

JCOG Report to ATC

JCOG Experience with ATC Method 1 for JCOG 0403

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Radiotherapy Support Center**

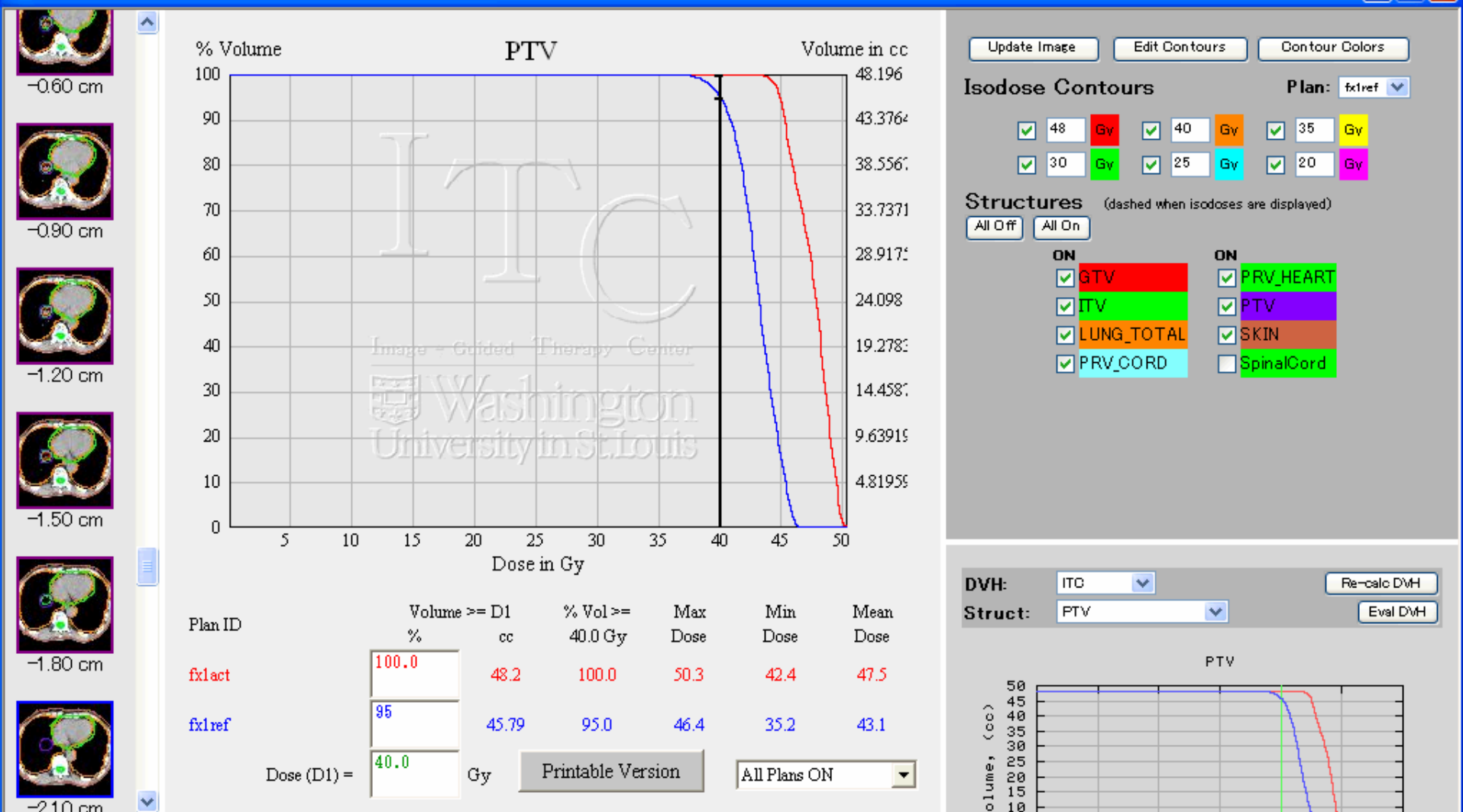
A phase II study of stereotactic body radiation therapy in patients with T1N0M0 non-small cell lung cancer (JCOG 0403)

- To evaluate the safety and efficacy of stereotactic body radiation therapy (SBRT) for T1N0M0 NSCLC
 - ? SBRT as a standard care in medically inoperable patients
 - ? SBRT as a treatment option in operable patients
- Primary endpoint: 3-year overall survival
- Sample size 165
 - Operable, 65; Inoperable, 100
 - Accrual: 3 years

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- Fractionation, 48 Gy/4 fx/4-8 days
- Prescription point, isocenter
- Lung heterogeneity correction, yes
- Algorithm in MU calculation, Clarkson

-Dose distribution calculated by Superposition is also submitted as a reference plan.



