The Results of Radiation Therapy in Non-Small Cell Lung Cancer*

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= Abstract =

From March 1983 through January 1990, two hundred sixty six patients with non-small cell lung cancer were treated with external radiation therapy at the Department of Therapeutic Radiology, Kangnam St. Mary's Hospital, Catholic University Medical College.

A retrospective analysis was performed on eligible 116 patients who had been treated with radiation dose over 40 Gy and had been able to be followed up. There were 104 men and 12 women. The age ranged from 33 years to 80 years (median ; 53 years). Median follow up period was 18.8 months ranging from 2 months to 78 months.

According to AJC staging system, there were 18(15.5%) patients in stage II, 79 (68.1%) patients in stage III and 19(16.4%) patients in stage IV. The pathologic classification showed 72(62.8%) squamous cell carcinomas, 16(13.8%) adenocarcinomas, 7(6%) large cell carcinomas, 5(4%) undifferentiated carcinomas, and 16(13.8%) unknown histology.

In Karnofsky performance status, six (5.2%) patients were in range below 50, 12 (10.4%) patients between 50 and 60, 46(39.6%) patients between 60 and 70, 51(44.0 %) patients between 70 and 80 and only one (0.8%) patient was in the range over 80.

Sixty (51.7%) patients were treated with radiation therapy (RT) alone. Thirty three (28.4%) patients were treated in combination RT and chemotherapy, twenty three (19.8%) patients were treated with surgery followed by postoperative adjuvant RT, and of 23 patients above, five (4.3%) patients, were treated with postoperative RT and chemotherapy. Overall response according to follow-up chest X-ray and chest CT scans was noted in 92.5% at post RT 3 months. We observed that overall survival rates at 1 year were 38.9% in stage II, 27.8% in stage III, and 11.5% in stage IV, and 2 year overall survival rates were 11.1% in stage II, 20.8% in stage III and 10.5 % in stage IV, respectively. We evaluated the performance status, radiation dose, age, type of histology, and the combination of chemotherapy and/or surgery to see the influence on the results following radiation therapy as prognostic factors. Of these factors, only performance status and response after radiation therapy showed statistical significance ($P<0.05$).

Key Words : Non-Small Cell Lung Cancer, Radiation Therapy, Survival.
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INTRODUCTION

Non-small cell lung cancer (NSCLC) is a disease of steadily increasing incidence with no significant improvement in survival during the past few decades[1]. Because of the difficulty in making an early diagnosis and propensity of the tumor to develop lymphatic and hematogenous metastasis, most patients are treated at a relatively advanced biologic state, regardless of the clinical stage[1]. Despite of the continuous efforts for improving the effect of chemotherapy, radiation therapy (RT) and surgery, the results are still not satisfiable. In non-small cell lung cancer patients, only 20 to 30% of them are candidates for surgical resection known as the most probable way of obtaining cure. However, after completion of surgical staging, fewer than 20% of the patients fall into this category[2].

For patients with unresectable lung cancer subjected to high dose RT, the cure rates are of the order of 5 to 10% at 5 years across the country[1]. Radiation therapy serves a great role in palliation of distressing symptoms caused by the intrathoracic tumor or its distant manifestation in patients with unresectable lung cancer or in medically inoperable patients. And it is also carried out as an adjuvant therapy to surgery in a subset of patients with resectable lung cancer[3].

The purpose of this study is to analyze the results of radiation therapy of non-small cell lung cancer on eligible 116 patients.

METHODS AND METERIALS

From March 1983 through January 1990, total 266 patients with non-small cell lung cancer were treated at the Department of Therapeutic Radiology in Kangnam St. Mary's Hospital, Catholic University Medical College. Of two hundred sixty six patients with non-small cell lung cancer treated with radiation therapy, only 116 (43.6%) patients were able to be treated with over 40 Gy and analyzed in this study. We excluded the 123 patients who underwent below 40 Gy radiation dose and 27 patients who underwent over 40 Gy radiation dose but who were lost (Table 1).

Table 1. C.U.M.C tumor registry; 266 non-small cell lung cancer patients(1983–1990).

