

national practice processes of radiotherapy for selected malignancies over certain periods of time (3). In the PCS survey, detailed information about the structures, processes and outcomes of radiation treatment was collected. The 2003–05 PCS, which is the most recent PCS, included questionnaires designed to assess treatment planning practices currently in use. The goal of this current report is to identify the treatment planning process for patients with localized prostate cancer in Japan.

PATIENTS AND METHODS

The methods used in data collection for the PCS have been described previously (1–3). From a stratified Facilities Master List, 34 hospitals were randomly selected from A institutions (university hospitals/cancer centers) and 27 hospitals from B institutions (non-academic hospitals) (Table 1). Between August 2006 and September 2008, each of the chosen facilities was visited by member physicians of the PCS group. A total of up to 10 medical records from each institution were randomly selected and reviewed. The following eligibility criteria were used in the process survey. The patients were required to have been diagnosed with adenocarcinoma of the prostate without evidence of distant metastases; they had to have been treated with radiotherapy between 2003 and 2005; and the patients must not have been diagnosed with any other malignancy nor have been previously treated with radiotherapy. From a total of 592 eligible cases (Table 1), 397 patients were evaluated who had been treated radically with external photon beam radiotherapy. Patients who were treated after surgery or after progression from hormonal therapy were excluded.

In this paper, we focused on the patterns of radiation treatment planning and delivery for localized prostate cancer. The data were stratified according to whether the treatment took place in academic or non-academic facilities, and compared on this basis. For statistical analysis, the differences between proportions were tested by the χ^2 test. A *P* value <0.05 was considered to indicate a statistically significant difference.

Table 1. The number of patients examined in this analysis

	No. of facilities	No. of total prostate patients	No. of patients in this study
A institutions (university hospitals and cancer centers)			
A1 (≥ 410 patients per year)	17	180	111
A2 (<410 patients per year)	17	164	105
B institutions (non-academic hospitals)			
B1 (≥ 130 patients per year)	15	148	117
B2 (<130 patients per year)	12	100	64
Total	61	592	397

RESULTS

TREATMENT PLANNING AND IMPLEMENTATION

The computed tomography (CT) simulation usage rates are shown in Table 2. CT data were used for planning in ~90% of the patients. The majority of the CT data were obtained from dedicated CT scanners in A institutions, but almost half of the CT data were obtained from diagnostic CT scanners in B institutions. X-ray simulation was used more frequently in B institutions. Contrast was rarely used for treatment planning.

Verification of the treatment fields using portal films or electric portal imaging devices was undertaken in most of the patients. However, regular or multiple verifications in addition to initial treatment and/or portal volume changes were performed in only 30% of the patients.

POSITION AND IMMOBILIZATION OF PATIENTS

Simulations and treatments were performed in the supine position in almost all patients (Table 3). Immobilization devices were used for only 15% of the patients.

TREATMENT TECHNIQUES

Treatment techniques are shown in Table 4. The most commonly used photon energy was 10 MV. In B institutions, lower energies <10 MV were used more frequently.

Table 2. Treatment planning and implementation

	Stratification ^a		<i>P</i> value
	A	B	
Simulation			0.021
CT simulation with/without X-ray simulation	203 (94.0%)	158 (87.3%)	
Dedicated CT	171 (79.2%)	82 (45.3%)	
Diagnostic CT	32 (14.8%)	76 (42.0%)	
X-ray simulation only	13 (6.0%)	23 (12.7%)	
Contrast used for treatment planning			0.871
None	213 (98.6%)	179 (98.9%)	
Rectal barium	0	2 (1.1%)	
Urethrogram	1 (0.5%)	0	
Both	1 (0.5%)	0	
Portal verification			0.031
None	9 (4.2%)	0	
Initial treatment or field change only	147 (68.1%)	128 (70.7%)	
Regular or multiple intervals	60 (27.8%)	53 (29.3%)	

CT, computed tomography.

^aBecause some data were missing, the total numbers of patients may be less than the actual numbers.

Table 3. Position and immobilization of patients

	Stratification		P value
	A	B	
Position			0.403
Supine	216 (100%)	179 (98.9%)	
Prone	0	2 (1.1%)	
Immobilization			0.434
None	174 (80.6%)	158 (87.3%)	
Cast ^a	24 (11.1%)	14 (7.7%)	
Body frame ^b	9 (4.2%)	9 (5.0%)	
Others/unknown	9 (4.2%)	0	

^a'Cast' was defined as a firm body support system, such as vacuum pillows.
^b'Body frame' was defined as an immobilized system, such as a system using a base plate and body shells.

The typical beam arrangement for treatment of the prostate consisted of a four-field box. Treatment plan included a moving field in one-third of the patients. 3D conformal techniques including IMRT were generally applied less frequently in B institutions than in A institutions (A1, 97.3%; A2, 53.3%; B1, 59.8%; and B2, 37.5%). Modernized multileaf collimators (MLC) with leaf widths ≤10 mm were used in about two-thirds of the patients.

TOTAL DOSE

The median dose given to the prostate was 70 Gy (A1, 70 Gy; A2, 70 Gy; B1, 67.8 Gy; and B2, 66 Gy). Figure 1 shows the distributions of doses delivered to the prostate according to the leaf width of MLC. Although the doses were affected by the leaf width, there were no significant differences between the dosages delivered at 5 mm and those delivered at 10 mm MLC leaf width (P = 0.12).

DISCUSSION

This is the first detailed survey report focusing on the radiation treatment planning for prostate cancer in Japan. This report provides a clear picture of the present practices relating to treatment planning in this country. Because few reports exist on treatment planning practices for prostate cancer (4,5), these data will serve as a baseline for future surveys as well as for the multicenter trials including radiotherapy.

The results in this study show that contrast was rarely used for treatment planning in Japan. In the 1989 US PCS (4), contrast was used in the bladder and rectum in 25% and 34% of the patients, respectively. However, only 51% of the patients had CT data for planning in the 1989 PCS (4). It is recommended that rectal or bladder dye should be utilized to

Table 4. Treatment techniques

	Stratification		P value
	A	B	
Energy (MV)			0.0000
4-5.9	10 (4.8%)	13 (7.4%)	
6-9.9	8 (3.9%)	42 (24.0%)	
10-14.9	149 (72%)	113 (64.4%)	
≥15	40 (19.3%)	7 (4.0%)	
Field arrangement for the prostate			0.0000
2-field	36 (16.8%)	15 (8.4%)	
3-field	7 (3.3%)	2 (1.1%)	
4-field	49 (22.9%)	71 (39.7%)	
5-field	33 (15.4%)	4 (2.2%)	
≥6-field	26 (12.2%)	12 (6.7%)	
Rotational	21 (9.8%)	16 (8.9%)	
Pendulum	41 (19.2%)	54 (30.2%)	
3DCRT/IMRT technique			0.0000
3DCRT-dynamic	64 (29.6%)	54 (29.8%)	
3DCRT-static	87 (40.3%)	38 (21.0%)	
IMRT-step and shoot	13 (6.0%)	2 (1.1%)	
IMRT-sliding window	0	0	
None	52 (24.1%)	87 (48.1%)	
Width of multileaf collimator leaves			0.0000
5 mm	38 (17.6%)	53 (29.3%)	
10 mm	120 (55.6%)	52 (28.7%)	
20 mm	10 (4.6%)	19 (10.5%)	
Block	15 (7.0%)	31 (17.1%)	
None	26 (12.0%)	26 (14.4%)	
Unknown	7 (3.2%)	0	

3DCRT, three-dimensional conformal radiotherapy; IMRT, intensity-modulated radiotherapy.

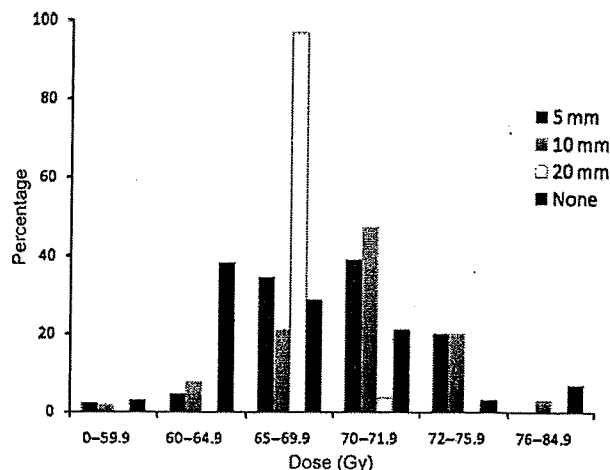


Figure 1. Distribution of radiation doses delivered to the prostate according to the leaf widths of multileaf collimators.

help design field blocking and beam arrangements, if X-ray simulation is used (4,6). However, contrast may not be needed to determine the position of the prostate when CT simulation is performed. In this survey, there were no questionnaires on the usage of magnetic resonance imaging (MRI) images for prostate cancer treatment planning. Going forward, it is expected that MRI/CT image fusion techniques will be increasingly important to define the anatomical structures including the prostate (7,8). The next PCS survey will take this issue into consideration.

Regular or multiple verifications of the treatment fields were performed in only 30% of the patients in this study. In the USA, radiation fields were verified with regular intervals in 60% of the prostate patients surveyed in the 1989 PCS (4). It is hoped that if electric portal imaging devices become more popular in Japan, verification of the treatment fields will be performed more frequently.