Update Image | Edit Contours | Contour Colors

Isodose Contours Plan: fxlref

- 48 Gy
- 40 Gy
- 35 Gy
- 30 Gy
- 25 Gy
- 20 Gy

Structures (dashed when isodoses are displayed)

All Off | All On

- GTV
- ITV
- LUNG_TOTAL
- PRV_CORD
- PRV_HEART
- PTV
- SKIN
- SpinalCord

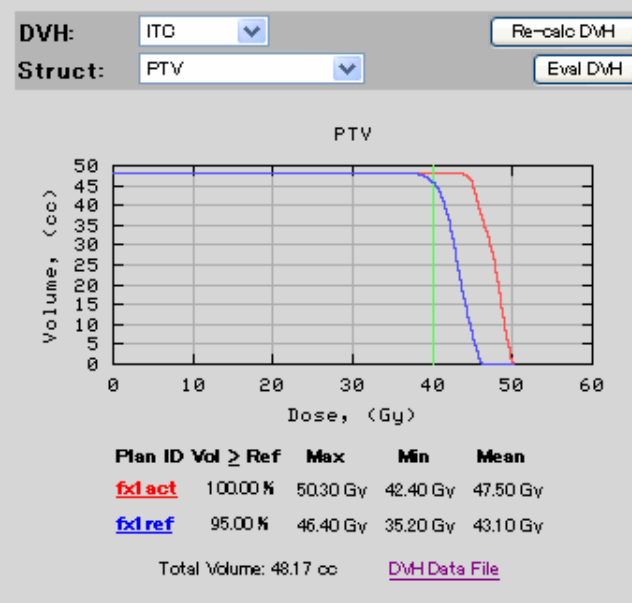


Image Click Mode Re-Center

Window/Level Preset: Default (soft tissue)

Window: 470 | Level: 20 | Update

EXIT

A phase II study of stereotactic body radiation therapy in patients with T1N0M0 non-small cell lung cancer (JCOG 0403)

Dose constraint (excl. the rib and the chest wall)

LUNG_TOTAL-PTV	40Gy/4fx, $\leq 100\text{cc}$ Mean Lung Dose, $\leq 18\text{Gy}$ V15, $\leq 25\%$ V20, $\leq 20\%$	PRV_HEART	48Gy/4fx, $\leq 1\text{cc}$ 40Gy/4fx, $\leq 10\text{cc}$
PRV_CORD	25Gy/4fx, max	PRV_GREAT_VESS	48Gy/4fx, $\leq 1\text{cc}$ 40Gy/4fx, $\leq 10\text{cc}$
PRV_ESOPHAGUS	40Gy/4fx, $\leq 1\text{cc}$ 35Gy/4fx, $\leq 10\text{cc}$	PRV_BPplex_CNTR	48Gy/4fx, $\leq 1\text{cc}$ 40Gy/4fx, $\leq 10\text{cc}$
PRV_STOMACH	36Gy/4fx, $\leq 10\text{cc}$ 30Gy/4fx, $\leq 100\text{cc}$	PRV_BPplex_IPSI	48Gy/4fx, $\leq 1\text{cc}$ 40Gy/4fx, $\leq 10\text{cc}$
PRV_BOWEL	36Gy/4fx, $\leq 10\text{cc}$ 30Gy/4fx, $\leq 100\text{cc}$	PRV_OTHERS	48Gy/4fx, $\leq 1\text{cc}$ 40Gy/4fx, $\leq 10\text{cc}$
PRV_TRACHEA	40Gy/4fx, $\leq 10\text{cc}$	SKIN (isodose line)	$\leq 40\text{Gy/4fx}$
PRV_MAIN_BRONC	40Gy/4fx, $\leq 10\text{cc}$		

**JAPAN CLINICAL ONCOLOGY GROUP
JCOG 0403**

A PHASE II STUDY OF STEREOTACTIC BODY RADIATION THERAPY IN PATIENTS WITH T1N0M0 NON-SMALL CELL LUNG CANCER

Institutions participating in protocol JCOG 0403 submit digital data representing CT images, structure sets, treatment plans, 3D dose distributions, and DVHs to Dr. Satoshi ISHIKURA in the Division of Radiation Oncology, National Cancer Center Hospital East, Kashiwa, JAPAN.

Dr. Ishikura forwards these data to the Image-guided Therapy QA Center (ITC) in St. Louis, Missouri, USA for processing. Data are reviewed by Dr. Ishikura or his delegate using the ITC Remote Review Tool.

Currently, 13 institutions are eligible to enroll patients and capable of digital data submission on JCOG 0403. (One other institution, which is eligible to enroll patients but NOT capable of digital data submission, has been exceptionally allowed to participate in the study.)

