

Local Control and Survival in Radiation Treatment of Locally Advanced Non-Small Cell Lung Cancer

Mi Hee Song M.D., Jin Yeung Yang M.D., Won Young Oh M.D.,
Nam Soo Yoo M.D.* and In Soon Whang M.D.

Department of Radiation Oncology, Chest Medicine, National Medical Center, Seoul, Korea*

The retrospective analysis was performed on 37 patients with stage III non small cell lung cancer who received the radiotherapy from Feb. 1986 to Dec. 1990 at the Dept. of Radiation Oncology, National Medical Center. This analysis, with 29 patients (78.4%) having been followed from 10 to 60 months, was done to know the survival rate and significant prognostic factor.

The actuarial 2, 5-year survival rates were 20.6%, 6.9% in our all patients and median survival time was 10 months. Of patients with KPS (Karnofsky performance status) greater than 80%, the 2, 5 year survival rate and median survival time were 29.2%, 9.7% and 13 months, respectively. The 2-year survival rate and median survival time of patients with KPS less than 80% were 13.7% and 7 months, respectively. The survival difference according to performance status was statistically significant (29.2% vs. 13.7%) ($p < 0.05$). In stage IIIa, the 2, 5-year survival rate and median survival time were 29.2%, 9.7% and 12 months, respectively. The 2-year survival rate and median survival time of stage IIIb were 8.6% and 10 months, respectively. The survival difference between stage IIIa and IIIb did not show statistical significance ($p > 0.1$).

Of the prognostic factors, the difference of survival rate by initial performance status was statistically significant ($p < 0.05$). But the difference of survival rates by pathologic cell type, stage, total radiation dose, radiotherapy response, and combination with chemotherapy were not statistically significant.

Key Words: Radiation Therapy, Locally advanced non small cell lung cancer

INTRODUCTION

For many years, radiation therapy has been the treatment of choice for patients with inoperable or unresectable non small cell lung cancer¹⁾. On the basis of comparative clinical trials, doses of 5,000 to 6,000 cGy are considered standard²⁾, although such treatment is associated with a median survival of only 9 to 11 months, with 2 year survival of 10 to 20% and 3 year survival of 5 to 10%³⁾.

RTOG has reported on 2 randomized studies concerning the effects of various doses of radiation and fractionation schedules on the tumor control and survival of patients with non small cell lung cancer^{4,5)}. These trials concluded that by increasing dose of radiation from 4,000 up to 6,000 cGy, there was both improved intrathoracic tumor control as well as survival. The anatomic patterns of failure in above patients were analyzed³⁾. The intrathoracic failure rate within irradiated volume was 48% with 4,000 cGy continuous, 38% with 4,000 cGy split course or 5,000 cGy continuous, 38% with 4,000 cGy split course or 5,000 cGy continuous, and 27%

for patients receiving 6,000 cGy continuous course. The failure rate within nonirradiated lung ranged from 25% to 30% in various groups. The incidence of distant metastasis was 75% to 80% in all histologic groups. More higher dose of irradiation would be necessary in order to improve intrathoracic tumor control and survival in non small cell lung cancer³⁾.

The purpose of this retrospective analysis is to study local control, survival rate and significant prognostic factors of irradiated 37 patients with non small cell lung cancer and to plan more effective treatment modality and radiation methods forward.

MATERIALS AND METHODS

From Feb. 1986 to Dec. 1990, 37 stage III non small cell lung cancer patients enrolled into the our study were treated by the radiation therapy at Dept. of Radiation Oncology, National Medical Center. The follow-up period was ranged from 10 to 60 months and the follow-up rate was 78.4% (Table 1).

