there were 3 locoregional recurrences after surgery. A 3-D treatment planning system with BEV was used for all patients. Patients underwent limited elective nodal irradiation of 56 Gy. The GTV with 1 cm margin received a dose of at least 70 Gy. Acute and late toxicity were estimated according to the RTOG/EORTC score.

**Results:** The mean follow-up was 217 (80–360) days. Seventeen patients received 74 Gy, two had 72 Gy, and one had 70 Gy. One patient died as a result of radiation pneumonitis. In other patients the acute toxicity was acceptable. Seventeen patients were evaluable for response. There were 3 (18%) complete responses, all in patients staged I and II, seven (41%) partial responses, 5 (29%) non-responses and two (12%) local progressions. Two local progressions and two distant failures occurred in stage III patients.

**Conclusions:** Dose escalation > 70 Gy using 3-DCRT in management of NSCLC is feasible with acceptable acute toxicity.

## 560 Exclusive radiotherapy for inoperable stage I Non Small Cell Lung Cancer (NSCLC): A multicentric study

D. Gouders[1], P. Maingon[2], P. Rodrigus[3], B. Hahn[4], M.D. Arnaiz[5], T. Nguyen[6], C. Landmann[7], J.F. Bosset[8], S. Danhier[1], P. Van Houtte[1]. *[1]Institut Jules Bordet, Brussels, Belgium, [2]Centre Leclerc, Dijon; [6]Institut J. Godinot, Reims; [8]CHU Besançon, France, [3]B. Verbeeten Instituut, Tilburg, Netherlands, [4]CHU Vaudois, Lausanne; [7]Kantonsspital Basel, Basel, Switzerland, [5]Institut Català d'Oncologia, Barcelona, Spain*

Radical radiotherapy for NSCLC remains a controversial issue regarding the outcome and the radiation technique. This multicentric study included 87 patients treated in 8 European centers from 1982 till 1994. Criteria of inclusion included a stage I NSCLC, an exclusive irradiation without any chemotherapy except a relapse, no prior cancer neither any endoluminal brachytherapy. Age range was between 56 and 88 years, tumor size from 1 to 10 cm. There was 22 T1N0 and 65 T2N0. Doses varied from 32.5 to 74 Gy and were converted into 2 Gy per fraction schedule: 22 patients received less than 45 Gy and 14 had no mediastinal irradiation. The 2-year survival rates were 26% for the series, 45% for T1 and 20% for T2. Local failure occurred in 27 patients, 5 T1 and 22 T2. A single mediastinal relapse was only seen in 1 patient. Only for T1, doses in excess of 59 Gy decreased the local failure rate: 30% versus 16%. No difference was observed for T2, tumor location or mediastinal irradiation.

In conclusion, results remains dismal in this series of stage I NSCLC with a high rate of local failure outlining the necessity to improve the quality of the radiation treatment by increasing the total dose. Tumor size is also an important prognostic factor for radiotherapy

## 561 How reliable are the conclusions from randomised trials on palliation?: An example from the MRC/BTS LU 17 randomised trial

W. Qian, D.J. Girling, M.K.B. Parmar. *On Behalf of All Collaborators; MRC Clinical Trials Unit, London, UK*

The LU 17 trial was designed to study the role of immediate thoracic radiotherapy (TRT) in preventing or palliating chest symptoms in patients with inoperable non-small cell lung cancer (NSCLC) not suitable for radical TRT with curative intent. Patients were randomised to supportive care plus either immediate TRT (IM), or TRT delayed (D) until needed. The principal outcome measure was defined as alive and without moderate or severe chest symptoms at 6 months. Patients were to be assessed at 1, 2, 4, and 6 months. Between Sept. 1992 and May 1999, 115 patients were randomised into each group. The chi-squared test showed that there was no difference in the prevention of chest symptoms at 6 months at significance level 0.05. However, 12 (10%) of the IM patients received TRT after 4 weeks and 10 received no TRT. 47 (41%) of the D patients received TRT with the median time to start of 3.6 months. In view of the fact that the time to treatment from randomisation was sometimes not very long in the D group and late in the IM group, it is desirable to make comparisons across the 6-month period to assess the robustness of the single 6-month point analysis. However, the numbers of patients assessed in the IM and D groups at 1, 2, 4 and 6 months, were 65 (57%) and 93 (81%), 74 (64%) and 67 (58%), 99 (86%) and 95 (83%), and 96 (83%) and 100 (87%), respectively. A large proportion of assessments was missed and it is impossible to recover such missing information. Various approaches should be implemented to assess the reliability of any conclusions. We first compared the prevention of chest symptoms at each assessment time separately.

