

Table 4. Structure and personnel by PCS institutional stratification

	Structure and personnel				p-value	Total (n = 712)
	A1 (n = 66)	A2 (n = 67)	B1 (n = 290)	B2 (n = 289)		
Institutions/total institutions (%)	9.3	9.4	40.7	40.6		100
Institutions with RT bed (n)	57 (86.4)	35 (52.2)	127 (43.8)	68 (23.5)		287 (40.3)
Average RT beds/institution (n)	14.0	4.8	3.4	1.0		3.6
JASTRO-certified RO (full time)	181	62	139	44		426
Average JASTRO-certified RO/institution (n)	2.7	0.9	0.5	0.2	<0.0001	0.6
Total (full-time and part-time) RO FTE*	290.9	95.55	258.77	129.24		774.46
Average FTE ROs/institution	4.41	1.43	0.89	0.45	<0.0001	1.09
Patient load/FTE RO	188.7	224.1	343.0	202.1	<0.0001	246.8
Total RT* technologists	388.6	176.3	637.7	431.9		1634.5
Average technologists/institution (n)	5.9	2.6	2.2	1.5	<0.0001	2.3
Patient load/RT technologist	141.2	121.5	139.2	60.5	<0.0001	117.0
Total nurses/assistants/clerks (n)	202.2	92.4	390.55	221.8		907
Full-time medical physicists + part-time (n)	51 + 10.1	8 + 7	39 + 7	19 + 6		117 + 30.1
Full-time RT QA staff + part-time	81 + 0	31 + 7	102.5 + 3	42.3 + 3		256.8 + 13

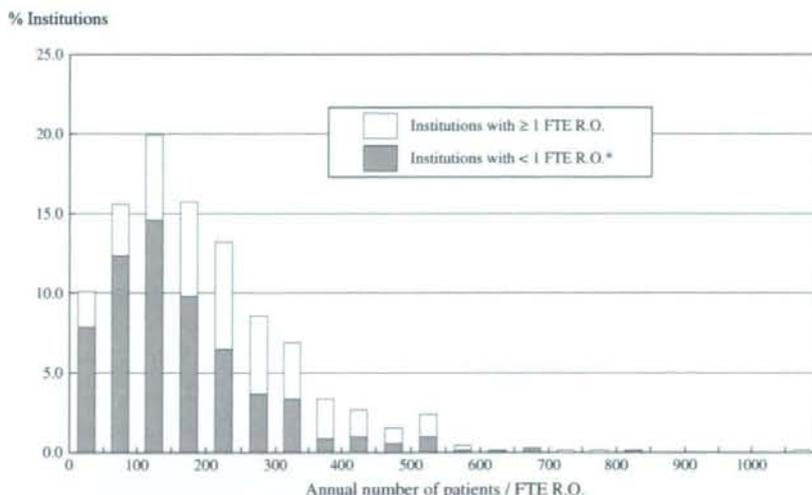
Abbreviations: JASTRO = Japanese Society of Therapeutic Radiation Oncology; RO = radiation oncologist; FTE = full-time equivalent (40 h/wk only for RT practice); QA = quality assurance; other abbreviations as in Table 2.

Data in parentheses are percentages.

significantly during the next 15 years, with respective increases by factors of 2 and 2.6 compared with those in 1990 (3). However, the use rate of RT for new cancer patients remained at 25%, less than one-half the ratio in the United States and European countries. The anticancer law was enacted in Japan to promote RT and education for ROs, as well as medical physicists or other staff members, from April 2006. For the implementation of this law, comparative data of the structure of radiation oncology in Japan and the United States, as well as relevant PCS data, proved helpful. Because

the increase in the elderly population of developed countries is the greatest in Japan, RT is expected to play an increasingly important role.