Institution	Location	RTP System	Approval Date
Hiroshima University	Hiroshima, Japan	Philips Pinnacle3	Nov 5, 2004
Hokkaido University	Sapporo, Japan	CMS FOCUS/Xio	Aug 11, 2004
Institute of Biomedical Research and Innovation	Kobe, Japan	CMS FOCUS/Xio	Aug 6, 2004
Keio University	Tokyo, Japan	CMS FOCUS/Xio	Nov 2, 2004
Kitasato University	Sagamihara, Japan	Philips Pinnacle3	Dec 27, 2004
Kyoto University	Kyoto, Japan	Varian Eclipse	Aug 25, 2004
Kyushu University	Fukuoka, Japan	Varian Eclipse	Nov 24, 2004
Nihon University	Tokyo, Japan	CMS FOCUS/Xio	Oct 21, 2004
Sapporo Medical University	Sapporo, Japan	CMS FOCUS/Xio	Sep 27, 2004
Tohoku University	Sendai, Japan	Varian Eclipse	Oct 1, 2004
Tokyo Metropolitan Komagome Hospital	Tokyo, Japan	CMS FOCUS/Xio	Sep 3, 2004
Tokyo Women's Medical University	Tokyo, Japan	CMS FOCUS/Xio	Dec 27, 2004
University of Yamanashi	Tamaho, Japan	CMS FOCUS/Xio	Jul 29, 2004

JCOG0403 • Ⅸ ⅠA • Ⅹ f V Fg

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RTP/version	/	memo:		
Ⅸ + Ⅸ Ⅸ Ⅸ Ⅸ	/ /	Ⅸ + Ⅸ Ⅸ Ⅸ Ⅸ / /	Ⅸ + Ⅸ Ⅸ Ⅸ Ⅸ	" Ⅸ
PTV	target delineation (margin) Ⅸ Ⅰ j		1 Per protocol	2 Deviatbn
PTV dose	Plan/actual	Prescribed (Gy/fx)	Max (Gy)	Min (Gy)
			HI (ratb)	D95 (Gy)
	Plan/reference	Prescribed (Gy/fx)	Max (Gy)	Min (Gy)
			HI (ratb)	D95 (Gy)
Dose constraint (excl the rib and the chest wall)				
LUNG_TOTAL-PTV	40Gy/4fx, ≤100cc		cc	1 Per protocol 2 Deviatbn
	Mean Lung Dose, ≤18Gy		Gy	1 Per protocol 2 Deviatbn
	V15, ≤25%			1 Per protocol 2 Deviatbn
	V20, ≤20%			1 Per protocol 2 Deviatbn
PRV_CORD	25Gy/4fx, max		Gy	1 Per protocol 2 Deviatbn
PRV_ESOPHAGUS	40Gy/4fx, ≤1cc		cc	1 Per protocol 2 Deviatbn
	35Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
PRV_STOMACH	36Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
	30Gy/4fx, ≤100cc		cc	1 Per protocol 2 Deviatbn
PRV_BOWEL	36Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
	30Gy/4fx, ≤100cc		cc	1 Per protocol 2 Deviatbn
PRV_TRACHEA	40Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
PRV_MAIN_BRONC	40Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
PRV_HEART	48Gy/4fx, ≤1cc		cc	1 Per protocol 2 Deviatbn
	40Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
PRV_GREAT_VESS	48Gy/4fx, ≤1cc		cc	1 Per protocol 2 Deviatbn
	40Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
PRV_BP_LX_CNTR	48Gy/4fx, ≤1cc		cc	1 Per protocol 2 Deviatbn
	40Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
PRV_BP_LX_PSI	48Gy/4fx, ≤1cc		cc	1 Per protocol 2 Deviatbn
	40Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
PRV_OTHERS ()	48Gy/4fx, ≤1cc		cc	1 Per protocol 2 Deviatbn
	40Gy/4fx, ≤10cc		cc	1 Per protocol 2 Deviatbn
SKIN (isodose line)	≤40Gy/4fx			1 Per protocol 2 Deviatbn

JCOG0403 Final Review

As of 2005/6/4

Case #	Submission	Completion of QA review
1	completed	2005/3/10
2	completed	2005/3/10
3	completed	2005/2/19
4	completed	2005/3/10
5	completed	2005/2/19
6	completed	2005/4/7
7	completed	2005/2/19
8	completed	2005/3/23
9	completed	2005/2/19
10	completed	2005/2/19
11	completed	2005/2/19
12	completed	2005/2/19
13	completed	2005/3/10
14	completed	2005/3/10
15	completed	2005/3/10
16	completed	2005/4/7
17	completed	2005/3/23
18	completed	2005/3/23
19	completed	2005/3/23
20	completed	2005/4/28
21	not yet	
22	completed	2005/4/21
23	completed	2005/4/28
24	not yet	
25	completed	2005/5/12
26	completed	2005/5/26
27	not yet	
28	not yet	

- We would also like to use the ATC resources in a coming phase I/II dose escalation trial using SBRT, if possible.

Or

- We would like to have our own data base to introduce the Netsys/Websys in Japan.