Simulations and treatments were performed in the supine position in almost all patients. Published literature suggests a variation in results between the use of the prone and supine positions for prostate cancer radiotherapy. Several authors demonstrated that the rectal dose was reduced in the prone position (9,10). However, in the absence of immobilization devices, daily setup reproducibility may be less accurate for the prone position, primarily due to systematic setup variations (10). Patient positioning procedures in prostate radiotherapy should be evaluated in each institution, in particular if the radiation doses to the prostate are high.

Immobilization was used in only 15% of the patients. This may be in part because immobilization devices for body malignancies are not covered by health insurance in Japan. As mentioned above, patient immobilization can be an important contributor to the reproducibility and accuracy of radiotherapy (11). More widespread use of immobilization devices will also be required with an increase in treatment using 3DCRT or IMRT, which utilize higher dosages of radiation.

The radiation doses delivered to the prostate were affected by the leaf width of MLC. However, there were no significant differences between a 5 mm and a 10 mm MLC leaf size. Leal et al. (12) showed that the impact on the clinical dose distribution due to the MLC leaf width change from 10 to 5 mm is quite low on the dose distribution in patients treated with 3DCRT and IMRT. On the other hand, Wang et al. (13) insisted that the use of the micro-MLC for IMRT of the prostate resulted in significant improvement in the dose distributions to the prostate and critical organs. Although narrower leaves give better sparing of organs at risks, the clinical value should be carefully evaluated.

Several significant variances in the process according to the stratification of institutions were also observed. Although CT data were used for planning in ~90% of the patients, 3D conformal techniques including IMRT were applied less frequently in B institutions. In particular, only 37.5% of the patients were treated with 3D conformal techniques in B2 institutions. In B institutions, lower photon energies

<10 MV were also used more frequently. Delivery of high radiation doses without the use of 3D conformal techniques may produce late morbidity of the surrounding tissues. Because some guidelines have recommended that 3DCRT or IMRT techniques should be employed in external beam radiotherapy for prostate cancer (14,15), structural improvement in B institutions should be urgently considered.

In conclusion, the results of the survey identified the standard of practice for treatment planning of prostate cancer in Japan. Although the preferred methods of planning and delivery have been defined somewhat differently at various institutions, it is necessary to define and develop recommended guidelines for the treatment planning process, in particular, for a clinical trial on radiotherapy for prostate cancer.

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Conflict of interest statement

None declared.

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Postoperative Radiotherapy for Localized Prostate Cancer: Clinical Significance of Nadir Prostate-specific Antigen Value within 12 Months

KAZUHIKO OGAWA¹, KATSUMASA NAKAMURA², TOMONARI SASAKI³, HIROSHI ONISHI⁴, MASAHIKO KOIZUMI⁵, MASAYUKI ARAYA⁴, NOBUTAKA MUKUMOTO⁶, MICHIHIDE MITSUMORI⁷, TERUKI TESHIMA⁶; and the Japanese Patterns of Care Study Working Subgroup of Prostate Cancer

¹Department of Radiology, University of the Ryukyus, Okinawa;

²Department of Clinical Radiology, Kyushu University at Beppu, Oita;

³Department of Radiation Oncology, National Kyushu Center, Fukuoka;

⁴Department of Radiology, Yamanashi University, Yamanashi;

Departments of ⁵Radiation Oncology and ⁶Medical Physics and Engineering, Osaka University, Osaka;

⁷Department of Radiation Oncology and Image-Applied Therapy, Kyoto University, Kyoto, Japan

Abstract. Aim: To analyze retrospectively the results of postoperative radiotherapy for localized prostate cancer and to investigate the clinical significance of nadir prostate-specific antigen (PSA) value within 12 months (nPSA12) as an early estimate of clinical outcome after radiotherapy. Patients and Methods: Seventy-six patients with localized prostate cancer treated with postoperative radiotherapy were retrospectively reviewed. Total radiation doses ranged from 50 to 70 Gy (median: 60 Gy), and the median follow-up period for all 76 patients was 47.9 months (range, 12.4-101.3 months). Results: The 5-year actuarial overall survival, progression-free survival, biochemical relapse-free survival (BRFS) and local control rates in all 76 patients after radiotherapy were 86.1%, 77.8%, 80.0% and 92.2%, respectively. Distant metastases and/or regional lymph node metastases developed in 11 patients (14%) after radiotherapy, while local progression was observed in only 5 patients (7%). Of all 76 patients, the median nPSA12 in patients with biochemical failure and that in patients without biochemical failure were 1.16 ng/ml and 0.05 ng/ml, respectively. The 5-year BRFS rates in patients with low nPSA12 (<0.5 ng/ml) and those with high nPSA12 (≥0.5 ng/ml) were 92.7% and 42.2%, respectively ($p < 0.0001$). In univariate analysis,

nPSA12, pre-radiotherapy PSA, Karnofsky performance status and the use of chemotherapy had a significant impact on BRFS, and in multivariate analysis, nPSA12 alone was an independent prognostic factor for BRFS. Conclusion: Postoperative radiotherapy results in an excellent local control rate for localized prostate cancer and nPSA12 is predictive of biochemical failure after postoperative radiotherapy.

Radical prostatectomy has been established as the primary curative procedure for the treatment of localized prostate cancer. However, despite a marked downward stage shift due to widespread serum prostate-specific antigen (PSA) screening and improvement in surgical techniques, approximately one-third of patients who undergo radical prostatectomy for their prostate cancer will experience biochemical recurrence after surgery (1-3). Many reports have indicated that the most significant risk factors for biochemical recurrence after prostatectomy are high Gleason score, extraprostatic extension, seminal vesicle invasion and a positive surgical margin (1, 4-8). Rising PSA levels following radical prostatectomy may be due to a local recurrence in the prostatic bed, occult distant metastases or a combination of both.

Although the optimal postoperative management of patients with localized prostate cancer has not yet been established, postoperative radiotherapy may be considered the treatment of choice to achieve both biochemical and local control (9-13). Recent randomized trials have demonstrated that in men who had undergone radical prostatectomy for pathologically advanced prostate cancer, adjuvant radiotherapy resulted in a significantly reduced risk of biochemical recurrence and disease recurrence compared with observation alone (11, 14).

Correspondence to: Dr. Kazuhiko Ogawa, Department of Radiology, University of the Ryukyus, 207 Uehara, Nishihara-cho, Okinawa, 903-0215, Japan. Tel: +81 988953331 (ext. 2401), Fax: +81 988951420, e-mail: kogawa@med.u-ryukyu.ac.jp

Key Words: Surgery, prostate cancer, nPSA12, radiotherapy, biochemical failure, prognostic factor.

However, little information regarding clinically useful markers of recurrence risk exists for prostate cancer patients who undergo postoperative radiotherapy.

For patients with untreated prostate cancer, PSA has been utilized as an important marker for treatment response and disease recurrence for prostate cancer (15, 16). The nadir in PSA (nPSA) after radiotherapy has been shown to predict biochemical failure (17, 18), distant metastasis (19, 20), cause-specific mortality (21, 22) and overall mortality (22). However, the nPSA usually takes several years to occur, even as long as 8-10 years in some patients, and as a consequence, nPSA has little practical clinical value. It would be ideal to identify a surrogate nPSA that describes the lowest PSA achieved during a well-defined, relatively short time interval after completion of radiotherapy. Recently, time-limited survey of PSA, such as nPSA value within 12 months (nPSA12), has been reported to be an early predictor of biochemical failure, distant metastasis, and mortality that is independent of radiotherapy dose and other determinants of outcome after radiotherapy for previously untreated localized prostate cancer (15, 16).

Because nPSA12 has been shown to be a useful predictor of treatment outcome for untreated localized prostate cancer treated with radical radiotherapy, we hypothesized that nPSA12 may also have potential applications in the monitoring of localized prostate cancer treated with postoperative radiotherapy. In the current study, we first analyzed the treatment results of postoperative radiotherapy for patients with localized prostate cancer. Next, we examined the nPSA12 level in patients with localized prostate cancer treated with postoperative radiotherapy and investigated whether nPSA12 could be a prognostic factor of clinical outcomes for these patients.

Patients and Methods

We used the detailed data from patients with localized prostate cancer who were included in the Japanese Patterns of Care Study (PCS). The PCS, which has been developed in the United States as a quality assurance program, was conducted in Japan in an attempt to obtain data on the national standards of radiotherapy for several diseases including prostate cancer (23). The Japanese PCS Working Subgroup of Prostate Cancer initiated a nationwide process survey for patients who underwent radiotherapy between 1996 and 1998. Subsequently, a second PCS of Japanese patients treated between 1999 and 2001 was conducted. We have previously reported the results of the first and second PCS surveys with respect to postoperative external beam radiotherapy for prostate cancer patients (24).

PCS methodology has been described previously (23, 25, 26). In brief, the PCS surveys were extramural audits that utilized a stratified two-stage cluster sampling design. The PCS surveyors consisted of 20 radiation oncologists from academic institutions, and each radiation oncologist collected data by reviewing patients' charts from their institution. Patients with a diagnosis of

adenocarcinoma of the prostate were eligible for inclusion in the present study unless they had one or more of the following conditions: i) evidence of distant metastasis; ii) concurrent or prior diagnosis of any other malignancy; iii) prior radiotherapy. The PCS data used in the current study are from two Japanese national surveys conducted to evaluate prostate cancer patients treated with radiotherapy in the 1996-1998 and 1999-2001 PCS surveys. Of the 839 patients comprising the 1996-1998 and 1999-2001 PCS survey populations, a total of 169 patients who received postoperative radiotherapy after radical prostatectomy were identified. Of these, 93 patients with insufficient nPSA12 data and/or patients who received total doses of less than 50 Gy were excluded, and in total, 76 patients with measurable nPSA12 were subjected to this analysis. The disease characteristics of these 76 patients, such as the tumor stage and pre-treatment PSA levels, were not significantly different compared to those of 93 patients having insufficient data for nPSA12 and/or those who received total doses of less than 50 Gy. All 76 patients received surgical resection initially, followed by postoperative radiotherapy.

