

Breast and Medical Oncology Division

Introduction

The Breast and Medical Oncology Division is committed to improving the treatment of adult patients with cancer. To meet this mission, we engage in a broad range of translational research, clinical research, patient care, and training of clinical fellows.

We mainly treat patients with breast cancer, gynecologic cancer, sarcomas of soft tissues, extragonadal germ cell tumors and tumors of unknown primary sites. Our cardinal goal is to provide comprehensive, state-of-the-art care for individual patients. In order to achieve this goal, practicing of evidence-based management of patients on one hand is indispensable, and conducting clinical research is also very important on the other hand. Here in this annual report, the issues that we confront presently in the National Cancer Center Hospital are made clearly.

Routine Activities

The members of our division have been composed by 4 staff physicians, 3 chief clinical fellows and 1 clinical fellow since 2003. Staff physicians have 3-day duty of outpatient clinic a week, and chief clinical fellows have 2-day duty under the supervision of staff physicians. Almost all chemotherapy regimens except cisplatin are given in outpatient setting. In the meantime, we have 30-40 inpatients. Clinical teams leading by chief clinical fellows provide care for inpatients. In order to share the most up-to-date medical problems of each patient, we have a conference of morning briefing from 8:00 to 8:30 AM everyday. All staff physicians, clinical fellows and clinical trainees attend the meeting. Newly admitted patients and patients with problems are quickly reviewed and relevant evidence-based discussion may follow. In addition to daily rounds, a ground round are scheduled on every Friday. We organize multi-

disciplinary case conferences for breast cancer and gynecologic cancer patients every week. Medical oncologists, surgical oncologists, gynecologic oncologists, radiation oncologists, diagnostic radiologists and pathologists discuss the best care plan for each patient. We have started a TV case conference with a breast cancer treatment group of National Kyushu Cancer Hospital since 2003. Evidence-based practical approach for patient care has been presented and educational materials are provided for all participants.

Research Activities

Our research activities are based on translational research and clinical research. In translational research, we are collaborating basic researchers (Dr Nishio's laboratory) and biostatisticians (Department of Biostatistics of Kitasato University) and launched innovative translational research programs using DNA microarray technique in order to define predictive factors for neoadjuvant therapy of breast cancer.

In clinical research, we are dedicating to develop a new therapeutic approach for adult solid tumors. We are conducting many clinical trials, and are leading multi-center cancer treatment clinical trial groups in the field of breast cancer and gynecologic cancer in Japan. On the other hands, we are conducting in-house clinical trials for specific oncologic treatment.

In breast cancer, most concern has recently been moving to primary chemotherapy. We have approached the primary chemotherapy for breast cancer for several years. In our in-house clinical trial, Tokunaga et al. reported that neurotoxicity might be enhanced when doxorubicin combined with docetaxel followed by weekly paclitaxel are given as primary chemotherapy.

In gynecologic cancer, we have pioneered multi-center clinical trials as medical oncologists in Japan. We are committed to JCOG (Japan Clinical Oncology

Group) and JGOG (Japanese Gynecologic Oncology Group). JGOG is the largest clinical trial group in gynecologic cancer. JGOG was recently reformed as a non profitable organization (NPO), and has starting international collaboration in clinical trial with GOG (Gynecologic Oncology Group) in USA.

An approach to primary unknown cancer is enterprising for us, because the concept of "unknown primary site of cancer" is not widely accepted in Japanese physicians. So, we are innovating a new chemotherapy regimen for primary unknown cancer.

Clinical Trials

Ongoing clinical trials are listed in Table 1. HERA is international multi-institutional randomized trial of adjuvant herceptin vs. no herceptin for HER 2 positive primary breast cancer. JCOG 9802 is a randomized

study of the first line chemotherapy comparing AC (adriamycin and cyclophosphamide) and docetaxel in metastatic breast cancer patients. 441 patients were accrued and now are on following-up. Three neoadjuvant trials are active and DNA microarray is analyzed as ancillary study respectively. In the field of gynecological cancer, multi-institutional trials of chemotherapy are actively conducted. For the front-line chemotherapy against ovarian cancer, randomized trial of conventional paclitaxel and carboplatin vs. dose-dense weekly paclitaxel and carboplatin is activated. In addition to these active trials, a phase III trial of cisplatin and paclitaxel vs. carboplatin and paclitaxel for metastatic cervical cancer, and a phase II trial for sarcoma patients as a investigator initiated IND (Investigational New Drug) trial are prepared for activating in 2004. ● Y. Fujiwara ●

Table 1 Ongoing Clinical Trials in 2003

Target disease	Phase	Protocol/Regimen
Breast cancer	III	NSASBC02, AC, DTX, PTX
	III	JCOG9802, AC, DTX
	III	JCOG01111, TAX1 to 3
	III	EORTC10951, exemestane vs. TAM
	III	CGP42446
	II, III	TAP-144-SR
	II	S1
Ovarian cancer	II	SK&F104864
Endometrial cancer	II	Docetaxel
	II	Paclitaxel
Cervical cancer	III	JCOG0102, NAC
	II	Paclitaxel/Carboplatin
Cancer of unknwn primary site	II	Docetaxel/CDDP
Metastatic bone tumor	I	CAL

Table 1. Ongoing Clinical Trials in 2003

Disease		Phase	Protocol/Regimen
Breast cancer	adjuvant	III	NSASBC02, 4 arms RCT ACT vs. ACD vs. PTX vs. DTX
	adjuvant	III	NSASBC03, TAM vs. anastrozole
	adjuvant	III	HERA, herceptin
	metastatic	III	JCOG9802, 3 arms RCT AC vs. DTX vs. AC→DTX
	metastatic	III	JCOG0111, tri-weekly vs. weekly paclitaxel
	neoadjuvant	I	CEF→weekly paclitaxel
	neoadjuvant	I	weekly paclitaxel
	neoadjuvant	I	anastrozole
	metastatic	I	paclitaxel/carboplatin
Ovarian cancer	metastatic		pharmacologic study of weekly paclitaxel
	advanced	III	JGOG3016, standard vs. dose dense paclitaxel/carboplatin
Ovarian stromal tumor	neoadjuvant	feasibility	JCOG0206, neoadjuvant chemotherapy
	metastatic	I	GOG187, paclitaxel
Cervical cancer	neoadjuvant	III	JCOG0102, neoadjuvant BOMP
	metastatic	I	paclitaxel/carboplatin
Primary unknown cancer		I	carboplatin/irinotecan
Urotheal cancer	metastatic	I	weekly paclitaxel/carboplatin
Metastatic bone tumor		I	CAL