Compared with 1990, the number of linear accelerator systems increased significantly by 2.3 times, and the percentage of systems using telecobalt decreased to 7%. Furthermore, the functions of linear accelerators, such as dual energy, three-dimensional conformal RT (multileaf collimator width <1 cm), and IMRT improved. The number of high-dose-rate RALS in use increased by 1.4 times and the use of



* Number of FTEs for institutions with FTE < 1 was calculated as FTE = 1 to avoid overestimating patient load/RO.

Fig. 1. Percentage of institutions by patient load/full-time equivalent (FTE) staff of radiation oncologists (RO) in Japan. White bars represent institutions with one or more FTE staff, and gray bars represent institutions with fewer than one FTE radiation oncologist. Each bar represents interval of 50 patients/FTE radiation oncologist.

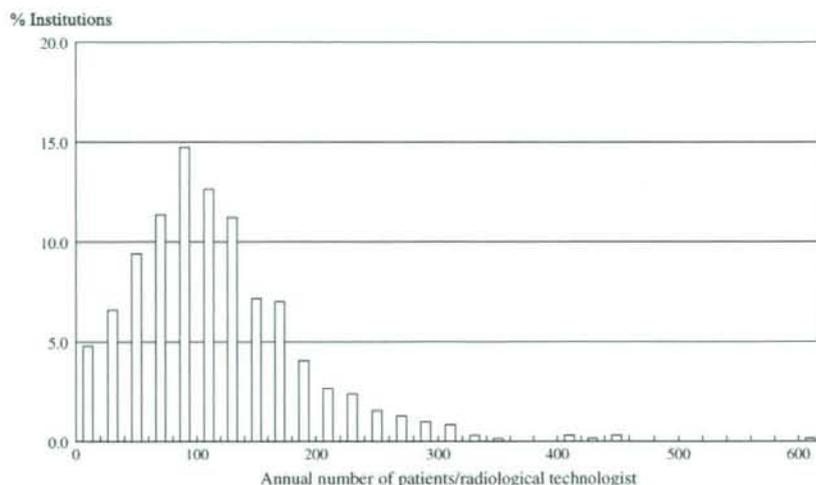


Fig. 2. Percentage of institutions by patient load/radiotherapy technologist in Japan. Each bar represents interval of 20 patients/full-time equivalent staff.

^{60}Co -RALS has largely been replaced by ^{192}Ir -RALS. CT simulators were installed in 55% of institutions nationwide, and RT planning systems were used in 93%, for an increase in the number of RT planning systems of 4.87 times. The maturity of the functions of linear accelerator and greater possession rates of CT simulators and systems using ^{192}Ir -RALS were closely related to the institutional stratification by PCS, which could therefore aid in the accurate discrimination of structural maturity and immaturity and the identification of structural targets to be improved. The Japanese PCS group published structural guidelines based on the PCS data (16), and we plan to use this structural data for a new PCS to revise the Japanese structural guidelines.

The staffing patterns in Japan also improved in terms of numbers. However, the institutions that had fewer than one FTE RO on their staff still accounted for >60% nationwide, and this rate did not change during the 15 years from 1990 to 2005. In Japan, most institutions still rely on part-time ROs. First, the number of cancer patients who require RT is increasing more rapidly than the number of ROs. Second, specialist fees for ROs in academic institutions are not recognized by the Japanese medical care insurance system, which is strictly controlled by the government. Most ROs must therefore work part-time at affiliated hospitals in the B1 and B2 groups to earn a living. Thus, to reduce the number of institutions that rely on part-time ROs and might encounter

Table 5. Primary sites of cancer treatment with RT in 2005 by PCS institutional stratification for new patients