All patients were evaluated by detailed history

Table 1. Patients Characteristics of NSCLC

Age (%)	
<49	6(16.2)
50~59	10(27.0)
60~69	15(40.5)
>70	6(16.2)
Sex (M:F=11.3:1)(%)	
Male	34(91.9)
Female	3(8.1)
Performance status (%)	
I (KPS≥80)	27(73.0)
II (KPS<80)	10(27.0)
Site (%)	
RUL	13(35.1)
RML	6(16.2)
RLL	2(5.4)
LUL	12(32.4)
LLL	4(10.8)
Pathology (%)	
squamous	27(73.0)
adenoca	10(27.0)
Stage (%)	
IIIa	20(54.1)
IIIb	17(45.9)
T stage (%)	
T1	1(2.7)
T2	7(18.9)
T3	22(59.5)
T4	7(18.9)
N stage (%)	
N0	3(8.1)
N1	3(8.1)
N2	18(48.6)
N3	13(35.1)
Follow-up	
range (months)	10~60
rate (%)	78.4

and through physical examination, routine serum chemistry, complete blood counts, simple chest X-ray, and chest C-T scan. Histologic diagnosis was performed by the results of sputum cytology, bronchoscopy with biopsy, and supraclavicular lymph node biopsy. Some patients were done the operation finding, whole body bone scan, liver scan, brain C-T.

The performance status was divided into 2 groups based on the scale introduced by Karnofsky, e.g., group I (over KPS 80%), group II (less than KPS 80%). The 21 patients could be restaged by the TNM staging system of the American Joint Committee revised on 1988⁶⁾.

All patients were received external beam irradi-

ation with ⁶⁰Co Teletherapy Unit. The planned total tumor dose was 5,000 to 6,500 cGy in 5 to 7 weeks with conventional fractionation for curative aim and 3,500 to 4,000 cGy in 4 to 5 weeks for palliative aim. The treatment portal was designed to have 2 cm margin around any gross tumor and approximately 1 cm margin around electively treated regional lymph node areas (ipsilateral hilum, mediastinum, sometimes supraclavicular area). Parallel opposed anterior and posterior shaped fields were used until maximum dose to the spinal cord was 4,500 cGy. Parallel opposed lateral fields that encompass the entire mediastinum anterior to vertebral bodies were given 500 to 1,500 cGy, an oblique pair or an anterior-posterior pair of opposed fields including the known tumor was carried the full dose.

Also, all patients except 4 patients were treated with combination chemotherapy from 1 to 10 cycles (mean 4 cycles). The combination chemotherapy was used by the various kinds of regimen, variable amount of dosage, and various timing. CMF, CMF-oncovin, CAP, CMV, CMV plus VP-16, FP, CAF, VIP, VP were used variously. The patients were divided and analyzed with 2 groups: patients with combination chemotherapy over 3 cycles and less than 3 cycles.

The nominal standard dose (NSD) of Ellis was calculated using, the formula, TD (total dose)= NSD (T^{0.11})(N^{0.24}).

One month after completion of irradiation, the response to radiation treatment was divided complete response, partial response, no response. Complete response was defined as the disappearance of all clinical, radiologic and laboratory evidence of cancer. Partial response was defined as 50% or greater decrease in the sum of products of two perpendicular diameters of all measured lesions without simultaneous increase in the size of any other lesion, or the appearance of any new lesion. No response was defined as less than 50% reduction, or no change in lesion size, or an increase in the size of any measured lesion, or the development of one or progressive lesions.

After completion of radiotherapy, all patients were followed up periodic visit to hospital. Eight patients (21.6%) were not followed in this manner. We could know patients conditions, alive, or death contacting by telephone or mail at their home addresses. Survival was calculated from initiation of radiotherapy. The survival rate was plotted using the Kaplan-Meier method⁷⁾ and the statistical significance of the survival was analysed by the

log-rank test.

RESULTS

1. Patients Characteristics

In this study, 34 male and 3 female patients were investigated (male to female ratio was 11.3:1). The age distribution ranged from 28 to 76 years old (median: 58 years old) and most of patients were about 5 or 6 decades (67.6%).

The site of origin of lung cancer was the right lung in 21 patients (58.8%) and the left in 16 patients (43.2%). The lesion of the upper lobe was in 25 patients (67.6%).