Table I shows the patient characteristics of all 76 patients. Postoperative radiotherapy was administered as an adjuvant therapy (undetectable PSA and postoperative radiotherapy in 3-12 months after surgery) to 42 patients and the remaining 34 patients received radiotherapy as salvage therapy (elevated PSA and/or delayed rise in PSA after surgery). PSA was defined as the PSA value before initial treatment and pre-radiotherapy PSA was defined as the PSA value just before radiotherapy.

The method of treatment is shown in Table II. Hormonal therapy was administered either alone or in combination with orchiectomy, estrogen agents, luteinizing hormone-releasing hormone (LH-RH) agonists or antiandrogens after radiotherapy. The median duration of hormonal therapy was 15.4 months (range, 0.1-77.6 months). Regarding chemotherapy, 11 patients (14%) were also treated with chemotherapy, such as estramustine and 5-fluorouracil.

Regarding radiotherapy, the majority of patients were treated with >10 MV linear accelerators and also treated with 4 or more portals. The median radiation dose delivered to the prostate bed was 60 Gy (range, 50-70 Gy), and the median dose per fraction was 2 Gy (range, 2-2.2 Gy). Thirty patients (39%) received treatment to the pelvic nodes in addition to prostate bed, and the remaining 46 patients (61%) received irradiation only to the prostate bed. Regarding lymph node status, 6 out of 7 patients (86%) with pathologically positive lymph nodes received treatment to the pelvic nodes in addition to prostate.

nPSA12 was defined as the lowest PSA level achieved during the first year after completion of radiotherapy. The median number of PSA evaluations within 12 months after radiotherapy was 4 times (range, 1-17) in all 76 patients. The median follow-up of all patients was 47.9 months (range, 12.4-101.3 months), and all patients without biochemical failure had at least 1 year's follow-up. Biochemical failure is defined according to the Phoenix consensus definitions: failure is considered when PSA levels reach 2 ng/ml or more above nadir (27). Concerning clinical failure, patients were categorized as having progression after radiotherapy if they developed local, pelvic nodal, or distant failure. Alone or combination of chest radiography, liver ultrasound, computed tomography scans and magnetic resonance imaging scans were used for confirmation of suspected progression.

Statistical analyses were performed using the Statistical Analysis System at the PCS statistical center (28). Overall survival,

Table I. Patient characteristics.

	No. of patients
Age (median: 67.0116 years)	
<70	51
≥70	25
Type of therapy	
Adjuvant	42
Salvage	34
Surgical margin	
-	31
+	15
Unknown	30
Capsular invasion	
-	15
+	34
Unknown	27
Seminal vesicle invasion	
-	30
+	14
Unknown	32
Pathological T stage	
T0-2	11
T3-4	62
Unknown	3
Pathological N stage	
N0	52
N1	7
Unknown	17
KPS (%)	
≤80	17
>80	58
Unknown	1
Pre-treatment PSA (ng/ml)	
Median (range)	14.7 (0.0-268.2)
<20	40
≥20	29
Unknown	7
Pre-radiotherapy PSA (ng/ml)	
Median (range)	0.6435 (0.01-22.90)
<2	42
≥2	12
Unknown	22
Gleason combined score	
≤6	24
>6	19
Unknown	33
Differentiation	
Well/Moderate	49
Poor	22
Unknown	5

KPS, Karnofsky performance status; PSA, prostate-specific antigen.

progression-free survival (PFS), biochemical relapse-free survival (BRFS) and local control rates were calculated actuarially according to the Kaplan-Meier method (29) and were measured from the start of radiotherapy. Differences between groups were estimated using the chi-square test, Student's *t*-test, Mann-Whitney *U*-test and the log-rank test (30). Multivariate analysis was performed using the Cox

Table II. Treatment characteristics.

	No. of patients
Radiation field	
Whole pelvis plus boost	30
Prostate only	46
CT-based treatment planning	
Yes	63
No	13
Conformal therapy	
Yes	30
No	40
Unknown	6
Total radiation dose (Gy)	
<60	30
≥60	46
Use of hormonal therapy	
Yes	57
No	18
Unknown	1
Use of chemotherapy	
Yes	11
No	62
Unknown	3

KPS, Karnofsky performance status; PSA, prostate-specific antigen.

regression model (31). A probability level of 0.05 was chosen for statistical significance. The Radiotherapy Oncology Group (RTOG) late toxicity scales were used to assess the late morbidity (32).

Results

Seven out of 76 patients (9%) died during the period of this analysis. Of these patients, 6 patients died of prostate cancer and the remaining 1 patient died without any sign of clinical recurrence (intercurrent diseases). The 5-year actuarial overall survival, PFS, BRFS and local control rates in all 76 patients after radiotherapy were 86.1%, 77.8%, 80.0% and 92.2%, respectively (Figures 1 and 2). With regard to the site of recurrence, 15 patients had clinical failure (local only in 3, local with distant metastases in 2, regional in 1, distant metastasis in 7, regional and distant metastasis in 1 and unknown site in 1 patient). Distant metastases and/or regional lymph node metastases developed in 11 patients (11%) after radiotherapy, while local progression was observed in only 5 patients (7%). Regarding the total radiation dose (Table III), 51 out of 56 patients (91%) treated with less than 66 Gy achieved local control, while 20 out of 20 patients (100%) treated with 66 Gy or more achieved local control ($p=0.17$). Regarding the radiation field used, 28 out of 30 patients (93%) treated for the whole pelvis with boost and 43 out of 46 patients (93%) treated with a local field achieved local control; this difference was not statistically significant ($p=0.98$).

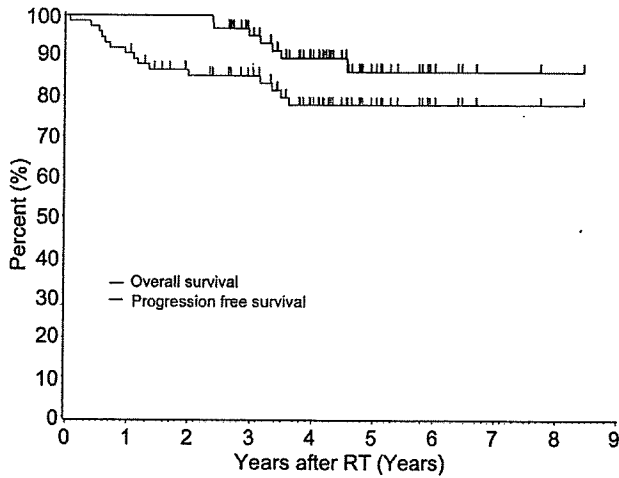


Figure 1. Actuarial overall and progression-free survival curves for 76 patients with prostate cancer treated with postoperative radiotherapy.

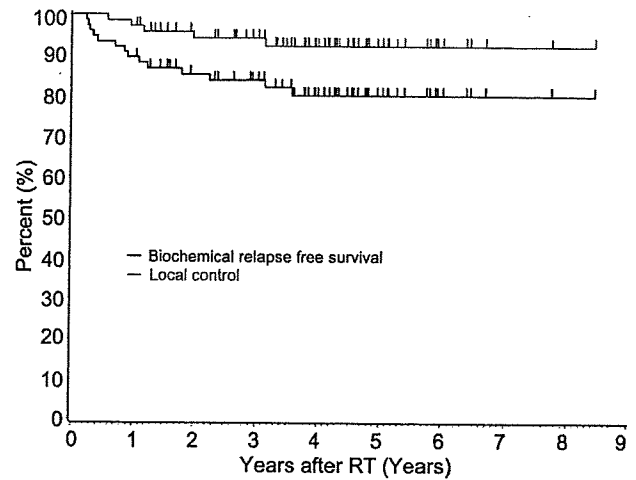


Figure 2. Actuarial biochemical-free survival and local control curves for 76 patients with prostate cancer treated with radiotherapy.

Table III. Local control according to the radiation dose and field.

Total dose (Gy)	No. of pts	No. of pts with LC	Incidence of LC	
			WP + B	Local
50-59.9	30	28 (93%)	18/19	10/11
60-61.9	23	21 (91%)	9/9	12/14
62-63.9	0	0	0/0	0/0
64-65.9	3	2 (67%)	1/2	1/1
66-67.9				
68-69.9	9	9 (100%)	0/0	9/9
70	11	11 (100%)	0/0	11/11
Total	76	71 (93%)	28/30 (93%)	43/46 (93%)

Pts, Patients; LC, local control; WP, whole pelvis; B, boost.