	No. of patients
Radiation dose>40 Gy	143 (53.8%)
Follow up	116 (43.6%)
Lost to follow up	27 (10.2%)
Follow up period	2–78 months
Median	18.8 months

Non-small cell lung cancer was diagnosed by sputum cytology, lymph node(L/N) biopsy, bronchoscopic biopsy or CT guided needle aspiration biopsy and/or pleural biopsy. The initial evaluation included meticulous physical examination, chest radiograph, bronchoscopy and chest CT scan. Some selected patients underwent the brain CT and/or radionuclide scans for bone and liver.

According to AJC (American Joint Committee on Cancer) staging classification, there were 18 (15.5%) patients in stage II, 79 (68.1%) patients in stage III and 19 (16.3%) patients in stage IV. One hundred four (89.6%) patients were males and 12 (10.4%) patients were females. The age ranged from 33 years to 80 years (median age 53 years).

Six (5.2%) patients were in range of scores below 50, 12 (10.3%) patients between 50 and 60, 46 (39.6%) patients between 60 and 70, 51 (44.0%) patients between 70 and 80, and only one patients (0.9%) patients over 80 in Karnofsky performance status (KPS).

There were 72 (62.8%) squamous cell carcinomas, 16 (13.8%) adenocarcinomas, 7 (6%) large cell carcinomas, 5 (4%) undifferentiated carcinomas and 16 cases (13.8%) of unknown histology (Table 2).

The patients treated with curative intent were given radiation doses ranging from 5000 cGy to 8020 cGy during the period of 5–8 weeks. Radiation field for curative aim encompassed the primary tumor, mediastinum, both hila

Table 2. Patients characteristics

		Primary RT(%)	Postop. RT(%)
Age(years)	-40	4(4.3)	1(4.3)
	41-50	12(12.9)	6(26.1)
	51-60	38(40.9)	8(34.8)
	61-70	30(32.3)	8(34.8)
	71-	9(9.6)	
Sex	male	83(89.2)	21(91.3)
	female	10(10.8)	2(8.7)
Pathology	sq. cell ca	61(65.5)	11(47.8)
	adenoca	6(6.5)	10(43.5)
	large cell ca	5(5.4)	2(8.7)
	Undifferentiated	5(5.4)	-
	unknown	16(17.2)	-
KPS	-50	6(6.5)	-
	50-60	10(10.8)	2(8.7)
	60-70	35(37.5)	11(47.8)
	70-80	41(44.1)	10(43.5)
	80-	1(1.1)	-
Stage	II	8(8.6)	10(43.5)
	III	698(73.1)	11(47.8)
	IV	17(18.3)	2(8.7)
Chemotx.	Yes	60(64.5)	18(78.3)
	No	33(35.5)	5(21.7)
RT dose	4000-5000	19(20.4)	11(47.8)
(cGy)	5000-6000	66(71.0)	11(47.8)
	6000-	8(8.6)	1(4.4)

RT ; radiation therapy, Chemotx ; chemotherapy
KPS ; Karnofsky performance status.

and both supraclavicular lymph node areas. When the spinal cord dose was given 40-45 Gy with a daily 180 cGy fraction, we changed irradiation ports including posterior 2 oblique or bilateral ports using the shrinking field technique. We used body contour or CT images to calculate isodose distribution on planning computer (Therac 2000, NEC). Radiation therapy fields were reshaped during the course of treatment after follow up serial chest X-ray to minimize the radiation damage to normal lung. Radiation therapy was done by a 6 MV linear accelerator using SAD technique.

Sixty (51.7%) patients were treated with radiation therapy (RT) alone and 33 (28.4%) patients with chemotherapy before or after RT. Postoperative adjuvant RT was performed in 23 (19.8 %) patients. Five of the postoperatively irradiated patients (4.3%) were treated with combination chemotherapy.