The distribution of performance status was 73% (27 patients) in group I (KPS \geq 80%) and 27% (10 patients) in group II (KPS < 80%). By histopathologic distribution, twenty-seven tumor (73%) were classified as squamous cell carcinoma, 10 tumors (27%) as adenocarcinoma, none as large cell carcinoma. Twenty-one patients was restaged by the TNM staging system of the American joint Committee revised on 1988. Stage IIIa was 20 patients (54.1%) and stage IIIb was 17 patients (45.9%). The patients in T1, T2, T3 and T4 were 1, 7, 22 and 7, respectively. In patients in NO, N1, N2 and N3 were 3, 3, 18 and 13, respectively (Table 1).

2. Survival

The overall survival of all patients was illustrated in Fig. 1. The actuarial 2 and 5-year survival rate of all patients were 20.6% and 6.9%, respectively.

The survival by the performance status was analyzed. The 2, 5-year survival rate and median survival time of patients with KPS over 80% were

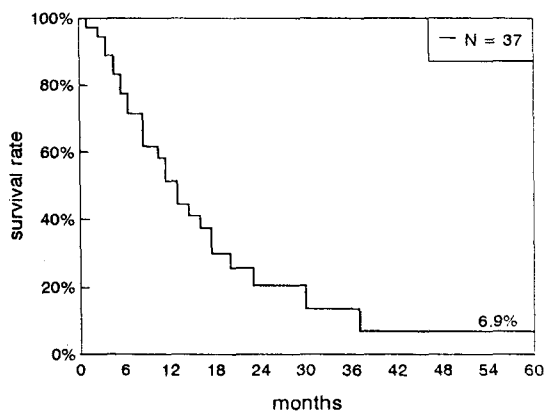


Fig. 1. Overall survival of stage III non small cell lung cancer.

29.2%, 9.7%, and 13 months, respectively. The 2-year survival rate and median survival time of patients with KPS less than 80% were 13.7% and 7 months and all these patients died within 2 years. Patients with good performance status (KPS \geq 80%) showed better survival rate and longer median survival time than patients with poor performance status (KPS < 80%) and there was statistically significant difference ($p < 0.05$) (Fig. 2, Table 2).

According to pathologic type, the 2, 5-year survival rate and median survival time of squamous cell carcinoma were 25.2%, 12.6% and 10 months, respectively. The 2-year survival rate and median survival time of adenocarcinoma were 15.0% and 17 months and all these patients of adenocarcinoma died within 3 years. There was no statistically significant difference of survival by the histopathologic type (Fig. 3, Table 2).

The survival was analyzed according to stage.

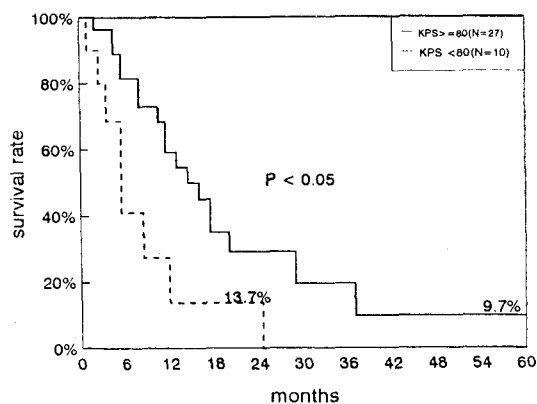


Fig. 2. Survival by the performance status.

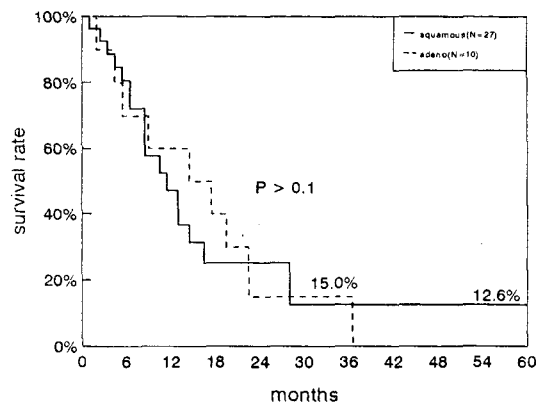


Fig. 3. Survival by the pathologic type.

