Comprehensive Support Project

Survey of patients with pathological stage I(T1> 2cm) NSCLC, who were excluded from a clinical trial of adjuvant therapy (CSPOR LC-03)

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Conflict of Interest disclosure slide for representative speakers or investigators

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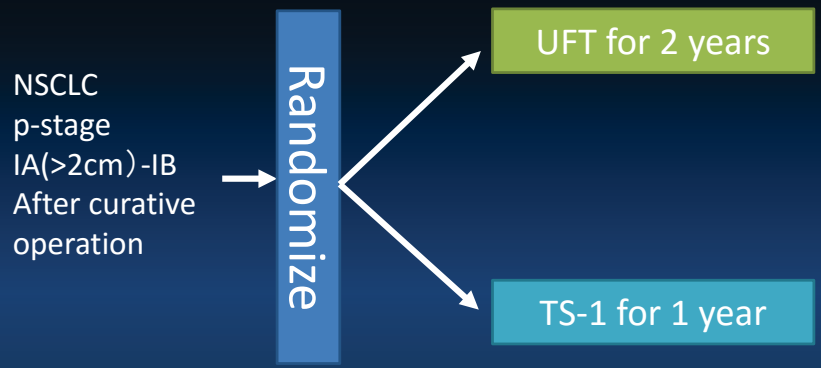
JSMO Japanese Society of Medical Oncology

Study setting

This study is a multicenter observational cohort study for the patients who had completely resected p-stage I (tumor size>2 cm) NSCLC but were not enrolled in a clinical trial, such as JCOG0707 study.

JCOG0707
Randomized phase III trial



Primary Endpoint: OS
Sample size: *480* in each arm
Acceptable TRD rate <1%

Purpose

This study (CSPOR LC-03) consists of two subsets of studies (study A and B)

Study A

Study A is conducted to clarify background factors and postoperative treatment of patients who had completely resected p-stage I (>2cm) NSCLC.

Purpose

Study B

Study B is conducted to clarify the long-term survival of patients (with a follow-up period>5 years) enrolled in Study A.

Methods of analysis

The reasons why the patients have not participated in the clinical trial (JCOG0707) are classified into the 5 categories

1) Failure to satisfy the eligibility criteria for clinical studies.
2) Refusal of patients.
3) Protocol was temporarily unavailable.
4) Attending physician forgot to give information about the study.
5) Attending physician judged that postoperative chemotherapy should be specifically decided for the patient.

Methods of analysis

Study B
The patient backgrounds and overall survival will be analyzed among the 3 groups.

1) Patients who have participated in JCOG0707 study and have received allocated postoperative chemotherapy.

2) Patients who have not participated in JCOG0707 study but have received postoperative chemotherapy as a clinical practice.

3) Patients who have neither participated in JCOG0707 study nor received any postoperative chemotherapy.

Endpoints

Study A

Primary endpoint:

Reasons why the patients have not been enrolled in the clinical trial (JCOG0707) and the percentages

Secondary endpoints:

(1) Patient backgrounds
(2) Implementation rate, contents, and adherence for postoperative chemotherapy

Endpoints

Study B

Primary endpoint:

Overall survival*

Secondary endpoints:

(1) Disease specific survival*
(2) Patient backgrounds*
(3) Implementation rate and adherence for postoperative chemotherapy*
(4) Correlations among above endpoints

* Will be comparatively analyzed with the survival data of the patients enrolled in JCOG0707 study.

Eligibility criteria

(1) Pathologically diagnosed NSCLC except for low-grade malignant tumors.
(2) Pathological stage I disease with a tumor size >2cm.

(3) Complete (R0) resection has been confirmed pathologically.

(4) Lobectomy or larger lung resection has been performed.

(5) Hilar/mediastinal lymph node dissection (ND2a or selective lymph node dissection) has been performed.
(6) No prior treatment before lung resection.

(7) Not enrolled in a prospective clinical trial, such as JCOG0707 study.

Enrollment and study period

Enrollment period:

From Jan/ 2015 to Jun/ 2015

Study period:

(Study A) From Jan/ 2015 to Mar/ 2016
(Study B) From Apr/ 2016 to Mar/ 2019

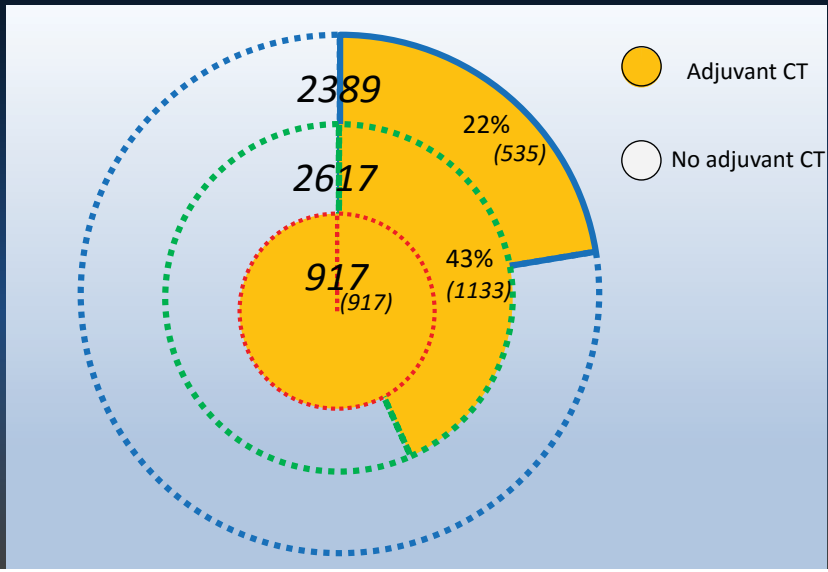
Results

Enrollment case in the survey (including JCOG0707)