Tumor response was evaluated by serial chest radiographs and chest CT scans at post RT 3 months. A complete response (CR) was defined as a complete disappearance of all clinical and radiographic evidence of disease by follow-up chest X-ray or CT scan. Moderate response (MR) was defined as a reduction over 70% in mass size and partial response (PR) was defined as a reduction over 50-70% in mass size . All other patients were classified as non-responders (NR). Follow up periods ranged from 2 months to 78 months (median 18.8 months) counting from the end of RT. Statistically, oneway ANOVA and Mann-whitney test were used for analyze prognostic factors effecting on survival and post radiation response, and Kaplan-Meier method was used for the acturial survival analysis.

The acturial survival and therapeutic response were evaluated depending on the age, stage, performance status, histology, radiation dose, use of chemotherapy and postoperative RT. We also analyzed the radiation treatment related complications.

RESULTS

A clinical analysis of 93 primary irradiated patients showed 7 (7.6%) CR, 39 (42.4%) MR, 40 (43.5%) PR and 7 (7.6%) NR, respectively (Table 3). The overall response rate was 92.5% at post

Table 3. Clinical responses following primary irradiated 93 non small cell lung cancer patients

Response	No. of pts(%)
Complete response(CR)	7(7.6)
Moderate response(MR)	39(42.4)
Partial response(PR)	40(43.5)
No response(NR)	7(7.6)

Table 4. Factors affecting the response following primary irradiated NSCLC* patients

Stage	p>0.05
Histology	p>0.05
Radiation dose	p<0.05
Chemotherapy	p>0.05

*NSCLC ; Non-small cell lung cancer

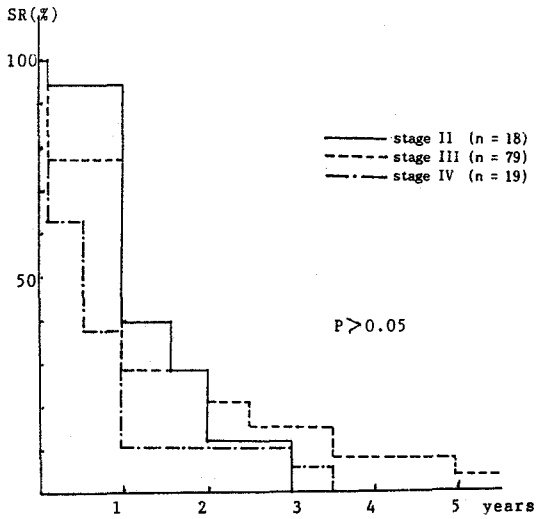

Fig. 1. Overall survival rate by stage

RT 3 months.

As more radiation dose was given, better radiation response of NSCLC was obtained in this result ($P<0.05$). But other factors such as stage, histologic type and the use of chemotherapy did not influence the response rate following radiation therapy ($P>0.05$) (Table 4.).

The overall survival rates after primary RT at 1-year and 2-year were 38.9% and 11.1% in stage II, 27.8% and 20.8% in stage III, and 11.5 % and 10.5% in stage IV, respectively. The survival curves by the stage were shown in Fig-1, but had no significant difference at the long term end results. However, in the postoperatively irradiated patients in whom accurate pathologic staging were performed, 2 year survival rates were 50.0% in stage II and 32.7% in stage III. Median survival times were 27 months in stage II and 13 months in stage III ($P<0.05$) (Table 6. & Fig 2.) . The better survival rates were obtained in patients with good performance status (Fig-3), and the responders by RT showed better survival time with statistical significance ($P<0.05$) (Fig 4). Of the other prognostic factors such as age, stage, radiation dose, weight loss, symptom duration and combined treatment modalities, only performance status and response following RT were statistically significant ($p<0.05$) (Table 5.).

Table 5. Factors affecting survival following primary irradiated NSCLC* patients

stage	p>0.05
KPS	p<0.05
response	p<0.05
radiation dose	p>0.05
weight loss	p>0.05
chemotherapy	p>0.05

*NSCLC ; Non-small cell lung cancer,
KPS ; Karnofsky performance status.