Then a statistical model was applied, in which all assessments were combined and possible influencing factors were incorporated. Both of these more extensive approaches showed no difference in the prevention of chest symptoms. Hence, we believe that the initial conclusion of LU 17 based on a single time point analysis, that immediate palliative TRT in minimally symptomatic patients with locally advanced NSCLC confers no improvement of symptom control compared with TRT on symptomatic progression, is robust and reliable.

## 562 Definitive radiation therapy for non-small cell lung cancer directly invading chest wall and vertebral body

M. Furuta, M. Nozaki, Y. Murakami, Y. Kitazumi, M. Iimuro, N. Iwasaki, Y. Hamashima, K. Nagao. *Koshigaya Hospital, Dokkyo University School of Medicine, Koshigaya, Japan*

**Purpose:** To clarify clinical usefulness of radiation therapy for non-small cell lung cancer (NSCLC) directly invading chest wall (T3 disease) and vertebral body (T4 disease).

**Patients and Methods:** From 1985 to February 1999, 22 patients with NSCLC obviously invading chest wall and spine were treated mainly with definitive radiation therapy. Median age was 70 (range 47–83 years), and performance status (0/1/2/3) was 0/11/7/4. Adenocarcinoma was present in 10 patients, squamous cell ca. in 7, and others in 5. Eleven patients had clinical T3N0 disease, four T3N2, one T3N3, five T4N0, and one T4N3. Tumor invasion to the rib/vertebral body was diagnosed by obvious bone destruction on chest radiograph/CT. Intercostal muscle involvement was diagnosed by tumor invasion more than 1 cm outwards from the pleural plane on CT. Chest wall (muscle/rib/both) and vertebral body invasion were noted in 15 (3/4/8) and 7 patients. Median tumor size was 7.0 cm (range 4.3–11.5 cm) for chest wall involvement, while 5.0 cm (3.2–8.0 cm) for vertebral invasion ($p < 0.011$). No statistical differences in age, PS, histology, nodal involvement, and total dose of radiotherapy were noted between the two groups. All patients suffered from pain due to local tumor invasion before the treatment.

**Results:** Pain was reduced in all patients, and administration of analgesic was discontinued in 8 patients (53%) with chest wall invasion and in 4 patients (57%) with vertebral invasion (n.s.). Initial response of tumor to the treatment (CR/PR/NC/PD) was 1/7/7/0 for chest wall disease and 1/1/5/0 for vertebral disease (n.s.). Two-year local control rate including 7 cases lost for follow-up was 34% for chest wall disease and 64% for vertebral disease (n.s.), and the 2-year overall survival rate was 21% and 46%, respectively (n.s.). Median time of local control was 6 months for patients with chest wall involvement, and 11 months for vertebral invasion. Two of 7 patients with vertebral involvement survived over three years without recurrence.

**Conclusions:** Improved QOL is expected by radiation therapy in patients with NSCLC directly invading chest wall and vertebral body. No better local control of the disease was observed in patients with chest wall involvement (T3 disease) compared to those with vertebral involvement (T4 disease).

## 563 Radiation therapy for patients with stage III inoperable squamous cell lung carcinoma

Y. Nakayama, K. Hayakawa, M. Furuta, N. Mitsuhashi, H. Niibe. *Gunma University Maebashi, Japan*

**Purpose:** To evaluate the role of radiation therapy (RT), we analyzed the prognostic factors of the patients with stage III squamous cell carcinoma (SCC) treated with definitive RT.