Table 2. Survival by Variable Prognostic Factors

	No. of Patients	Survival	
		2YSR* (%)	MST* (months)
Performance status			
I (KPS ≥ 80)	27(73.0)	29.2	13
II (KPS < 80)	10(27.0)	13.7	7
Pathology			
Squamous	20(73.0)	25.2	10
Adenoca.	10(27.0)	15.0	17
Stage			
IIIa	20(54.1)	29.2	12
IIIb	17(45.9)	8.6	10
T stage			
T1+T2	8(21.6)	28.6	10
T3	22(59.5)	16.2	11
T4	7(18.9)	25.7	7
N stage			
N0+N1	6(16.2)	41.7	12
N2	18(48.6)	26.2	14
N3	13(35.1)	10.1	10
Total radiation dose			
≥1500 ret	28(75.7)	15.6	12
<1500 ret	9(24.3)	0	7
RT response			
responder (CR 5 + PR 17)	22(59.5)	26.3	12
nonresponder	15(40.5)	14.3	10
Chemotherapy			
yes	24(64.9)	15.6	12
no	13(35.1)	15.4	6
Total	37(100)	20.6	10

*YSR: year survival rate

*MST: median survival time

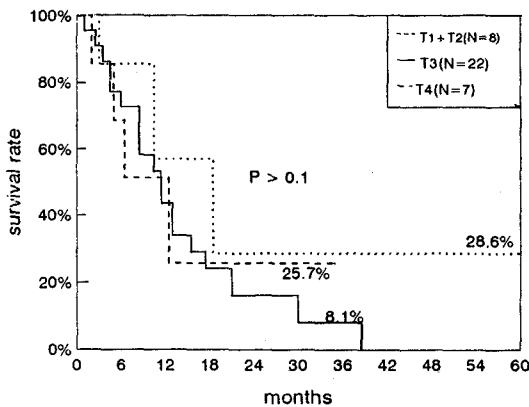


Fig. 4. Survival by the stage.

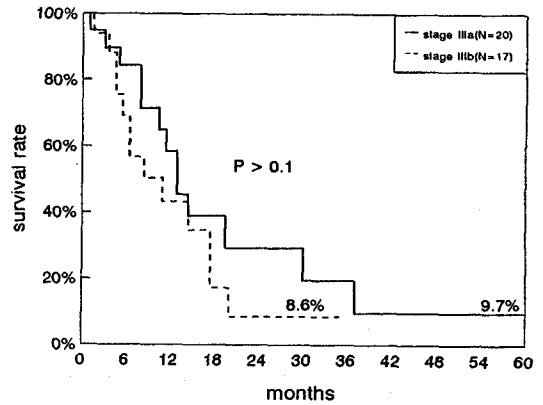


Fig. 5. Survival by the T stage.

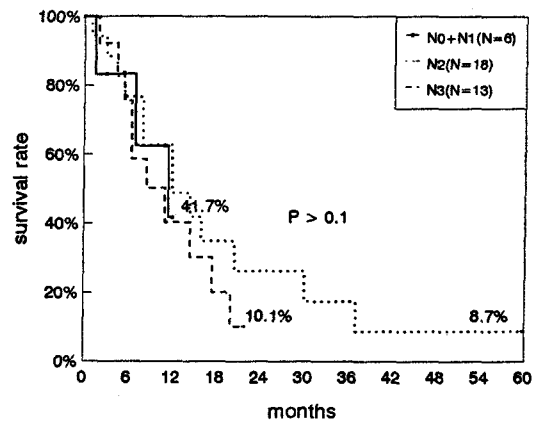


Fig. 6. Survival by the N stage.