Table 6. Survival rate of 23 postoperatively irradiated patients

	No. of pts	median survival (months)	2yr survival rate(%)
stage II	10	27.0	50.0
III	11	16.5	32.7
IV	2	6.0	0.0

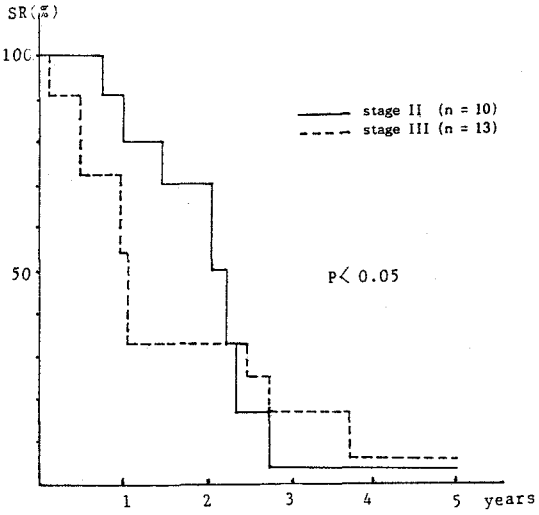

Fig. 2. Overall survival rate by stage in postoperative irradiated patients

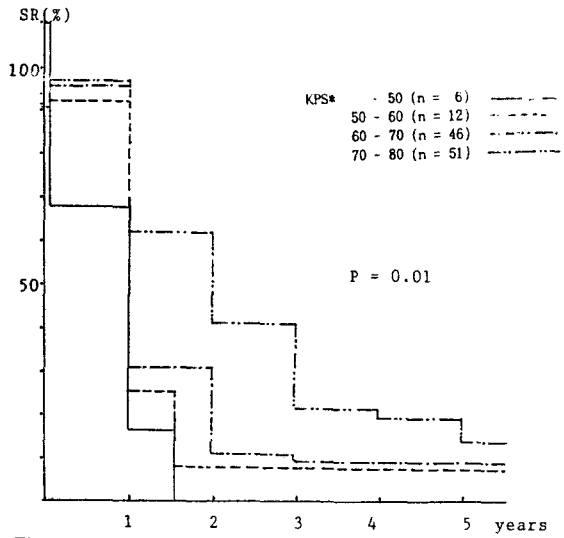

Fig. 3. Overall survival rate by performance status

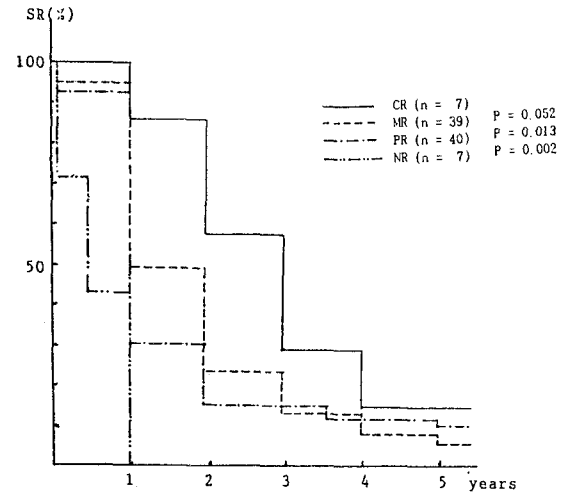

Fig. 4. Overall survival rates by the radiation response

Radiation induced complications were transient esophagitis in 65 (56%) cases , mild to moderate degree of pneumonitis in 26 (22.4%) cases and dry or wet desquamated dermatitis in 27 (23.3 %) cases (Table 7.). Radiation induced esophagitis appeared in fifty five (84.6%) of 65 patients in the range of 1000 cGy to 3000 cGy with sore throat or odynophagia (Table 8.). In the dose of 3000 cGy to 5000 cGy, dry or wet desquamated dermatitis was seen in 23 (85%) patients (table 9.). In 18 (68.6%) of 26 patients, radiation pneumonitis were developed between 1 and 3 months after radiation therapy (table 10.).

At first, we expected that chemotherapy might increase the radiation related complications and it also might start earlier than those of radiation alone group, but there showed no differences between the two groups (Table 8,9,10) in this study. Bronchoesophageal fistula was seen in one patient (Table 7.). And there were no fatal complications during or after RT.