Primary site	A1 (n = 65)		A2 (n = 67)		B1 (n = 285)		B2 (n = 284)		Total (n = 701)	
	n	%	n	%	n	%	n	%	n	%
Cerebrospinal	2,603	5.6	770	4.5	4,431	6.4	795	3.6	8,599	5.6
Head and neck (including thyroid)	6,318	13.7	2,372	13.9	6,033	8.7	1,650	7.5	16,373	10.6
Esophagus	3,164	6.9	1,171	6.9	4,426	6.4	1,452	6.6	10,213	6.6
Lung, trachea, and mediastinum	7,069	15.3	2,639	15.5	14,946	21.5	5,386	24.6	30,040	19.4
Lung	5,469	11.8	2,272	13.3	12,917	18.6	4,734	21.6	25,392	16.4
Breast	8,945	19.4	3,049	17.9	14,148	20.4	4,119	18.8	30,261	19.6
Liver, biliary tract, pancreas	1,936	4.2	713	4.2	2,742	3.9	964	4.4	6,355	4.1
Gastric, small intestine, colorectal	1,897	4.1	806	4.7	3,742	5.4	1,399	6.4	7,844	5.1
Gynecologic	3,253	7.0	1,156	6.8	3,405	4.9	855	3.9	8,669	5.6
Urogenital	5,544	12.0	2,043	12.0	8,068	11.6	2,905	13.3	18,560	12.0
Prostate	4,290	9.3	1,385	8.1	5,627	8.1	1,916	8.8	13,218	8.6
Hematopoietic and lymphatic	2,460	5.3	1,052	6.2	3,624	5.2	904	4.1	8,040	5.2
Skin, bone, and soft tissue	1,607	3.5	749	4.4	1,830	2.6	1,018	4.6	5,204	3.4
Other (malignant)	705	1.5	235	1.4	822	1.2	313	1.4	2,075	1.3
Benign tumors	664	1.4	268	1.6	1,289	1.9	135	0.6	2,356	1.5
Pediatric <15 y (included in totals above)	435	0.9	123	0.7	187	0.3	302	1.4	1,047	0.7
Total	46,165	100	17,023	100	69,506	100	21,895	100	154,589 [†]	(100)

Abbreviations as in Table 2.

[†]Number of total number of new patients different with these data, because no data on primary sites were reported by some institutions.

Table 6. Distribution of specific treatments and numbers of patients treated with these modalities by PCS stratification of institutions

Specific therapy	A1 (n = 66)		A2 (n = 67)		B1 (n = 290)		B2 (n = 289)		p	Total (n = 712)	
	n	%	n	%	n	%	n	%		n	%
Intracavitary RT (n)									<0.0001		
Treatment facilities	61	92.4	37	55.2	71	24.5	12	4.2		181	25.4
Cases	1,670		527		974		75			3,246	
Interstitial RT									<0.0001		
Treatment facilities	42	63.6	14	20.9	18	6.2	5	1.7		79	11.1
Cases	1,818		286		638		31			2,773	
Radioactive iodine therapy for prostate cancer									<0.0001		
Treatment facilities	25	37.9	6	9.0	7	2.4	1	0.3		39	5.5
Cases	1,166		152		430		17			1,765	
Total body RT									<0.0001		
Treatment facilities	60	90.9	36	53.7	78	26.9	17	5.9		191	26.8
Cases	706		237		687		108			1,738	
Intraoperative RT									<0.0001		
Treatment facilities	23	34.8	12	17.9	20	7.0	11	3.8		66	9.3
Cases	212		39		111		25			387	
Stereotactic brain RT									<0.0001		
Treatment facilities	46	69.7	31	46.3	91	31.4	29	10.0		197	27.7
Cases	1,680		482		8,513		447			11,122	
Stereotactic body RT									<0.0001		
Treatment facilities	31	50.0	14	20.9	36	12.4	11	3.8		92	12.9
Cases	482		263		679		234			1,658	
IMRT									<0.0001		
Treatment facilities	16	24.2	4	6.0	12	4.1	1	0.3		33	4.6
Cases	426		67		212		50			755	
Thermoradiotherapy									0.0004		
Treatment facilities	10	15.2	4	6.0	15	5.2	7	2.4		36	5.1
Cases	339		27		134		81			581	

Abbreviations: PCS = Patterns of Care Study; RT = radiotherapy; IMRT = intensity-modulated radiotherapy.