The 2, 5-year survival rate and median survival time of stage IIIa were 29.2%, 9.7%, and 12 months, respectively. The 2-year survival rate and median survival time of stage IIIb were 8.6% and 10 months. The survival difference between stage IIIa and stage IIIb was not statistically significant ($p > 0.1$) (Fig. 4, Table 2).

By T staging, the 2-year survival rate and median survival time of T1+T2, T3, T4 patients were 28.6%, 16.2%, 25.7%, 10, 11, 7 months, respectively. By N staging, the 2-year survival rate and median survival time of N0+N1, N2, N3 patients were 41.7%, 26.2%, 10.1%, 12, 14, 10 months, respectively. The survival difference by T and N staging was not statistically significant ($p > 0.1$) (Fig. 5, 6, Table 2).

By total radiation dose, the 2-year survival rate and median survival time of the 9 patients treated with less than 1,500 ret were 0% and 7 months, respectively. The 2, 5-year survival rate and median survival time of patients treated with more than 1,

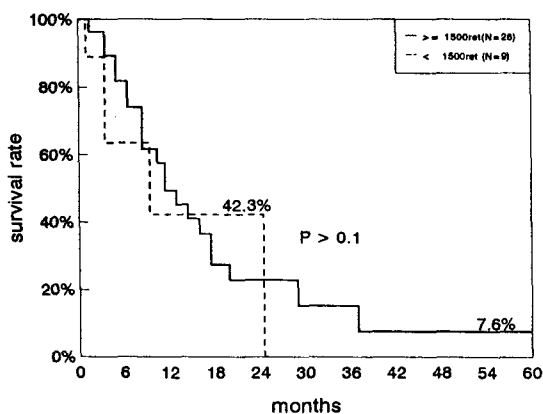


Fig. 7. Survival by the total radiation dose.

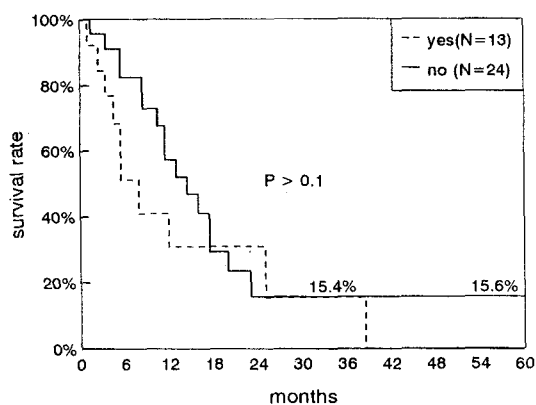


Fig. 9. Survival by the chemotherapy.

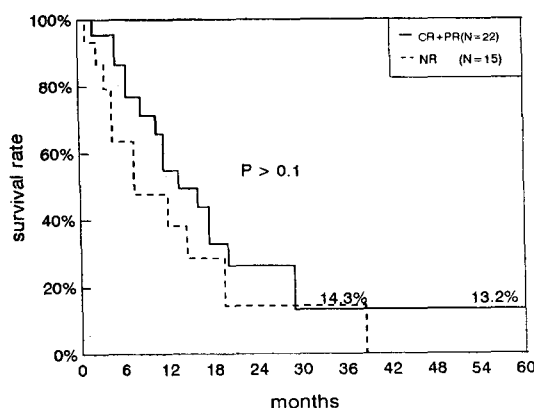


Fig. 8. Survival by the radiation response.

500 ret were 15.6%, 7.6%, 12 months, respectively. There was no significant difference of survival by the total radiation dose ($p \geq 0.1$) (Table 2, Fig. 7).

The 2, 5-year survival rate and median survival time of 22 responder (complete & partial response) were 26.3%, 13.2% and 12 months, respectively. Two year survival rate and median survival time of 15 nonresponder were 14.3%, and 10 months, respectively. There was no significant difference of survival between responder and nonresponder ($p \geq 0.1$) (Table 2, Fig. 8).