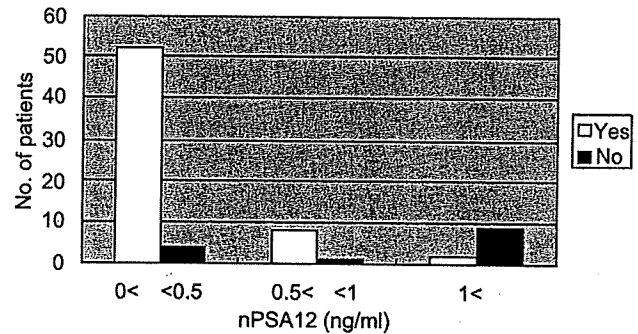


Figure 3. Distribution of nPSA12 values according to biochemical control (yes: controlled, no: not controlled). Over 80% of patients with biochemical control had a nPSA12 <0.5 ng/ml, while only 29% of patients who experienced biochemical failure had a nPSA12 <0.5 ng/ml.

Of all 76 patients, the median nPSA12 in patients with biochemical failure and that in patients without biochemical failure were 1.16 ng/ml and 0.05 ng/ml, respectively. Patients treated with adjuvant therapy had significantly lower nPSA12 (median: 0.07 ng/ml) than those treated with salvage therapy (median: 0.23 ng/ml, $p=0.018$). On the other hand, patients treated with hormonal therapy had almost similar nPSA12 (median: 0.10 ng/ml) compared to those without hormonal therapy (median: 0.09 ng/ml, $p=0.45$). Figure 3 shows the distribution of nPSA12 according to the achievement of biochemical control. Over 80% of patients with biochemical control (52 out of 62 patients, 84%) had a nPSA12 of <0.5 ng/ml, while only 4 patient out of 14 patients (29%) with biochemical failure had a nPSA of <0.5 ng/ml ($p<0.0001$). For the 52 patients who achieved a nPSA12 level <0.5 ng/ml

and who did not experience biochemical failure, the median time from the completion of radiotherapy to achievement of a nPSA12 level <0.5 ng/ml was 2.0 months (range, 0.2-11.5 months).

When dividing patients into low (<0.5 ng/ml) and high (>0.5 ng/ml) nPSA12 groups, the 5-year BRFS rates in patients with low nPSA12 and those with high nPSA12 were 92.7% and 42.2%, respectively ($p<0.0001$) (Figure 4). In univariate analysis, nPSA12, pre-radiotherapy PSA, Karnofsky performance status (KPS) and the use of chemotherapy had a significant impact on BRFS, and other factors, such as type of therapy (adjuvant vs. salvage), the total radiation dose and the use of hormonal therapy, did not influence BRFS (Table IV). In multivariate analysis, nPSA12 alone was an independent prognostic factor for BRFS after radiotherapy (Table V).

Table IV. Univariate analysis of various potential prognostic factors for biochemical-free survival in patients with prostate cancer treated with postoperative radiotherapy.

	Univariate analysis		
	n	BFS, 5-year rate (%)	p-Value
nPSA12 (ng/ml)			
<0.5	56	92.7%	0.0002
≥0.5	20	42.2%	
Therapy			
Adjuvant	42	81.9%	0.6615
Salvage	34	77.3%	
Surgical margin			
-	31	84.8%	0.2738
+	15	68.6%	
CAP			
-	15	92.9%	0.2497
+	34	75.2%	
SV			
-	30	88.4%	0.4448
+	14	75.0%	
Pathological T stage			
T0-2	62	100.0%	0.3445
T3-4	11	77.2%	
Pathological N stage			
N0	52	78.4%	0.6818
N1	7	71.4%	
Pelvic irradiation			
Yes	30	86.7%	0.3865
No	46	75.5%	
Age (years)			
<70	51	76.9%	0.2856
≥70	25	86.5%	
KPS (%)			
≤80	17	64.2%	0.0239
>80	58	84.6%	
Pre-treatment PSA (ng/ml)			
<20	40	72.5%	0.2022
≥20	29	85.0%	
Pre-radiotherapy PSA (ng/ml)			
<2	42	89.5%	0.0160
≥2	12	50.0%	
Gleason combined score			
≤6	24	95.8%	0.1315
>6	19	78.6%	
Differentiation			
Well/Moderate	49	79.0%	0.4524
Poor	22	82.6%	
T stage			
T0-2	62	100.0%	0.3445
T3-4	11	77.2%	
Use of chemotherapy			
Yes	11	45.5%	0.0033
No	62	86.6%	
Use of hormone therapy			
Yes	57	75.7%	0.1717
No	18	93.8%	
Use of postRT hormonotherapy			
Yes	40	73.8%	0.4407
No	26	82.0%	
Total radiation dose (Gy)			
<60	30	78.9%	0.7143
≥60	46	80.6%	

nPSA12, Nadir prostate-specific antigen within 12 months; KPS, Karnofsky performance status; BFS, biochemical-free survival; PSA, prostate-specific antigen.

Table V. Multivariate analysis of various potential prognostic factors for biochemical-free survival in patients with prostate cancer treated with postoperative radiotherapy.

	Multivariate analysis	
	RR (95% CI)	p-Value
nPSA12 (ng/ml)		
<0.5	7.403 (1.296-42.287)	0.0244
≥0.5		
KPS (%)		
≤80	2.156 (0.423-10.981)	0.3552
>80		
Pre-radiotherapy PSA (ng/ml)		
<2	2.107 (0.441-10.077)	0.3507
≥2		
Use of chemotherapy		
Yes	0.471 (0.061-3.608)	0.4685
No		

PSA, Prostate-specific antigen; KPS, Karnofsky performance status; RR, relative ratio; CI, confidence intervals.

Regarding clinical control, the median nPSA12s in patients without clinical failure after radiotherapy and those with clinical failure were 0.04 ng/ml (range, 0.00-5.90 ng/ml) and 0.90 ng/ml (range, 0.00-5.00 ng/ml), respectively. The 5-year actuarial PFS rates in patients with high nPSA12 levels and patients with low nPSA12 levels were 92.7% and 35.9%, respectively (Figure 5). The difference between these two groups was statistically significant ($p < 0.0001$). In a univariate analysis, nPSA12, surgical margin status, KPS, pre-radiotherapy PSA and the use of chemotherapy had a statistically significant impact on PFS (Figure 5; Table VI). However, in a multivariate analysis, no factors were independent prognostic factors for PFS (Table VII).

Late morbidity of RTOG grade 2-3 was observed in 8 patients (11%). A total of 4 patients experienced late rectal toxicity and the remaining 4 patients had late urinary toxicity. There were no cases of grade 4 toxicity (Table VIII). Regarding 4 patients who suffered grade 3 late complications, CT-based treatment planning was carried out in only 1 patient (25%), and conformal therapy was supplemented in 1 patient (25%).

Discussion

The current study indicated that postoperative radiotherapy gave an excellent local control rate for patients treated with radical prostatectomy. Several reports have also indicated that postoperative radiotherapy gave an excellent local control rate for these tumors (11, 33-35). The EORTC trial reported the cumulative incidence of locoregional failure at 5 years of follow-up, and a statistically lower incidence of failure was seen

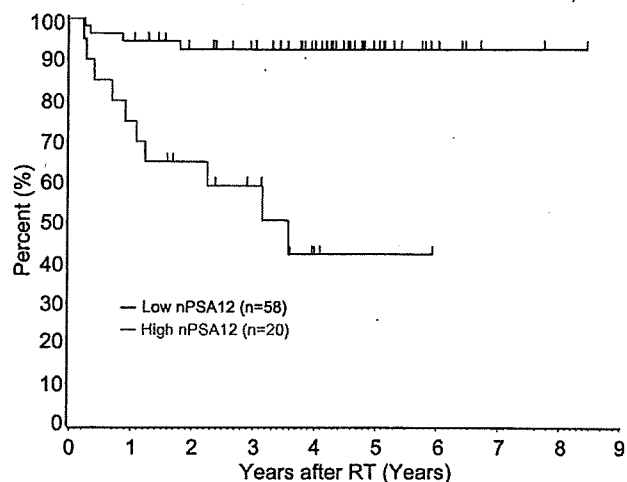


Figure 4. Actuarial biochemical-free survival curves according to the level of nPSA12. There were significant differences in PFS between patients with a low nPSA12 value (<0.5 ng/ml) and those with a high nPSA12 value (≥ 0.5 ng/ml).

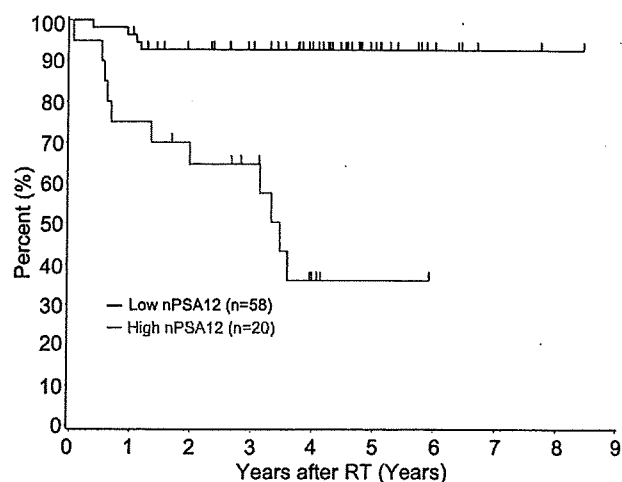


Figure 5. Actuarial progression-free survival curves according to the level of nPSA12. There were significant differences in PFS between patients with a low nPSA12 value (<0.5 ng/ml) and those with a high nPSA12 value (≥ 0.5 ng/ml).

in the adjuvant radiotherapy arm (5.4%) than in the observation arm (15.4%) (11). Cozzarini *et al.* retrospectively analyzed 237 patients who underwent postoperative radiotherapy (within 6 months of surgery), and indicated that the actuarial 8-year local control rate was 93% (33). In the current study, only 5 out of 76 patients (7%) developed local failure after radiotherapy.

