

COMPARISON OF STAGE IIIB AND STAGE IV SQUAMOUS CELL LUNG CANCER IN PATIENTS WITH RECEIVING RACOTUMOMAB VACCINE AS SWITCH MAINTANENCE THERAPY

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Introduction - Purpose: Non-small cell lung cancer (NSCLC) constitutes the predominant histologic type among the lung neoplasias, representing approximately 85% of all lung tumors. Unfortunately, little progress has been achieved in the overall survival (OS) of patients with advanced NSCLC after first-line chemotherapy. We also wanted to retrospectively evaluate the efficacy of the racotumomab vaccine, in which a survival benefit was demonstrated by a randomized controlled trial by Alfonso et al., published 2014.

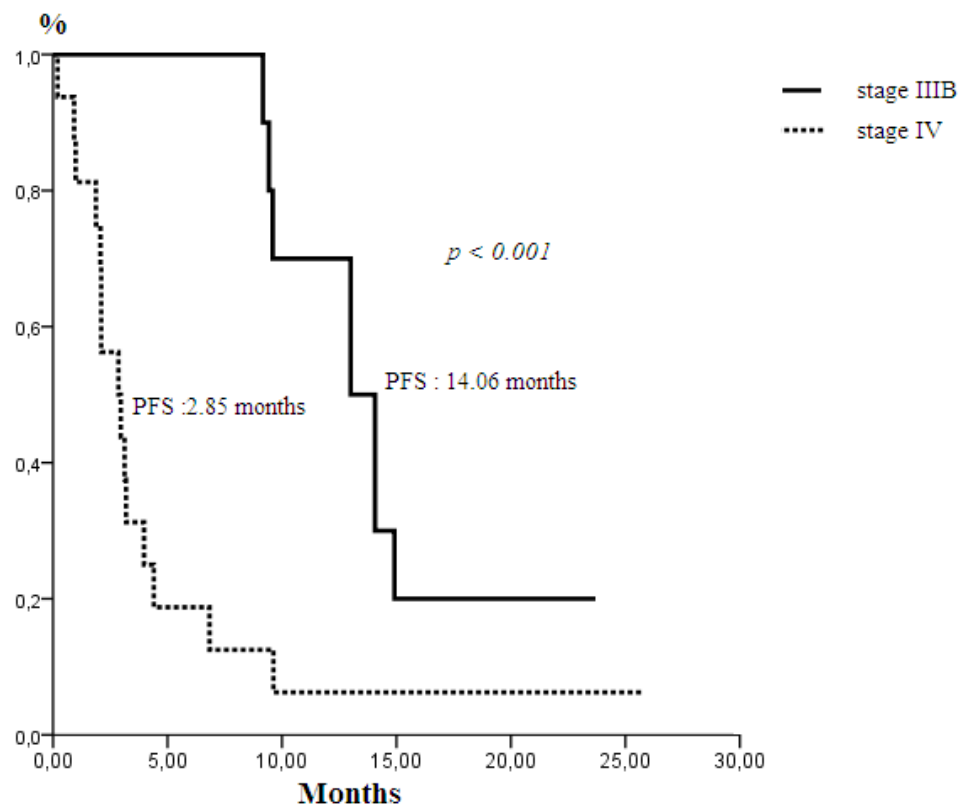
Methods - Tools: Racotumomab injected as intradermally of 1 mg/ml and concurrent antitumor therapy was not permitted. The induction phase consisted of 5 doses administered every 2 weeks. After induction, patients were vaccinated every 4 weeks until 31 May 2016 and the patients were followed up to 31 May 2017. First evaluation was performed after 5 doses of Racotumomab and after every 3 following doses.

Findings: Of the 26 squamous cell lung cancer (SCLC) patients included, 10 were stage IIIB and 16 were stage IV. Most patients were male and younger than 65 years, had an ECOG performance-status score of 0, were current or former smokers, had lymph node or counter-lung metastases, had received cisplatin plus gemcitabine and responded as partially regression or stable disease in the first-line chemotherapy (table 1). The median follow-up duration was 19.0 months. Seventeen (65.4 %) patients had died during follow-up. The median dose of racotumomab was 7 (range, 1-18 cycles). Six patients had a partial response to therapy and 7 had a stable disease. The objective response rate was found as 23.1 % and the clinical benefit rate as 50.0 % (table 2). The median PFS was found as 14.06 months (95% CI= 8.56-19.56 months) in the stage IIIB cancer and the median PFS was found as 2.85 months (95% CI= 1.18-4.53 months) in the stage IV cancer. ($p < 0.001$). Whereas, median OS was not reached in stage IIIB and 5.71 months (95% CI= 2.17-9.25 months) in stage IV cancer ($p = 0.002$) (Figure 1 and 2). Four patients (15.4%) had no progression despite 2 years of follow-up. There were no side effects except burning in 2 (7.7%) patients. No adverse events leading to death were related to the treatment.