Table 7. Radiation induced copmplication in eligible 116 patients

	No. of patients	Incidence
Transient esophagitis	65	56.0%
Mild or moderate pneumonitis	26	22.4%
Dry or wet desquamation	27	23.3%
Bronchoesophageal fistula	1	0.09%

Table 8. Radiation esophagitis in 116 patients according to radiation dose and time of appearance

cGy	RT alone (N=87)	RT+CTx (N=38)	Total (N=116)
1000-2000	20	7	27
2000-3000	19	9	28
3000-4000	3	4	7
4000-	1	2	3
Total	43(55.1%)	22(57.9%)	65

CTx ; chemotherapy, RT ; radiation therapy

Table 9. Radiation dermatitis in 116 patients according to radiation dose and time of appearance

cGy	RT alone (N=78)	RT+CTx (N=38)	Total (N=116)
2000-3000	1	0	1
3000-4000	8	2	10
4000-5000	9	4	13
5000-6000	1	2	3
Total	19(24.4%)	8(21.1%)	27

RT ; radiation therapy, CTx ; chemotherapy

Table 10. Radiation pneumonitis in 116 patients according to to sradiation dose and time of appearance

cGy	RT alone (N=78)	RT+CTx (N=38)	Total (N=116)
3000–4000	1	0	1
4000–5000	0	0	0
5000–6000	1	1	2
6000–7000	1	1	2
postRT 1 month	4	2	6
2 month	3	1	4
3 months	5	3	8
4 months	2	0	2
5 months	0	1	1
Total	17(21.8%)	9(23.7%)	26

RT ; radiation therapy, CTx ; chemotherapy

DISCUSSION

Non-small cell lung cancer (NSCLC), whenever resectable, should be treated surgically[4]. But only one third of all patients with lung cancer are eligible for a definitive resection[5] and after complete surgical staging, fewer than 20% of patients can be cured with surgery alone. Therefore radiation therapy is carried out as an adjuvant to surgery in patients with resectable NSCLC and it has been primary choice for localized unresectable disease or treatment modality with palliative aim for distressing symptoms which were localized or even the metastatic disease.

In definitive radiation therapy, most clinical results available today have been obtained with doses raging from 4000 cGy to 6500 cGy. It is known that the most important determinant of local control in NSCLC is the total dose of irradiation[6]. Medical college of Wiscosin reported the local control rate over 70% with radiation dose above 5800 cGy[6]. Also, Perez reported greater CR and PR rates for the patients receiving 5000–6000 cGy than for lower dose[7]. According to the RTOG study[6], they showed that a regimen using 400 cGy/fraction, 5 times a week followed by two weeks intermission and then another 400 cGy/fraction, 5 times a week total of 4000 cGy in 10 fraction in 4 weeks was clearly inferior to continuous regimens of 5000 to 6000 cGy in 25 to 30 fractions during 5 to 6 weeks using a conventional fractionation. Furthermore, the complications of the split course irradiation were equivalent to those with 6000 cGy in 6 weeks. A review of several experiences with hypofractionation that is 1 to 3 fractions per week, showed a similar reduction in tumor control[8]. Therefore, it can be concluded that the safest and most effective approach to definitive irradiation of patients with NSCLC is a continuous regimen with 5 fractions per week to a total dose of at least 6000 cGy[7]. For unresectable and non-disseminated NSCLC, a randomized trial[9] clearly demonstrated that 5000–6000 cGy was superior to 4000 cGy in terms of induction of tumor regression : 4000 cGy 55%, 5000 cGy 72%, and 6000 cGy 76%. Although increased radiation dose had beneficial effects on response and local control, no survival advantage was demonstrated[9]. Choi and Doucette found that five year survival following irradiation for localized, unresectable NSCLC did vary with radiation dose. Actuarial 5 year survival rate was 7.5% with the dose greater or equal to 5000 cGy, whereas there was no 5 year survivors from patients receiving less than 5000 cGy[10]. So we intended to analyze our data of 116 patients who received more than 40 Gy irradiation dose. Radiation Therapy Oncology Group (RTOG) demonstrated that patients achieving a complete response had a significant longer median survival than the poor responders, i.e. 14.5 months vs 6 months[11]. In RTOG protocol 7301, survival at 3 year was 23 % for complete responders, 10% for the partial responders, and 5% for patients with stable disease. In RTOG protocol 7302, complete responders had a survival of approximately 20% at 3 year, compared with 4% for partial responders and there were no survivors at 3 year in patients with tumor progression. Our results are also corresponded with above data. In general, overall 5