The 2-year survival rate and median survival time of 24 irradiated patients treated with combination chemotherapy over 3 cycles were 15.6%, and 12 months, respectively. Two year survival rate and median survival time of 13 patients treated with combination chemotherapy less than 3 cycles were 15.4%, and 6 months, respectively. There was no significant survival difference of patients treated

with combination chemotherapy between over 3 cycles and less than 3 cycles ($p \geq 0.1$) (Table 2, Fig. 9)

DISCUSSION

The lung cancer was highly lethal disease with poor prognosis. Five year survival rate of patients treated with radical resection was 20 to 50%⁸⁻¹⁰. Among the patients treated with definitive radiotherapy, 5 year survival rate was less than 10%¹¹⁻¹² and mean survival time was 6 to 9 months and only about 25% of patients were alive over 1-year¹³. Actuarial 2 and 5-year survival rate of our study were 20.6% and 6.9%, respectively, that was similar to results of the recent reports^{14,16}.

More than 5,000 patients who were included in a series of lung cancer trials conducted by Veterans Association Lung Cancer Study Group were analyzed to identify potential prognostic factors in inoperable lung cancer. Seventy seven parameters were included in these analyses. The response to irradiation and survival of those patients was affected various factors like these: 1) patients characteristics such as initial performance status and weight loss in the six months prior to diagnosis, 2) tumor characteristics such as the clinical stage, size of the lesion and histologic type, 3) technical parameters relative to the delivery of irradiation, such as the tumor dose and the volume treated. It appeared that performance status, extent of disease, and the amount of weight loss in the previous 6 months were the major prognostic determinants¹⁷.

In our study, the actuarial 2, 5-year survival rate and median survival time of group I (KPS 80%)

were 29.2%, 9.7% and 13 months, compared with 2 year survival rate of 13.7% and median survival time of 7 months in group II (KPS < 80%). This result was comparable to other reported series that performance status was statistically significant prognostic factor ($p < 0.05$) and closely related to the survival^{17,18}. The patients of stage IIIa showed 2, 5-year survival rate of 29.2%, 9.7%, respectively and median survival time of 12 months. The patients of stage IIIb showed 2-year survival rate of 8.6% and median survival time of 10 months. The survival difference between stage IIIa and stage IIIb did not show statistical significance but the survival showed good trend in earlier stage. In view of recently reported retrospective study showed no survival difference between stage IIIa and IIIb patients who received thoracic irradiation alone¹⁹. Bonomi et al²⁰. investigated pretreatment prognostic factors in stage III non small cell lung cancer patients receiving combined modality treatment. Performance status, eligibility for surgery and stage (IIIa vs. IIIb) revealed as significantly prognostic factors.

The correlation of survival with histologic type of non small cell lung cancer was controversial but most of reporters agreed that there was lack of correlation^{18,19,21}. It was not significant survival difference according to histologic type in our study too.

The only prospective randomized trial that compared radiation therapy with no treatment was that performed by the Veterans Administration²². Between 4,000 and 5,000 cGy were delivered to 308 male patients with lung cancer, 246 patients were treated with placebo. Although radiation had significant influence on survival, the clinical impact was small with only 22% of radiation patients alive at 1 year compared with 16% of controls.

Most clinical results available today have been obtained with doses ranging from 4,000 cGy to 6,000 cGy. Petrovich²³ reported that 1-year survival rate of 345 patients of locally advanced lung cancer was 50% in patients irradiated 1,600 ret above and 35% in patients irradiated with 1,600 ret or less. Perez³ reported that 3 year survival rate was 15% in 6,000 cGy, 10% in 5,000 cGy, 6% in 4,000 cGy. But our study did not show significant difference of survival between patients irradiated 1,500 ret above and patients irradiated with 1,500 ret or less.