Although the dose response in patients who undergo postoperative radiotherapy for localized prostate cancer has not yet been clearly established, higher doses with curative intent can result in favorable outcomes in some patients. In the current study, the 5-year local control in 76 patients treated with a median dose of 60 Gy was 92.2%, and 22 out of 22 patients (100%) treated with 66 Gy or more had achieved local control. Several reports have suggested that radiation doses of 65 Gy or more are associated with improved biochemical PFS (36, 37). Therefore, radiation doses of 65 Gy or more appear to be appropriate for prostate cancer patients when treated with postoperative radiotherapy. However, in the current study, it is important to note that the almost all patients who suffered grade 3 late complications were treated without CT-based treatment planning and/or conformal therapy. Therefore, CT-based treatment planning and/or conformal therapy should be required to reduce the late complications. Concerning the radiation field, we did not find significant differences in local control between patients treated for the whole pelvis with or without boost and those treated with a localized field only. Therefore, localized field irradiation may be sufficient in this patient population. Further studies are required to determine whether a localized field is sufficient for these patients.

The current study also indicated that patients with a high nPSA12 had a significantly lower BRFS rate than patients with a low nPSA12, and nPSA12 was an independent prognostic

factor for BRFS in patients with localized prostate cancer treated with postoperative radiotherapy. Moreover, patients with low nPSA12 levels had significantly higher PFS than those with high nPSA12 level, although nPSA12 was not an independent prognostic factor for PFS in the multivariate analysis. To our knowledge, this is the first report to demonstrate the utility of nPSA12 in determining prognosis in patients with localized prostate cancer treated with postoperative radiotherapy. Concerning previously untreated prostate cancer, Alcantara *et al.* indicate that nPSA12 is independent of radiation dose, T stage, Gleason score, pretreatment initial PSA, age and PSA doubling time, and dichotomized nPSA12 (≤ 2 versus >2 ng/ml) was independently related to distant metastasis and cause-specific mortality (15). Ray *et al.* indicated that patients with nPSA12 ≤ 2.0 ng/ml had significantly higher 8-year PSA failure-free survival and overall survival than patients with nPSA12 >2.0 ng/ml, and nPSA12 was an independent prognostic factor for prostate cancer patients treated with radiotherapy alone (16). Furthermore, Ogawa *et al.* indicated that nPSA12 was an independent prognostic factor for hormone-refractory prostate cancer patients treated with radiotherapy (38). These results suggest that nPSA12 may be a useful marker for patients with localized prostate cancer treated with postoperative radiotherapy as well as patients with previously untreated prostate cancer treated with radiotherapy and clinically localized hormone-refractory prostate cancer.

Several previous studies have suggested other potential factors associated with the risk of prostate cancer recurrence, such as pre-radiotherapy PSA, PSA velocity and PSA doubling time (PSADT) (9, 39-42). For patients treated with salvage radiotherapy, Gleason score, pre-radiotherapy PSA level, surgical margins, PSADT and seminal vesicle invasion are

Table VI. Univariate analysis of various potential prognostic factors for progression-free survival in patients with prostate cancer treated with postoperative radiotherapy.

	Univariate analysis		
	n	PFS, 5-year rate (%)	p-Value
nPSA12 (ng/ml)			
<0.5	56	92.7%	<0.0001
≥0.5	20	35.9%	
Therapy			
Adjuvant	42	72.7%	0.1838
Salvage	34	69.8%	
Surgical margin			
-	31	96.8%	0.0258
+	15	56.7%	
CAP			
-	15	86.7%	0.7355
+	34	77.6%	
SV			
-	30	93.3%	0.0997
+	14	68.8%	
Pathological T stage			
T0-2	62	90.9%	0.4793
T3-4	11	78.5%	
Pathological N stage			
N0	52	76.6%	0.8399
N1	7	71.4%	
Pelvic irradiation			
Yes	30	76.5%	0.9782
No	46	78.7%	
Age (years)			
<70	51	73.3%	0.2382
≥70	25	87.0%	
KPS (%)			
≤80	17	57.3%	0.0417
>80	58	82.8%	
Pre-treatment PSA (ng/ml)			
<20	40	74.8%	0.6650
≥20	29	82.6%	
Pre-radiotherapy PSA (ng/ml)			
<2	42	90.4%	0.0103
≥2	12	44.4%	
Gleason combined score			
≤6	24	95.8%	0.0706
>6	19	71.8%	
Differentiation			
Well/Moderate	49	85.3%	0.0744
Poor	22	65.4%	
Use of chemotherapy			
Yes	11	45.5%	0.0102
No	62	83.8%	
Use of hormonotherapy			
Yes	57	75.6%	0.3841
No	18	82.6%	
Use of postRT hormone therapy			
Yes	40	73.1%	0.5473
No	26	84.6%	
Total radiation dose (Gy)			
<60	30	72.7%	0.6112
≥60	46	81.2%	

nPSA12, Nadir prostate-specific antigen within 12 months; KPS, Karnofsky performance status; PSA, prostate-specific antigen; PFS, progression-free survival.

Table VII. Multivariate analysis of various potential prognostic factors for progression-free survival in patients with prostate cancer treated with postoperative radiotherapy.

	Multivariate analysis	
	RR (95% CI)	p-Value
nPSA12 (ng/ml)		
<0.5	5.183 (0.326-82.512)	0.2439
≥0.5		
Surgical margin		
-	12.683 (0.656-245.321)	0.0928
+		
KPS (%)		
≤80	10.998 (0.426-283.891)	0.1483
>80		
Pre-radiotherapy PSA (ng/ml)		
<2	0.255 (0.010-6.570)	0.4094
≥2		
Use of chemotherapy		
Yes	0.174 (0.007-4.082)	0.2771
No		

PSA, Prostate-specific antigen; KPS, Karnofsky performance status; RR, relative ratio; CI, confidence intervals.

Table VIII. Late complications in patients with prostate cancer treated with postoperative radiotherapy.

	Toxicity grade		Total dose (Grade 3)
	Grade 2	Grade 3	
Rectal			
Bleeding	3	1	67.8 Gy
Urinary			
Ureteral obstruction	1	0	
Incontinence	0	2	60 Gy
Incontinence + Structure	0	1	56.6 Gy

prognostic variables for a durable response to salvage radiotherapy (41). Sasaki *et al.* indicated that a low pre-radiotherapy PSA level is a significant predictor of biochemical control for postoperative radiotherapy in patients with prostate cancer (42). King *et al.* reported that postoperative PSA velocity independently predicts for the failure of salvage radiotherapy after radical prostatectomy (39). Numata *et al.* indicated that PSADT appears to be a good predictor of response to salvage radiotherapy in patients with biochemical recurrence after radical prostatectomy (9).

Concerning the timing of radiotherapy, adjuvant radiotherapy following radical prostatectomy has been compared to salvage therapy in numerous retrospective studies that have included patients with high-risk pathological features (10, 43-45). Overall, the results from those studies support the

use of adjuvant radiotherapy, with demonstrated improvements in local and biochemical control. In the current study, there was no significant difference in biochemical control between the adjuvant radiotherapy group and the salvage radiotherapy group. One of the reasons may be the small number of patients in the current study. Our results also indicated that pre-radiotherapy PSA, KPS and the use of chemotherapy had a significant impact on BRFS, although multivariate analyses failed to confirm the significance. Further studies are required to evaluate the influence of additional factors, such as PSA velocity and PSADT, on clinical outcomes for localized hormone-refractory patients treated with radiotherapy.

In conclusion, our results indicated that postoperative radiotherapy gave an excellent local control rate for localized prostate cancer after radical prostatectomy, and should be considered the treatment of choice for these tumors. Our results also indicated that nPSA12 is an early predictor of biochemical failure that is independent of radiotherapy dose and other determinants of outcome after postoperative radiotherapy for prostate cancer patients treated with radical prostatectomy. Therefore, nPSA12 could potentially help identify patients at high risk who might benefit from the earlier application of systemic therapy. However, this study is a retrospective study with various treatment modalities, and further prospective studies are required to confirm our results.