year survival rate of patients with NSCLC were 20–40% in stage II and 8–10% in stage III[12]. Seoul National University Hospital (SNUH) study (1984) showed that 2 year survival rates in stage II and III were 37% and 21%, respectively [13]. In our results, the poorer survival rate of stage II comparing with that of stage III may be explained by following reasons. The first, the majority of our patients with stage II were medically inoperable cases due to senile, poor pulmonary or cardiac status and other intercurrent disease. The second, at the beginning of our department, the diagnostic modalities were too variable to determine the accurate stages, especially lymph node staging. Shields reported that after surgical staging, there was a change of staging in over 35 % of all cases, especially in lymph node status[14]. Our postoperative RT resluts showed better survival rates in stage II than that stage III, of which was similar to other reports.

At recent, to improve the rates of local cotrol and survival in locally advanced NSCLS patients, there were many trials using combined mordality of chemotherapy and radiation therapy, and radiation therapy with various fractionation schedules.

There was significant reducing of the incidence of distant metastasis in patients with locally advanced NSCLC when combined mordality of VCPC (vindesine, cyclophosphamide, cisplatinum and lomustine) and thoracic radiotherapy was used. But there was no significant difference in overall survival rate compared with radiotherapy alone[15]. And also, EORTC (European Organization for Research and Treatment of Cancer) reported that significant increasing of 2 year survival rate (26%) were seen in the patients treated with concurrent daily cisplatin and thoracic radiotherapy in comparison with radiotherapy alone (13 %)[16].

Using various fractionation scheduled radiotherapy, hyperfractionation radiotherapy made the disease progression free survival at 9 months be 33 % in patients with locally advanced NSCLC when total dose of 69.6 Gy was given[17]. And continuous hyperfrationated accelerated radiotherapy (CHART) showed better results than conventional radiotherapy. Complete response, as observed radiographically, was achieved by 42 %, this can be compared with 15 % of the previous conventional radiotherapy series. At 1 year, the survival rate was 64% compaired with a previous 44% and at 2 years, 34% compaired with a previous 12%[18].

As well known prognostic factors, disease extent, performance status and weight loss were reported from many institutions[3]. Stanley et al described a variety of factors which affected the response to irradiation and survival of patients ; i) patients characteristics such as initial performance status and weight loss in the six months prior to diagnosis. ii) tumor characteristics such as the clinical stage, size of the lesion and histologic type. iii) technical parameters relative to the delivery of irradiation such as the tumor dose and the volume treated[19]. In our data, all the above parameters showed no statistical significance exept the performance status and post irradiation-responses.

Radiation pneumonitis is the clinical syndrome that occurs in upto about 10% of patients and consists of an acute transient phase usually occuring 6 to 12 weeks after radiation therapy[20]. This usually results in a clinical remission except the severe cases which are progressed into radiation fibrosis radiographically over the next 6 to 12 months. The contributing factors are concommitant chemotherapy, repeated courses of radiation therapy and steroid withdrawal[20]. The antitumor agents such as bleomycin, BCNU and busulfan have pulmonary toxicity[20]. These agents are known to be related with the acute or late pneumonitis, fibrosis and pneumopathy. We observed in 22.4% of all patients mild to moderate degree of radiation pneumonitis to be remissive by symptomatic conservative management. Radiation esophagitis, usually self limited and rarely severe, is a well recognized problem in patients receiving substantial radiation therapy to the mediastinum. Mediastinal radiation therapy to