JCOG0707 917

This study Eligible cases 2617(52%) } 5006 } Total **5923**

Not eligible cases 2389(48%)



Reasons for non-enrollment of JCOG0707 study (Not eligible case)

Not eligible case	2389
Concomitant malignancy	797 (33%)
Attending physician's clinical judgment	530 (22%)
Delay of recovery from surgery	386 (16%)
Age limitation	292 (12%)
Others	384 (16%)

Reasons for non-enrollment of JCOG0707 study(Eligible Case)

Eligible Case	2617
Patient refusal	1810 (69%)
Decision by attending physicians (No adjuvant chemotherapy) (Need adjuvant chemotherapy)	536 (21%) (414) (122)
Forget of physician's clinical judgement	190 (7%)
Protocol stopped-duration	56 (2%)
Others	25 (1%)

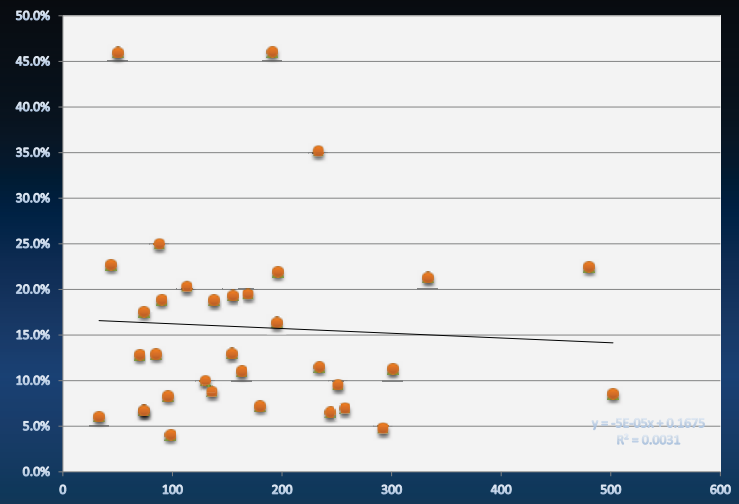
Back Ground (Eligible case)

		JCOG0707 n=917	Eligible Case n=2617	
			+Adjuvant(1133)	-Adjuvant (1484)
sex	Male	526	635	767
	Female	391	498	717
age	-39	5	11	8
	40-49	38	56	34
	50-59	160	195	197
	60-69	411	497	558
	70-79	298	370	650
	80-	5	4	37
	Median	66(33-80)		69(20-93)
tissue-Type	AD	740	912	1172
	SQ	131	151	252
	Other	46	90	60
pTNM	Ⅰ A	423	387	872
	Ⅰ B	490	673	543
	Ⅱ A	4	73	69

Proportion of trial participation(ACT+or-) by institutional

Post Therapy		n=5006
Adjuvant chemotherapy	Yes	No
	1659	3338
A institution	5.1%	94.1%
B institution	61.8%	38.2%
Mean	33%	67%

The accrual rate to JCOG0707



The accrual rate to JCOG0707 was various by institutions (4.1 to 46.1%), but was 25.9% (917 / [917+2617]) as a whole.

Results

Majority of patients (n = 3338, 66.7%) received no adjuvant chemotherapy.
This proportion differed according to p-T factor (T1: 75.3% vs. T2 : 57.8%, p<0.001).

Standard UFT and experimental S-1 were given in 1550 (31.0%) and 21 (0.4%) patients, respectively.
Among those who received adjuvant UFT, 971 (62.6%) took UFT for one year or longer. (cf. 70.7% in JCOG0707)

Conclusion

1. Only a minority of candidate pts, even when they met the eligibility criteria, were accrued to JCOG0707.
2. The excluded cases were treated with observation only (high age or stage IA) or standard therapy.
3. Further analysis of the population, including OS, would be needed to define the external validity of the randomized trial.
   (Study B will be compared with the data for the patients enrolled in JCOG0707 study).

Enrolled Institutions

1	National Cancer Center Hospital	13	National Hospital Organization Kyushu Cancer Center	25	Okayama University Hospital
2	National Cancer Center Hospital East	14	Nagoya University Hospital	26	Kyorin University Hospital
3	The Cancer Institute Hospital of JFCR	15	Osaka City General Hospital	27	Kumamoto University Hospital
4	Kanagawa Cancer Center	16	Hyogo Cancer Center	28	Tokyo Metropolitan Cancer and Infectious Diseases Center Komagome Hospital
5	Shizuoka Cancer Center	17	Kanazawa University Hospital	29	Kurashiki Central Hospital
6	Tokyo Medical University Hospital	18	Osaka Medical Center for Cancer and Cardiovascular Diseases	30	Gunma Prefectural Cancer Center
7	Aichi Cancer Center Hospital	19	Ibaraki Prefectural Central Hospital	31	Osaka Prefectural Medical Center for Respiratory and Allergic Deseases
8	Kyoto University Hospital	20	Kumamoto Chuo Hospital	32	Yokohama City University Medical Center
9	Shikoku Cancer Center	21	Hiroshima University Hospital	33	Tochigi Cancer Center
10	Chiba University Hospital	22	Tohoku University Hospital	34	National Hospital Organization Kure Medical Center and Chugoku Cancer Center
11	Niigata Cancer Center Hospital	23	Sendai Medical Center		
12	Juntendo University Hospital	24	Nagasaki University Hospital		

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