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全国放射線治療施設の2007年定期構造調査報告(第1報)

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全国放射線治療施設の2007年定期構造調査報告(第1報)

JASTROデータベース委員会

手島 昭樹^{*1}, 沼崎 穂高^{*1}, 渋谷 均^{*2}, 西尾 正道^{*3}, 池田 恢^{*4}, 関口 建次^{*5},
上紺屋 憲彦^{*6}, 小泉 雅彦^{*7}, 多湖 正夫^{*8}, 安藤 裕^{*9}, 塚本 信宏^{*10},
寺原 敦朗^{*11}, 中村 和正^{*12}, 光森 通英^{*13}, 西村 哲夫^{*14}, 晴山 雅人^{*15}

JAPANESE STRUCTURE SURVEY OF RADIATION ONCOLOGY IN 2007
(FIRST REPORT)

JASTRO Database Committee

Teruki TESHIMA^{*1}, Hodaka NUMASAKI^{*1}, Hitoshi SHIBUYA^{*2}, Masamichi NISHIO^{*3}, Hiroshi IKEDA^{*4},
Kenji SEKIGUCHI^{*5}, Norihiko KAMIKONYA^{*6}, Masahiko KOIZUMI^{*7}, Masao TAGO^{*8}, Yutaka ANDO^{*9},
Nobuhiro TSUKAMOTO^{*10}, Atsuro TERAHARA^{*11}, Katsumasa NAKAMURA^{*12},
Michihide MITSUMORI^{*13}, Tetsuo NISHIMURA^{*14}, and Masato HAREYAMA^{*15}

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Abstract: A national structure survey of radiation oncology in 2007 using questionnaires was conducted from March 2008 to January 2009 by JASTRO. The response rate was 721 out of 765 (94.2%) active radiotherapy institutes. The total number of new cancer patients and the total number of cancer patients (new-repeat) treated with radiation were estimated to be approximately 181,000 and 218,000, respectively. The numbers of linac, telecobalt, Gamma Knife[®], ⁶⁰Co RALS, and ¹⁹²Ir RALS in actual use were 807, 15, 46, 45, and 123, respectively. The linac has a dual energy function in 539 (66.8%), 3DCRT in 555 (68.8%), and IMRT in 235 (29.1%). The numbers of JASTRO-certified radiation oncologists, full time equivalent (FTE) radiation oncologists, medical physicists, radiotherapy QA personnel, radiation therapists, radiation therapy nurses, and clerks were 477, 826 FTE, 64 FTE, 106 FTE, 1,634 FTE, 494 FTE, and 329, respectively. There were significant increases in the use of ¹²⁵I for prostate cancer patients by 52% and IMRT by 271% between 2005 and 2007. Geographically, there was still a significant variation in the use of radiotherapy from 0.8 new patients per 1,000 population to 1.8 (average 1.3).

Key words: Structure survey, Radiotherapy facility, Radiotherapy equipment, Radiotherapy personnel

はじめに

1990年に恒元らによって第1回日本放射線腫瘍学会(JASTRO)全国放射線治療施設構造調査が実施された¹⁾。1993年以降は定期的(2年ごと)に構造調査を学会事業として行っている²⁾⁻¹⁰⁾。これらのデータ分析によってJASTROは、わが国における放射線治療のおかれている状況を装備、人員、患者数などを中心に正確に把握し、国や地方自治体レベルでの施策の提言や個々の医療機関における構造の改善に役立つ情報を提供してきた。この調査への協力は

JASTROによる放射線治療施設の施設認定制度における認定を受けるための必要条件ともなっている。

今回、2007年を対象とした第9次全国放射線治療施設の構造調査を行った。データはすでにJASTROホームページ(<http://www.jastro.jp>)よりdownload可能にしている¹¹⁾。本報告ではこれらのデータを示すとともに、データベース委員会が目しているデータについて解説と考案を行った。なお、人員負荷などの詳細な分析は、第2報以降に報告する。

このデータはJASTROの共有財産であり、各施設の構造を改善するために利用されることを最終目標としている。

^{*1} 大阪大学大学院医学系研究科医用物理工学講座(〒565-0871 大阪府吹田市山田丘1-7)(Department of Medical Physics & Engineering, Osaka University Graduate School of Medicine) (1-7 Yamadaoka, Suita, Osaka 565-0871, JAPAN)(委員長、沼崎 解析担当), ^{*2} 東京医科歯科大学医学部放射線科(Department of Radiology, Tokyo Dental and Medical University), ^{*3} 国立病院機構北海道がんセンター放射線科(Department of Radiology, National Hospital Organization Hokkaido Cancer Center), ^{*4} 市立堺病院放射線治療科(Department of Radiation Oncology, Sakai Municipal Hospital), ^{*5} 聖路加国際病院放射線腫瘍科(Department of Radiation Oncology, St. Luke's International Hospital), ^{*6} 兵庫医科大学放射線医学(Department of Radiology, Hyogo College of Medicine), ^{*7} 大阪大学医学部附属病院オンコロジーセンター(Oncology Center, Osaka University Hospital), ^{*8} 東邦大学医療センター大森病院放射線科(Department of Radiology, Toho University Omori Medical Center), ^{*9} 放射線医学総合研究所重粒子医科学センター医療情報課(Department of Medical Informatics, Heavy Ion Medical Center, National Institute of Radiological Sciences), ^{*10} 埼玉医科大学国際医療センター放射線腫瘍科(Department of Radiation Oncology, Saitama Medical University International Medical Center), ^{*11} 東京大学医学部附属病院放射線科(Department of Radiology, University of Tokyo Hospital), ^{*12} 九州大学病院別府先進医療センター放射線科(Department of Radiology, Kyushu University Hospital at Beppu), ^{*13} 京都大学大学院医学研究科放射線医学講座放射線腫瘍学・画像応用治療学(Department of Radiation Oncology and Image-applied Therapy, Graduate School of Medicine Kyoto University), ^{*14} 静岡県立がんセンター放射線治療科(Division of Radiation Oncology, Shizuoka Cancer Center)(副委員長), ^{*15} 札幌医科大学放射線医学講座(Department of Radiology, Sapporo Medical University)(2008年JASTRO会長)

Table 1 Category of radiation oncology facilities

調査票送付時の分類	集計時の分類
[U] : 大学附属病院	U : 大学附属病院
[N] : 独立行政法人国立病院機構(がんセンター等を除く)	G : 国立がんセンター・成人病センター・地方がんセンター*
[P] : 公立(都道府県市町村立)病院(がんセンター等を除く)	N : 独立行政法人国立病院機構(がんセンター等を除く)
[G] : 国立がんセンター・成人病センター・地方がんセンター	P : 公立(都道府県市町村立)病院(がんセンター等を除く)
[S] : 赤十字病院・済生会病院	O : 赤十字病院・済生会病院, 企業/公社病院, 国保/
[C] : 企業/公社病院	社保/共済/労災/組合/厚生連病院等
[L] : 国保/社保/共済/労災/組合/厚生連病院等	H : 医療法人・医師会病院・個人病院・その他
[H] : 医療法人・医師会病院・個人病院等	
[O] : その他	

*厚生労働省の本省に置かれた6つの国立高度専門医療センターを含める。

各施設での具体的交渉用にcustomizeされたデータが必要な場合、常時応ずるので連絡願いたい。

調査対象と調査経過

2008年3月末に、2007年に放射線治療装置があると想定された全国814施設にJASTRO事務局から、2007年1月1日～12月31日までの放射線治療の診療実態についての構造調査票が郵送された。2008年度JASTRO会長とデータベース委員長連名にて、本調査への協力を正式に依頼した。2009年1月末までに721施設から回答が得られた。すでに放射線治療を止めている施設もあり、2007年に放射線治療を行っている施設は765施設と推定された。解析対象施設数は721施設(94.2%)となった。調査票の内容は2007年4月から、委員会で調査開始直前まで検討された。2005年の調査票との整合性を保ちながら、新たな調査項目としてlinacのIGRT機能、focal(CT on rail)機能：同室CT機能、on board imaging(OBI)機能：照射位置照合機能を加えた。さらに放射線腫瘍医の常勤、非常勤勤務の兼務による実質的マンパワー分析のために、名前や会員番号によって常勤の病院と非常勤の病院におけるデータ照合ができるようにした。放射線治療担当技師の実質的なマンパワーFTE(full time equivalent：週40時間放射線治療専任業務に換算)数、医学物理士FTE数、放射線治療品質管理士FTE数、放射線治療担当看護師FTE数も加えた。また、2005年調査データと同様に、国際原子力機関IAEAの施設構造調査DIRAC(Directory of Radiotherapy Centres)へのデータ協力のための調査も同時に行い、573施設(79.5%)からデータ提供の承諾を得た。ウィーンのIAEA本部で沼崎委員により、2008年10月31日にデータ更新を完了した。これは装置名などの詳細な情報であり、IAEAのホームページ(<http://www-naweb.iaea.org/nahu/dirac/default.asp>)にすでに公開されている。

結 果

1. 施設分類、規模、地域と施設数

Table 1 に、施設分類一覧を示す。集計時の分類として

[S]：赤十字病院・済生会病院，[C]：企業/公社病院，[L]：国保/社保/共済/労災/組合/厚生連病院等をOとして一括した。[H]：医療法人・医師会病院・個人病院等，[O]：その他をHとして一括した。厚生労働省の本省に置かれた6つの国立高度専門医療センターはGに含めた。

Table 2 に、地域と施設数を示している。関東(27.5%)、近畿(17.6%)、九州・沖縄、東海、東北、中国、信越・北陸、北海道、四国(3.7%)の順となっている。2005年に比して、関東で0.7%、近畿で1.4%増加している。

Table 3 に、施設組織区分と施設規模(年間新患者数)を示す。U：大学附属病院，G：国立がんセンター・成人病センター，地方がんセンターではF：500人以上が最も多かった。N：国立病院機構，P：公立病院，O：赤十字病院・済生会病院，企業/公社病院，国保/社保/共済/労災/組合/厚生連病院等，H：医療法人・医師会病院・個人病院・その他ではB：100～199人が最も多くなっていた。全体で見ると，Bが32.3%，A：99人以下が25.4%，C：200～299人が16.0%，D：300～399人が10.1%，E：400～499人は5.1%であった。F：500人以上を治療する施設は11.1%である。わが国の74%の施設は300人未満の年間新患者数(A, B, C)を治療している。2005年に比してBの施設割合で0.7%，D, EおよびFの施設で、それぞれ1.1%，0.6%，1.9%増加していた。