dose over 2000 cGy commonly accompany mild dysphagia and radiographic evidence of impaired motility, but rarely necessitate treatment break or hospitalization or produce demonstrable ulceration or stricture formation[22,23]. We gave the antiacid drugs from the starting day of RT to prevent or modify there prevalent dysfunctions. Of the chemotherapeutic agents, adriamycin has not been reported to cause esophagitis by itself[21], but adriamycin and supervoltage irradiation potentiate each other's toxicity to myocardium and skin[24,25]. Peter et al confirmed the observation of adriamycin enhanced radiation esophagitis in childhood, and extended the minimal radiation dose range to 500 cGy, below the level at which even mild dysphagia has been reported[21]. This finding shows that the interaction of chemo-therapeutic agents and radiation therapy affects not only the severity of the reaction but also the threshold for its development. But in our result, we could not observe these findings. It was perhaps the reason why we did not analyze the incidence and severity of radiation esophagitis by the chemotherapeutic agents and sequence of chemotherapy and radiation therapy. We observed one case of bronchoesophageal fistula. This patient had extrinsic mid-esophageal compression by the cancer mass of the left lung. That fistula was developed between left main stem bronchus and esophagus at the level of the fourth thoracic vertebral body. Radiation induced skin reactions include erythema, dry or wet dermatitis, epilation, achromia, fibrosis, atrophy and telangiectasia. A skin dose of 3000 to 4000 cGy in 3 weeks using photon with a half value layer of 1mm Cu delivered to the cervical skin, will usually produce a brisk acute reaction followed by moderate late changes[26].

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=국문초록=

비소세포성 폐암에서의 방사선 치료 결과

가톨릭의과대학 치료방사선과학교실

계철승 • 장홍석 • 길학준 • 윤세철 • 신경섭

가톨릭 의과 대학 부속 강남 성모 병원 치료 방사선과에서는 1983년 3월부터 1990년 1월까지 방사선 치료를 받았던 비소세포성 폐암 환자 266명중 추적 조사가 가능하고 조사 선량이 40 Gy 이상이었던 116명에 대하여 방사선 치료후의 반응율과 생존율, 그리고 방사선 치료와 관련된 합병증에 대하여 알아보고자 후향성 분석을 시행하였다.

환자들의 성별은 남자가 104명, 여자가 12명이었다. 환자들의 연령은 33세부터 80세까지였으며 중간 값은 53세였다. 추적 기간은 2개월부터 78개월이었으며 중간 값은 18.8개월이었다.

AJC 병기분류에 따라, II기에 속했던 경우가 18명(15.5%), III기가 79명(68.1%), IV기가 19명(16.3%)였다.

Karnofsky의 수행 능력으로 환자들의 전신 상태를 표시 하면, 50 이하가 6명(5.2%), 50에서 60사이가 12명(10.4%), 60에서 70사이가 46명(39.6%), 70에서 80사이가 51명(44.0%)이었고 80이상인 경우는 1명(0.8%)였다.

조직학적으로는 72명(62.8%)의 환자가 편평상피세포암이었으며, 16명(13.8%)이 선암, 7명(6%)이 대세포암, 5명(4%)이 미분화 세포암이었고, 조직 검사를 시행하지 않은 경우를 포함하여 조직학적으로 불분명한 경우가 16명이었다.

치료별로 보면, 60명(51.7%)은 외부 방사선 치료만으로 치료하였으며, 33명(28.4%)의 환자에서는 방사선 치료와 화학 요법을 병행하였다. 수술 후 방사선 치료를 받은 환자는 23명(19.8%)이었으며, 이들 중 5명(4%)에서는 화학 요법이 병행되었다.

관해율은 완전 관해와 부분 관해를 합쳐서 92.5%였다. 병기별 II기, III기와 IV기에서의 1년 생존율은 각각 38.9%, 27.8%와 11.5%였으며, 2년 생존율은 II기, III기, IV기에서 각각 11.1%, 20.8%, 10.5%였다.

치료 결과에 영향을 주는 인자들로는, 수행 능력, 치료 선량, 환자의 연령, 조직학적 형태, 치료에 대한 반응율과 수술 혹은 화학 요법의 병행 여부등에 대하여 분석하였으나 이 들중 수행 능력과 방사선 치료후의 반응 정도가 환자의 생존율에 유의한 영향을 주었다($p<0.05$).