The RTOG⁵ has investigated the effect of various dose of radiation therapy delivered in conventional fractionation (200 cGy/day, 5 days per week) on the outcome of patients with locally advanced

disease. Patients with T1-3N0-2 disease were randomized to 4,000 cGy split course, or 4,000 cGy, 5,000 cGy, 6,000 cGy continuous courses. A higher complete response rate (24%), intrathoracic tumor control (67%), and 3 year survival (15%) was observed with 6,000 cGy, compared with lower dose of irradiation (4,000 or 5,000 cGy). This suggested that the continuous course treatment of 50 to 60 Gy was superior to the 40 Gy split-course or continuous course program.

The anatomic patterns of failure of 551 evaluable patients with unresectable or inoperable disease were reported by Perez³. The intrathoracic failure rate within irradiated volume was 48% with 4,000 cGy continuous, 38% with 4,000 cGy split course or 5,000 cGy continuous, and 27% for patients receiving 6,000 cGy continuous course. The failure rate within nonirradiated lung ranged from 25% to 30% in various groups. The incidence of distant metastasis was 75% to 80% in all histologic groups.

The poor survival obtained with conventional radiation therapy for locally advanced non small cell lung cancer could be attributed to the inability of a local treatment modality to control a disease with marked tendency of distant spread, inadequate delivery of dose to target volume, radioresistance and the deleterious effect of excessive toxicity on normal tissues. The efforts to increase its efficacy were justified so that it could achieve its primary objective of effectively eliminating local disease. The most important determinant factor of local control by radiation therapy for carcinoma of lung is to increase radiation dose. But the lack of incorporation of higher dose of radiation therapy has the causes as the followings, the complex anatomy of the thorax, the proximity of the lung tumor to many vital organs, and the concern regarding acute and late complication of radiation therapy.

Several studies have been suggested many methods that are possible to deliver higher dose of radiation therapy to the tumor while not exceeding the tolerance dose to critical normal structures. This has led to the investigation of new radiation fractionation strategies that include hyperfractionated and accelerated approaches. More recently radiation dose escalation studies using three-dimensional conformal dose delivery. The RTOG performed a randomized phase I / II trial of hyperfractionated radiation therapy (1.2 Gy twice daily separated by ≥ 4 hours) to total dose of 60 to 79.2 Gy for locally advanced non small cell lung cancer. They reported median survival of 13 months and 2-year survival rate of 29% for patients with 69.

6 Gy arm. There was a dose response relationship for survival with the 69.6 Gy arm being significantly better ($p=0.02$) than lower total dose arms among 350 patients who had excellent performance status (70~100%) and minimal weight loss (<5%) and no supraclavicular nodes²⁴). An interesting study of continuous, hyperfractionated, accelerated radiotherapy (CHART) from the Mount Vernon Hospital²⁵) was recently reported. Sixty-two patients were treated with 1.4 to 1.5 Gy fraction three times daily separated by 6 hours for consecutive days to total doses of 50.4 to 54.0 Gy. An impressive 42% of the patients achieved a complete radiographic response, and the survival at 1 and 2-years was 64% and 34%. This represented a substantial survival gain over the historical 1 and 2-year survival rates of 44% and 12%.

Carcinoma of lung has a high tendency to develop distant metastasis, therefore local tumor control by radiation therapy may not result in better survival. Because distant failure is common after radiation therapy for locally advanced non small cell lung cancer, many attempts have been made to improve survival by adding chemotherapy to radiation therapy. A combination of chemotherapy and radiotherapy was prospectively compared with the best supportive care in another randomized trial²⁶). The median survival was 11 months for patients treated with 3 cycles of induction cisplatin and etoposide chemotherapy followed by 4,000 cGy thoracic irradiation compared with 7 months for best supportive care ($p=0.05$).

