

Thoracic Oncology Division

Introduction

The incidence of lung cancer in Japan is increasing especially in female and elderly population, and lung cancer has remained the most common cancer death in male patients since 1994. The majority of lung cancer patients are diagnosed at the advanced stage, and the prognosis of these patients is still poor. It is extremely important to establish new effective treatments against advanced lung cancer.

The goals of the Thoracic Oncology Division are to provide the highest quality of treatment and also to establish new effective treatments against lung cancer and other thoracic malignancies through innovative clinical and laboratory research. The Thoracic Oncology Division includes six staff physicians. A total of four chief residents and 11 residents joined the division during 2004. The division organizes a large clinical study group throughout Japan to develop rationally designed novel therapies and to establish the state-of-the-art therapy. The phase I study group was organized in 1996, and some members of the Thoracic Oncology Division play a key role in the phase I study group.

Routine Activities

The staff physicians attend outpatient service for thoracic diseases, and the division has approximately 80 beds in the hospital. Inpatient care is carried out by five teams. Each team consists of one staff physician and one or two residents.

Protocol and case conferences are scheduled for every Monday morning and afternoon, respectively. The journal club is scheduled for Thursday mornings. A chest conference is held on Thursday evening to discuss with thoracic surgeons, pathologists, radiologists and radiation oncologists.

Total of 334 new patients were admitted in 2004. The initial treatments are chemotherapy in 181, chemoradiotherapy in 55, radiotherapy in 39, supportive care or others in 59.

The treatment strategy for the patients is based on the established evidence and/or the clinical protocols approved by the institutional review board. Patients with stage IV non-small cell lung cancer are treated with platinum-based two-drug combination

chemotherapy. For locally advanced stage III non-small cell lung cancer, combined modality treatment with concurrent CDDP-based chemotherapy and thoracic radiotherapy (TRT) is indicated. The standard treatment for patients with recurrent/refractory tumor as a second-line chemotherapy is monotherapy with DTX. Recently, gefitinib, a tyrosin kinase inhibitor of epidermal growth factor receptor (EGFR), showed a response rate of 30% as a second-line treatment, although the impact of gefitinib on survival is still unclear. The standard treatments for limited stage and extensive stage small cell lung cancer have been established based on the results of two JCOG phase III trials. Limited stage patients are treated with concurrent etoposide (ETOP)-CDDP chemotherapy and twice-daily TRT. Extensive stage patients are treated with combination chemotherapy with CDDP plus CPT-11. Patients with small cell lung cancer who achieve complete response to initial treatment receive prophylactic cranial irradiation to prevent brain metastasis.

Research Activities

Research activities of the Thoracic Oncology Division can be divided into five diverse yet interrelated subjects: (1) multi-institutional phase III studies to establish new standard treatments against lung cancer and other thoracic malignancies; (2) combination phase I/II studies to develop new effective chemotherapy regimen, (3) phase I and phase II studies to evaluate new anticancer drugs, (4) pharmacokinetic and pharmacodynamic (PK/PD) studies to investigate interpatient variability, optimal administration schedule and drug-drug interactions; and (5) translational research from bench to bed-side or from bed-side to bench for the development of innovative treatment strategy.

Clinical Trials

Clinical trials carried out in 2004 are shown in the table. Some studies are based on the research program of JCOG, and some are carried out under contract with pharmaceutical companies. Approximately 65% of our inpatients are treated in clinical trials.

● Y. Ohe ●

Clinical Trials Carried Out in 2004

Target disease	Stage	Phase	
NSCLC	advanced	II	gefitinib vs. CBDCA/PTX
NSCLC	advanced	II	weekly PTX
NSCLC	advanced	I/II	S1/CDDP
NSCLC (LCNEC)	advanced	II	CPT-11/CDDP
NSCLC	postope rec.	II	gefitinib
NSCLC (elderly)	advanced	III (JCOG 0207)	DTX vs. CDDP/DTX
NSCLC	III	II	VP/TRT-DTX
NSCLC	III	I/II	nedaplatin/PTX/TRT
NSCLC (elderly)	III	III (JCOG 0301)	CBDCA/TRT vs. TRT
NSCLC	III	I/II (JCOG0402)	CDDP/VNR f/b gefitinib/TRT
NSCLC	recurrent	III (JCOG 0104)	DTX vs. DTX/GEM
NSCLC	recurrent	III	DTX vs. gefitinib
NSCLC	recurrent	II	Ro-508231
NSCLC	recurrent	II	LY231514
SCLC	limited	III (JCOG 0202-MF)	EP/TRT-EP vs. EP/TRT-IP
SCLC	extensive	II	IP vs. IEP
SCLC	recurrent	II	weekly EP/CPT-11
SCLC	recurrent	II	amurubicin
SCLC	recurrent	II	weekly PTX
SCLC (elderly)	extensive	III (JCOG 9702)	ETP/CBDCA vs. EP
Thymoma	IV	II (JCOG 9606)	weekly CODE
Thymoma	III	II (JCOG 9605)	weekly CODE-Ope/TRT
NSCLC, pericardial effusion		III (JCOG 9811)	drainage +/- BLM
Lung cancer, anemia		PK/PD	KRN321
Lung cancer, anemia		II	KRN321
Lung cancer, anemia		III	EPOCH
Lung cancer, neutropenia		II	KRN125
NSCLC		PK	gefitinib
Lung cancer (Phase I Team)		Pharmacogenomics	paclitaxel, gemcitabine, CPT-11
Solid tumor	advanced	I	JNS002, HTI-286, ABT-627 BMS-247550, 2C4, AMG706

NSCLC; non-small cell lung cancer, SCLC; small cell lung cancer, LCNEC; large cell neuroendocrine carcinoma
CBDCA; carboplatin, PTX; paclitaxel, DTX; docetaxel, CDDP; cisplatin, VP; vinorelbine/cisplatin, GEM; gemcitabine,
EP; etoposide/cisplatin, IP; irinotecan/cisplatin, IEP; irinotecan/etoposide/cisplatin,
CPT-11; irinotecan, ETP; etoposide, CODE; cisplatin/vincristine/doxorubicin/etoposide,
BLM; bleomycin, TRT; thoracic radiotherapy

Number of New Inpatients in 2004

Non-small cell lung cancer	267
Adenocarcinoma	187
Squamous cell carcinoma	45
Others	35
Small cell lung cancer	48
Thymoma/thymic cancer	8
Mesothelioma	5
Other solid tumor	6
Total	334

Initial Treatment for New Inpatients in 2004

Total number	334
Chemotherapy	181
Chemoradiotherapy	55
Radiotherapy	39
Supportive care	15
Others (no treatment, examination, etc.)	44