2. 年間患者数

Table 4-1 に、施設規模別の年間新患者数を示す。721施設で総計170,229人の新患者が治療されていた。全国の実施設数を765施設とした場合に、推定新患者数は約18万1,000人であった。施設組織区分では，U：大学附属病院が29.6%と最も多く，P：公立病院20.7%，O：赤十字病院・済生会病院，企業，保険団体，厚生連が18.4%であった。施設規模では，F：500人以上が34.0%，B：100～199人が19.2%，C：200～299人が16.4%，D：14.6%，E：9.4%であった。2005年と比較すると，A, BおよびCの施設で全体患者数に占める割合が減少し，D, EおよびFの施設で増加している。Table 4-2 に、施設規模別の年間実患者数(新患+再患)を示す。実患者数未入力施設が35施設あり，新患

Table 2 Region and number of radiation oncology facilities

地域(都道府県数)	郵送施設数	回答施設数 (対郵送施設割合 [%])	解析施設数 (対郵送施設割合 [%])	解析施設数/全国 [%]
北海道(1)	34	31(91.2)	30(88.2)	4.2
東北(6)	64	61(95.3)	59(92.2)	8.2
関東(8)	227	205(90.3)	198(87.2)	27.5
信越・北陸(5)	57	51(89.5)	50(87.7)	6.9
東海(4)	95	90(94.7)	87(91.6)	12.1
近畿(6)	141	131(92.9)	127(90.1)	17.6
中国(5)	59	54(91.5)	54(91.5)	7.5
四国(4)	34	30(88.2)	27(79.4)	3.7
九州・沖縄(8)	103	94(91.3)	89(86.4)	12.3
全国(47)	814	747(91.8)	721*(88.6)	100

*2007年放射線治療実施施設数は765施設と推測され、721施設は94.2%に相当。

Table 3 Number of radiation oncology facilities by annual patient load and category

施設規模 (年間新患者数)	施設組織区分						Total	施設割合 [%]
	U	G	N	P	O	H		
A(99人以下)	9	2	22	67	47	36	183	25.4
B(100~199人)	12	3	28	74	69	47	233	32.3
C(200~299人)	11	3	10	38	33	20	115	16.0
D(300~399人)	20	4	3	18	14	14	73	10.1
E(400~499人)	17	1	1	6	5	7	37	5.1
F(500人以上)	45	16	1	5	6	7	80	11.1
Total	114	29	65	208	174	131	721	
施設割合 [%]	15.8	4.0	9.0	28.8	24.1	18.2		100

Table 4-1 Annual number of new cancer patients by patient load and category of radiation oncology facilities

施設規模(施設数)	施設組織区分(施設数)						Total(721)	対全患者数割合 [%]	施設平均新患者数
	U(114)	G(29)	N(65)	P(208)	O(174)	H(131)			
A(183)	439	58	1,342	4,034	2,945	2,018	10,836	6.4	59.2
B(233)	1,796	453	3,909	10,316	9,538	6,686	32,698	19.2	140.3
C(115)	2,790	717	2,498	8,919	8,136	4,913	27,973	16.4	243.2
D(73)	6,847	1,341	995	6,057	5,087	4,490	24,817	14.6	340.0
E(37)	7,557	439	421	2,477	2,085	3,041	16,020	9.4	433.0
F(80)	30,922	13,786	731	3,481	3,584	5,381	57,885	34.0	723.6
Total(721)	50,351	16,794	9,896	35,284	31,375	26,529	170,229		
対全患者数割合 [%]	29.6	9.9	5.8	20.7	18.4	15.6		100	
施設平均新患者数	441.7	579.1	152.2	169.6	180.3	202.5			236.1

2007年放射線治療実施施設数を765施設と推測した場合の推定新患者数：約18万1,000人。

者数×1.2で補正した。施設規模は新患者数での分類を踏襲した。721施設で総計205,087人が治療されていた。全国規模では推定実患者数は約21万8,000人であった。施設組織区分、施設規模ではTable 4-1 とほぼ同様の傾向を示した。2005年と比し、特にFの扱う患者数の全体に対する比率の増加がそれぞれ3.4%、3.7%と高い。

Table 5-1 に、地域別施設数と年間新患者数を示してい

る。全新患者数比(%)で最も多いのは、関東の33.5%であった。次いで近畿の16.7%、九州・沖縄の11.2%、東海の10.8%と続いた。施設平均の新患者数は全国平均では236.1人で、関東288.0人、北海道275.6人、近畿224.1人と続いた。Table 5-2 に、同様に年間実患者数で示している。全実患者数比(%)も新患者同様の傾向であった。施設平均実患者数は全国平均284.4人で、北海道365.0人、関東342.4人、

Table 4-2 Annual number of total cancer patients (new+repeat) by patient load and category of radiation oncology facilities*

施設規模** (施設数)	施設組織区分 (施設数)						Total (721)	対全患者数割合 [%]	施設平均新患者数
	U (114)	G (29)	N (65)	P (208)	O (174)	H (131)			
A (183)	506	64	1,643	4,864	3,330	2,297	12,704	6.2	69.4
B (233)	2,095	515	4,623	11,993	11,395	8,463	39,084	19.1	167.7
C (115)	3,560	909	3,005	10,604	9,991	6,033	34,102	16.6	296.5
D (73)	8,374	1,800	1,258	7,861	5,802	5,472	30,567	14.9	418.7
E (37)	8,829	502	480	2,984	2,647	3,997	19,439	9.5	525.4
F (80)	37,191	17,178	804	4,105	4,245	5,668	69,191	33.7	864.9
Total (721)	60,555	20,968	11,813	42,411	37,410	31,930	205,087		
対全患者数割合 [%]	29.5	10.2	5.8	20.7	18.2	15.6		100	
施設平均新患者数	531.2	723.0	181.7	203.9	215.0	243.7			284.4

2007年放射線治療実施施設数を765施設と推測した場合の推定実患者数：約21万8,000人。

* 実患者数 = 新患者数 + 再患者数。実患者未入力施設は、新患者数 × 1.2で補正(未入力施設：35施設)。

** 施設規模は新患者数を100人単位で区切った分類を使用。

Table 5-1 Numbers of annual new cancer patients and radiation oncology facilities by region

地域 (都道府県数)	解析施設数	新患者数	全新患者数比 [%]	施設平均新患者数
北海道(1)	30	8,268	4.9	275.6
東北(6)	59	12,043	7.1	204.1
関東(8)	198	57,015	33.5	288.0
信越・北陸(5)	50	10,750	6.3	215.0
東海(4)	87	18,352	10.8	210.9
近畿(6)	127	28,460	16.7	224.1
中国(5)	54	10,858	6.4	201.1
四国(4)	27	5,424	3.2	200.9
九州・沖縄(8)	89	19,059	11.2	214.1
全国(47)	721	170,229	100	236.1

2007年放射線治療実施施設数を765施設と推測した場合の推定新患者数：約18万1,000人。

Table 5-2 Numbers of annual total cancer patients (new+repeat) and radiation oncology facilities by region

地域 (都道府県数)	解析施設数	実患者数	全実患者数比 [%]	施設平均実患者数
北海道(1)	30	10,951	5.3	365.0
東北(6)	59	14,753	7.2	250.1
関東(8)	198	67,799	33.1	342.4
信越・北陸(5)	50	12,311	6.0	246.2
東海(4)	87	22,910	11.2	263.3
近畿(6)	127	33,789	16.5	266.1
中国(5)	54	13,132	6.4	243.2
四国(4)	27	6,273	3.1	232.3
九州・沖縄(8)	89	23,169	11.3	260.3
全国(47)	721	205,087	100	284.4

2007年放射線治療実施施設数を765施設と推測した場合の推定実患者数：約21万8,000人。

近畿266.1人と続いた。施設平均実患者数は、2005年より7.5%増加していた。近畿で最も増加率が高かった。

3. 装備

Table 6 に、施設規模別の治療機器数とその機能を示している。全体ではlinac 807台、TomoTherapy® 9台、microtron

13台、telecobalt 15台(稼働分)、Gamma Knife®46台であった。このうち、linacはdual energy機能を539台(66.8%)に、3DCRT機能を555台(68.8%)に、IMRT機能を235台(29.1%)に有していた。施設規模で見ると、A：99人以下の施設では、それぞれ47.1%、48.2%、12.4%であったが、F：500人以上の施設では、75.3%、86.7%、58.4%に有していた。さ

Table 6 Number of equipments and their function by annual patient load of radiation oncology facilities