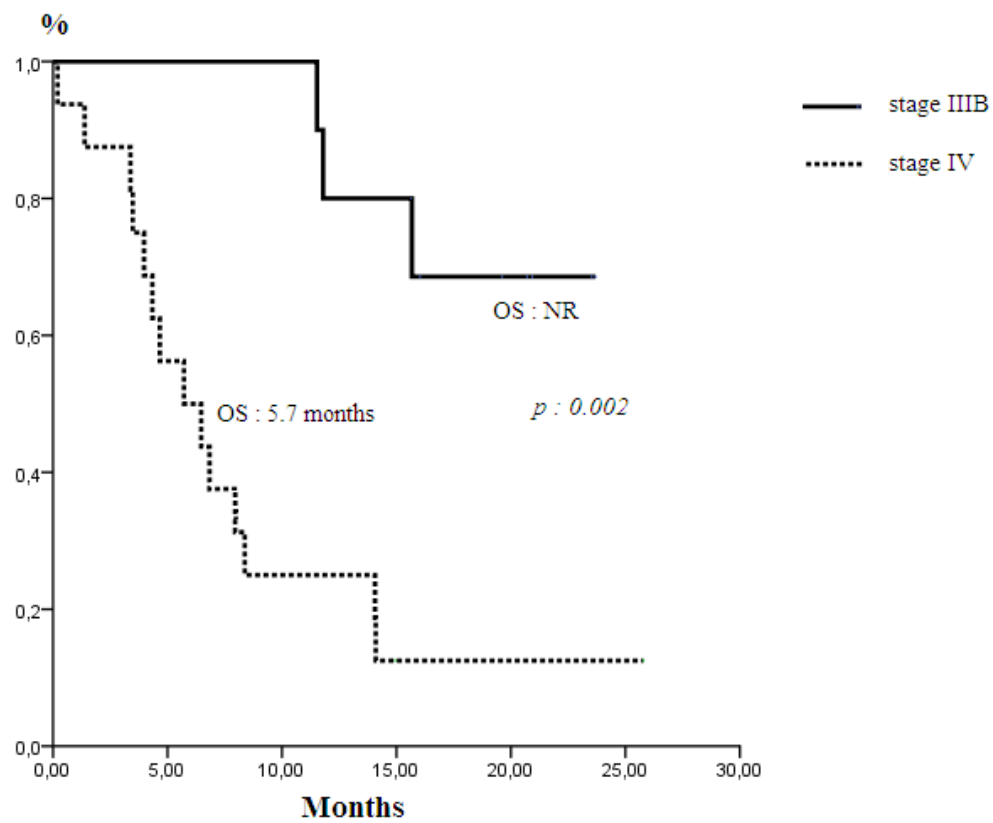
Discussion: This is the first retrospective study to demonstrate the efficacy of racotumomab vaccine as switch maintenance therapy for advanced SCLC in the literature. The most important reason why Racotumomab is more effective in stage IIIB patients may be that they have received radiotherapy before. There are a number of studies that show that radiotherapy improves the effectiveness of immunotherapies by removing the antigenic and inflammatory agents. Other causes may be the detrimental effect of distant metastasis on the immune system and inverse proportion between tumor burden and therapeutic vaccines, as shown in preclinical studies. Racotumomab may be recommended as switch maintenance in stage IIIB SCLC because of efficacy and no adverse event. However this should be confirmed with additional clinical evidence.

Keywords: racotumomab, vaccine, squamous cell lung cancer, switch maintenance therapy

Comparison of progression-free survival (PFS) between stage IIIB and stage IV squamous cell lung cancer



Comparison of overall survival (OS) between stage IIIB and stage IV squamous cell lung cancer



Comparison of patient demographics and characteristics between stage IIIB and stage IV squamous cell lung cancer

Characteristic	Total	Stage IIIB cancer	Stage IV cancer
Age (years)			
Median	59	56.5	61.5
Range	38-80	38-71	48-80
Gender			
Male	24 (92%)	8 (80%)	16 (100%)
Female	2 (8%)	2 (20%)	-
ECOG PS			
0	17 (65%)	9 (90%)	8 (50%)
1	9 (35%)	1 (10%)	8 (50%)
Smoking history			
Current smoker	5 (19%)	2 (20%)	3 (19%)
Former smoker	20 (77%)	7 (70%)	13 (81%)
Nonsmoker	1 (4%)	1 (10%)	-
Metastasis			
Lymph node	22 (85%)	10 (100%)	12 (75%)
Counter-Lung	6 (23%)	-	6 (37%)
Pleura	3 (11%)	-	3 (19%)
Liver	3 (11%)	-	3 (19%)
Bone	4 (15%)	-	4 (25%)
Surrenal	2 (8%)	-	2 (12%)
First-line chemotherapy			
Cisplatin/Gemcitabine	17 (65%)	4 (40%)	13 (81%)
Carboplatin/Paclitaxel	9 (35%)	6 (60%)	3 (19%)
Response to first-line therapy			
CR	1 (4%)	1 (10%)	-
PR	13 (50%)	3 (30%)	10 (62%)
SD	12 (46%)	6 (60%)	6 (38%)

Table 1. Comparison of patient demographics and characteristics between stage IIIB and stage IV squamous cell lung cancer

Comparison of tumor response rates between stage IIIB and stage IV squamous cell lung cancer

Tumor response	Stage IIIB	Stage IV	Total
CR	-	-	-
PR	5	-	5
SD	5	3	8
PD	-	13	13
Response Rate	50 %	0 %	19 %
Disease Control Rate	100 %	19 %	50.0 %

Table 2. Comparison of tumor response rates between stage IIIB and stage IV squamous cell lung cancer

CR; complete regression, PR; partial regression, SD; stable disease, PD; progressive disease