVE PATIENTS WITH ADVANCED EPIDERMOID CARCINOMA OF THE LUNG: A PHASE II STUDY OF GALICIAN LUNG CANCER GROUP

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PURPOSE

Schemes of polychemotherapy in non small cell lung cancer (NSCLC) have meant a small improvement in overall survival and quality of life. The standard treatment consists in the combination of two drugs, one of them a platinum derived. We conducted a multicenter study in advanced stage squamous NSCLC to evaluate the efficacy of first-line biweekly docetaxel-cisplatin. The end points were to evaluate the progression-free survival, overall survival, overall response rate and toxicity.

PATIENTS AND METHODS

Patients with pathologically confirmed epidermoid histology and stage IIIB (pleural effusion) and IV NSCLC were eligible for study. Patients received biweekly docetaxel (50 mg/m2 on days 1 and 14) and cisplatin (50 mg/m2 on days 1 and 14) every 28 days, with dexamethasone and antiemetic prophylaxis. The first restaging was performed after three cycles. Toxicity was assessed at each cycle, according to the National Cancer Institute Common Toxicity Criteria. In the absence of progression or undue toxicity, treatment was continued for a maximum or four cycles. Disease status was assessed according to Response Evaluation Criteria in Solid Tumors.

PATIENT CRITERIA	No. of Patients	(%)
Patient number	45	
Median age (Range)	63	(43-79)
Sex		
Male	41	91.1
Female	4	8.9
Stage		
IIIB	2	4.4
IV	43	95.6
ECOG Performance Status		
0	11	25
1	31	70.5
2	2	4.5

Table 1. Demographic data for squamous NSCLC patients treated with Docetaxel/Cisplatin

RESULTS

From June 2008 to October 2010, a total of 45 patients with epidermoid carcinoma were accrued from six centers across Galicia, Spain (patient demographic data summarised in Table 1). Of the 45 patients treated with cisplatin/docetaxel, 37 were assessable for response. There was a partial response in 17 patientes (45.9%), a stable disease in 7 patients (18.9%) and a progression disease in 13 patients (35.1%). The median time to disease progression was 4.7 months (95% CI, 3.9 to 5.5) and the median overall survival was 12.6 months (95% CI, 10 to 15.2).

Patients received a median of 4 cycles of therapy. Three received a single cycle before discontinuing treatment. In 2 of these, treatment was stopped due to rapid disease progression. In the other patient, treatment was discontinued on the basis of an adverse event. Eight other patients discontinued treatment following an adverse event after a range of 2-4 cycles of docetaxel/cisplatin.

The median dose of weekly docetaxel delivered was 25 mg/m2 and of cisplatin 25 mg/m2. In 6 patients (14%) dose reduction was required due to toxicity (renal dysfunction, 1 patient; neutropenia , 3 patients; neuropathy, 1 patient; diarrhea, 1 patient). Dose delay occurred in 14 patients, 1 for patients convenience and 13 for toxicity. Forty three patients were assessable for toxicity (see Table 3).

	No. of patients	Percent (%)	Valid Percent (%)
Overall response rate	17	37,8	45,9
Complete response	0	0	0
Partial Response	17	37,8	45,9
Progression Disease	13	28,9	35,1
Stable Disease	7	15,6	18,9
Total assessable	37	82,2	100,0
Not assessable	8	17,8	
Total	45	100,0	

Table 2. Response rates for squamous NSCLC patients treated with Docetaxel/Cisplatin

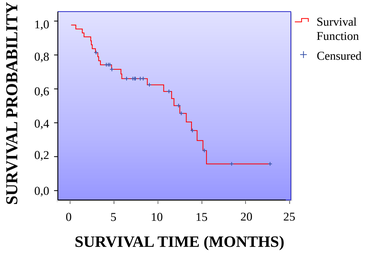

Fig. 1 (left). Kaplan Meier overall survival curve

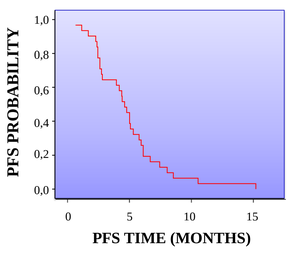

Fig. 2 (right). Kaplan Meier progression-free survival curve

GRADE	1 (%)	2 (%)	3 (%)	4 (%)
Anemia	21 48,8	7 16,3	0 0	0 0
Leukopenia	0 0	0 0	0 0	0 0
Neutropenia	3 7,0	10 23,3	4 9,3	0 0
Febrile Neutropenia	0 0	0 0	3 7,0	2 4,7
Thrombocytopenia	0 0	0 0	0 0	0 0
Renal Dysfunction	0 0	0 0	0 0	0 0
Liver Dysfunction	0 0	0 0	0 0	0 0
Nausea	13 30,2	3 7,0	0 0	0 0
Vomiting	9 20,9	4 9,3	0 0	0 0
Alopecia	5 11,6	1 2,3	0 0	0 0
Mucositis	2 4,7	1 2,3	1 2,3	0 0
Constipation	5 11,6	3 7,0	0 0	0 0
Diarrhea	9 20,9	4 9,3	2 4,7	0 0
Neuropathy	1 2,3	2 4,7	1 2,3	0 0
Skin	0 0	0 0	0 0	0 0
Edema	2 4,7	0 0	0 0	0 0
Asthenia	14 32,6	12 27,9	0 0	0 0
Anorexia	12 27,9	2 4,7	0 0	0 0

Table 3. Main toxic effects following treatment with Docetaxel/Cisplatin

CONCLUSION

These results demonstrate that biweekly docetaxel-cisplatin is an effective treatment and well tolerated in patients with advanced stage squamous NSCLC. We considered the outcomes obtained in response rate and survival time to be favorable as compared with results obtained with other used regimens.

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