治療機器と機能	A (183)	B (233)	C (115)	D (73)	E (37)	F (80)	Total (721)
linac	170	219	114	85	53	166	807
with dual energy function	80	141	89	61	43	125	539
with 3DCRT function(MLC width=<1.0 cm)	82	136	84	65	44	144	555
with IMRT function	21	35	31	25	26	97	235
with IGRT function	13	17	11	8	10	49	108
with CT on rail	12	11	5	8	0	11	47
with treatment position verification system	8	13	13	15	15	46	110
annual no. patients/linac	70.2	165.8	283.4	331.1	344.8	416.8	243.2
CyberKnife®	6	3	2	0	1	3	15
Novalis®	1	1	1	0	0	4	7
Synergy®	1	0	1	0	2	3	7
Trilogy®	2	1	0	0	2	4	9
Oncor®	4	3	1	1	1	4	14
TomoTherapy®	1	2	3	1	0	2	9
particle	1	0	0	0	0	5	6
betatron	0	0	0	0	0	0	0
microtron	1	2	4	1	1	4	13
telecobalt(actual use)	11(7)	2(2)	6(2)	3(0)	2(1)	4(3)	28(15)
Gamma Knife®	2	15	10	7	5	7	46
other accelerator	1	5	0	1	1	1	9
other external irradiation device	0	2	1	1	1	1	6
new type Co-60 RALS(actual use)	1(1)	5(5)	2(2)	2(2)	3(3)	3(3)	16(16)
old type Co-60 RALS(actual use)	2(1)	6(5)	9(6)	12(9)	5(4)	5(4)	39(29)
Ir-192 RALS(actual use)	1(1)	9(7)	19(19)	24(23)	17(17)	57(56)	127(123)
Cs-137 RALS(actual use)	0(0)	1(0)	0(0)	2(2)	0(0)	1(1)	4(3)

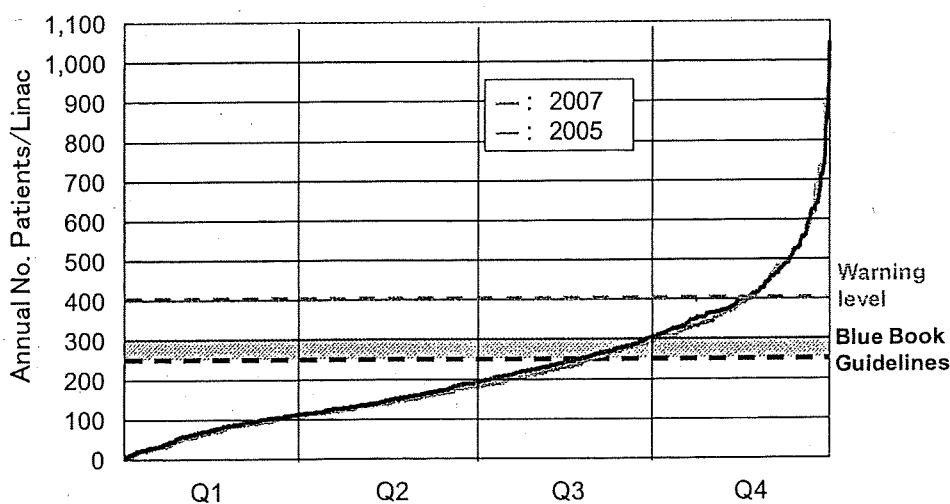


Fig. 1 Distribution of annual patient load/external treatment equipment in radiation oncology facilities. Horizontal axis represents facilities in order of increasing value of annual number of patients/treated equipment within facilities. Q1: 0-25%, Q2: 26-50%, Q3: 51-75%, Q4: 76-100%.

らに全体で、IGRT機能を108台(13.4%)、CT同室システム(CT on rail)を47台(5.8%)、照射位置照合システムを110台(13.6%)に有していた。D: 300~399人の施設では加速器を2台有し始め、Fの施設では全施設で2台以上有していた。1台のlinacで実患者数平均243.2人を治療していた。C: 200~299人の施設では283.4人、D: 300~399人で331.1人を治療していた。E: 400~499人では344.8人、F: 500人以上では416.8人を治療していた。全体で見ると、日本版ブルー

ブック¹²⁾の基準である250~300人/装置以上を全体の35%の施設では治療していた。逆に、65%の施設では、この基準範囲以下の治療がなされていた(Fig. 1)。上位1/4の施設では300人を超えて治療していた。特に上位12%では、改善警告値400人を超える患者を1台のlinacで治療していた。最新の装置としてCyberKnife®15台、Novalis®7台、Synergy®7台、Trilogy®9台、Oncor®14台が導入されていた。粒子線は、本登録では全国で6台稼動していた。小線源照射装置

Table 7 Number of treatment planning equipment and accessories by annual patient load of radiation oncology facilities

治療周辺機器	A (183)	B (233)	C (115)	D (73)	E (37)	F (80)	Total (721)
X-ray simulator	106	138	62	50	30	59	445
CT simulator	89	149	91	55	31	82	497
RTP computer(2 or more)	192(13)	248(24)	153(26)	107(25)	70(14)	300(66)	1,070(168)
X-ray CT(2 or more) for RT only	296(99)	501(183)	310(107)	223(63)	129(34)	369(72)	1,828(558)
MRI(2 or more) for RT only	46	93	62	49	25	78	353
computer use for RT recording	202(33)	339(100)	201(81)	142(59)	89(31)	216(66)	1,189(370)
water phantom(2 or more)	0	2	3	5	0	3	13
film densitometer(2 or more)	147	211	107	68	35	72	640
dosemeter(3 or more)	160(19)	223(30)	120(21)	80(17)	47(12)	116(25)	746(124)
	67(4)	78(4)	59(0)	45(3)	23(2)	71(4)	343(17)
	421(66)	620(105)	365(61)	209(35)	164(27)	402(54)	2,181(348)

Table 8 Number of treatment planning by its complexity and annual patient load by radiation oncology facilities (n=548*)

	放射線治療管理料数(放射線治療管理料総数に対する割合 [%])						Total (548)
	A (133)	B (181)	C (86)	D (52)	E (27)	F (69)	
単純 (1 門照射, 対向 2 門照射)	5,424 (62.6)	15,128 (54.8)	10,932 (48.6)	8,797 (45.7)	6,100 (49.0)	20,793 (39.1)	67,174 (46.8%)
中間 (非対向 2 門照射, 3 門照射)	1,884 (21.8)	7,023 (25.4)	6,732 (29.9)	5,946 (30.9)	3,530 (28.3)	16,074 (30.3)	41,189 (28.7%)
複雑 (4 門以上の照射, 運動照射, 原体照射)	1,352 (15.6)	5,450 (19.7)	4,835 (21.5)	4,516 (23.4)	2,827 (22.7)	16,259 (30.6)	35,239 (24.5%)
合計	8,660	27,601	22,499	19,259	12,457	53,126	143,602

*放射線治療管理料数が未記入であった施設：173施設。

(実稼動数)は⁶⁰Co RALSの新型が16台, 旧型が29台(計45台), ¹⁹²Ir-RALSが123台, ¹³⁷Cs-RALSが3台であった。施設規模ごとに検討すると, C:200~299人以上の大きい施設程, linacの各機能は充実していた。小線源治療装置もC以上の施設で装備され, 特に¹⁹²Ir-RALSはF:500人以上で7割の施設に装備されていた。

Table 7に, 施設規模別の治療周辺機器数を示している。全体ではX線シミュレータ 445台, CTシミュレータ 497台, 放射線治療計画コンピュータ(RTP) 1,070台, 放射線治療専用CT 353台, 放射線治療専用MRI 13台, 放射線治療の記録でのコンピュータ使用は640施設, 水ファントム保有 746施設, dosimeter 2,181台などであった。施設規模でCT simulatorの保有率を見ると, A:99人以下の施設では48.6%であったが, F:500人以上の施設では100%有していた。2005年に比べてX線シミュレータが減少し, CTシミュレータ, RTP, 水ファントム, dosimeterが増加していた。

Table 8に, 放射線治療管理料数とその難易度を施設規模で示す。未記入施設が173施設あったが, 最小規模施設Aと大規模施設Fでは単純(1 門照射, 対向 2 門照射)で23.5%(A多, F少), 中間(非対向 2 門照射, 3 門照射), 複雑(4 門以上の照射, 運動照射, 原体照射)で, それぞれ8.5%, 15.0%(A少, F多)の差が観察された。2005年に比べて, 単純と複雑において差は拡大していた。しかし, それぞれの施設規模では単純が減少して, 複雑が増加する傾向にあった。

4. 人員

Table 9に, 施設規模別の患者数とスタッフ数を示している。1施設当たりの年間総患者数(新患+再患)は284.4人であった。JASTRO認定医数(常勤)は477人であった。常勤の治療担当医総数は1,007人, 非常勤の治療担当医総数は534人であった。放射線治療専任業務時間を換算した実質的なマンパワーである合計(常勤+非常勤)治療担当医FTE数は826.3人であった。常勤治療担当技師総数は2,617人, 治療担当技師FTE数は1,634.1人, 常勤医学物理士総数は261人, 医学物理士FTE数は63.9人, 常勤放射線治療品質管理士総数は526人, 放射線治療品質管理士FTE数は105.6人, 治療担当看護師総数は1,064人, 治療担当看護師FTE数は494.4人, 看護助手数は86.4人, 事務員数は242.5人であった。放射線治療担当医 1 FTE当たりの患者数負荷は, 248.2(205, 087/826.3)人であった¹²⁾。(詳細分析は第2報参照)

5. 特殊治療

Table 10に, 一般的外部照射以外の特殊治療を列記している。腔内照射は3,235例(2005年 3,246例)が172施設にて行われていた。組織内照射(前立腺ヨード治療を含む)は3,301例(2005年 2,773例)が97施設にて行われ, 前立腺ヨード治療は2,690例(2005年 1,765例)が78施設にて行われていた。全身照射は1,633例(2005年 1,738例)が185施設にて, 術中照射は251例(2005年 387例)が41施設にて, 定位(脳)照射は