The Cancer and Leukemia Group B (CALGB study)²⁷) reported the randomized trial of induction chemotherapy plus high dose radiation versus radiation alone in stage III non small cell lung cancer. The patients were randomized to receive 6,000 cGy of thoracic irradiation with or without induction chemotherapy with vinblastin and cisplatin. The patients were selected by having a performance status of greater than 80%, weight loss of less than 5%, and a hematocrit of greater than 30%. Median survival was 14 months with chemotherapy compared with 10 months without chemotherapy ($p=0.006$) and 3-year survival was 23% with chemotherapy compared with 11% without.

The European Organization of Research and Treatment of Cancer (EORTC)²⁸) performed a randomized study that compared split-course RT alone with 55 Gy versus the same RT plus cisplatin administered daily (6 mg/m²) or weekly (30 mg/m²). Survival was significantly improved favoring daily cisplatin/radiation rather than radiation alone

($p=0.009$). The survival at 2 and 3-year were 26% and 16% in the daily cisplatin/radiation group versus 13% and 2% in the radiation alone group. Survival in the weekly cisplatin/radiation group was not significantly different from either of other two treatment groups.

This study was results of patients receiving conventionally fractionated radiation therapy and the survival was poor with 9.5% of 5 year survival rate as other previous results irradiated conventional radiotherapy. On the basis of the results of RTOG and CALHGB, we will investigate hyperfractionation radiotherapy and combination chemotherapy with irradiation for better survival and local control in locally advanced non small cell lung cancer.

CONCLUSION

The 37 patients of stage III non small cell lung cancer enrolled into the our study, who were treated with the radiation therapy at Dept. of Radiation Oncology, National Medical Center from Feb. 1986 to Dec. 1990. The results were as follows.

- 1) The overall 5-year survival rate and median survival time of all patients were 6.9% and 10 months respectively.
- 2) The initial performance status only was statistically significant prognostic factor affecting survival ($p<0.05$).

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국문초록 =

III 병기 비소세포성 폐암의 방사선 치료성적

국립의료원 치료방사선과, 흉부내과*

송미희 · 양진영 · 오원용 · 유남수* · 황인순

본 국립의료원 치료 방사선과 에서는 1986년 1월부터 1990년 12월까지 5년간 방사선 치료를 받은 III 병기 비소세포성 폐암 37예를 대상으로 후향성 조사를 통하여 임상적 특징과 생존율을 분석하여 보고하는 바이다. 이 중 29예가 사망시 또는 1991년 8월까지 추적 관찰이 가능하였으며 치료후 추적 조사 기간은 최소 10개월, 최고 60개월 이었고, 추적율은 78.4%이었다.

Kaplan-Meier법에 따른 전체 환자 37예의 2, 5년 생존율은 각각 20.6%, 6.9%이었으며 중앙생존 기간은 10개월 이었다. Performance status에 의하면 KPS가 80% 이상인 I군의 2, 5년 생존율과 중앙생존기간은 각각 29.2%, 9.7%, 13개월 이었고, KPS가 80% 이하인 II군의 2년 생존율과 중앙 생존기간은 13.7%와 7개월 로서, 통계학적으로 유의한 차이를 보였다($p < 0.05$).

AJCC 병기에 따른 생존율 및 중앙 생존기간을 보면 III_a 병기의 2, 5년 생존율 및 중앙 생존기간이 29.2%, 9.7% 및 12개월 이었고 III_b 병기의 2년 생존율과 중앙 생존기간은 8.6%와 10개월로 생존율 의 유의한 차이를 보이지 않았다($p > 0.1$). 그의 조직 병리학적 유형별, 방사선 선량별, 방사선 반응 군별, 항암화학요법 유무에 따른 생존율은 유의한 차이를 보이지 않았다.

결론적으로 overall 5년 생존율 및 중앙 생존기간은 6.7%와 10개월 이었고 performance status 만이 통계적으로 유의한 예후인자였으며, 병리조직학적 유형, 병기, 방사선 치료선량, 방사선 반응유 무와 항암화학요법 등의 예후인자들은 통계학적으로 유의하지 않았다.