problems with their quality of care, a drastic reform of our current medical care systems is required. However, great care is needed to ensure that the long-term success of radiation oncology in Japan and patient benefits are well balanced with the costs. Even under the current conditions, however, the number of FTE ROs increased by 2.1 times compared with the number in 1990 (3). However, the patient load/FTE RO also increased by 1.4 times to 247 during the same period, perhaps reflecting the growing popularity of RT because of recent advances in technology and improvement in clinical results. This caseload ratio in Japan has already exceeded the limit of the Blue Book guidelines of 200 patients/RO (15, 16). The percentage of distribution of institutions by patient load/RO showed a slightly smaller distribution than that of the United States in 1989 (3). Therefore, Japanese radiation oncology seems to be catching up quickly

with the western system despite limited resources. Furthermore, additional recruiting and education of ROs are now top priorities of the JASTRO.

The distribution of patient load/RT technologists showed that 13% of institutions met the narrow guideline range (100–120/RT technologist), and the rest were densely distributed around the peak. Compared with the distribution in the United States in 1989, >20% of institutions in Japan had a relatively low caseload of 10–60 because a large number of smaller B2-type institutions still accounted for nearly 40% of institutions exceeding the range of the guidelines. As for medical physicists, a similar analysis for patient load/FTE staff was difficult, because the number was still small, and they were working mainly in metropolitan areas. In Japan, radiation technologists have been acting as medical physicists, so that their education has been changed from 3 to 4 years

Table 7. Brain metastasis or bone metastasis patients treated with RT in 2005 by PCS institutional stratification

Metastasis	Patients				p	Total (n = 712)
	A1 (n = 66)	A2 (n = 67)	B1 (n = 290)	B2 (n = 289)		
Brain	2,565 (4.7)	1,204 (5.6)	9,774 (11.0)	1,778 (6.8)	<0.0001	15,321 (8.0)
Bone	6,243 (11.4)	2,845 (13.3)	13,331 (15.0)	5,057 (19.4)	<0.0001	27,476 (14.4)

Data presented as number of patients, with percentages in parentheses.

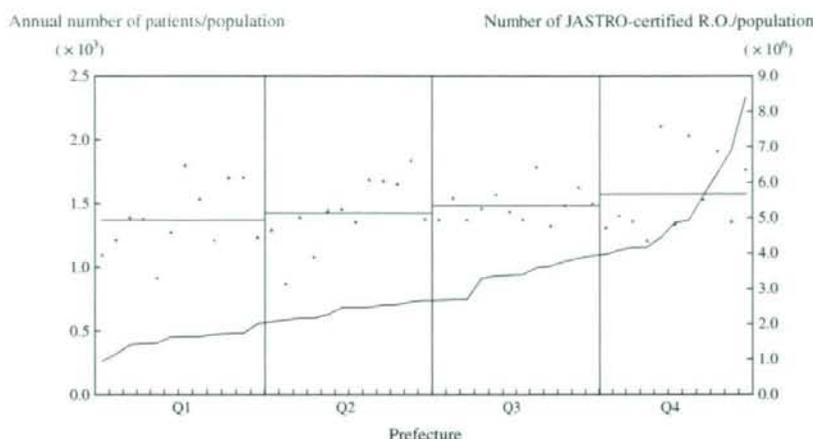


Fig. 3. Geographic distribution for 47 prefectures of annual number of patients (new plus repeat) per 1,000 population arranged in order of increasing number of Japanese Society of Therapeutic Radiation Oncology (JASTRO)-certified radiation oncologists (RO)/1,000,000 population by prefecture. Q1, 0–25%; Q2, 26–50%; Q3, 51–75%; and Q4, 76–100%. Horizontal bar shows average annual number of patients (new plus repeat) per 1,000 population of prefectures per quarter.

during the past decade and graduate and postgraduate courses have been introduced. Currently, those who have obtained a master's degree or radiation technologists with enough clinical experience can take the examination for qualification as a medical physicist, as can those with a master's degree in science or engineering, like those in the United States or Europe. In Japan, a unique education system for medical physicists might be developed because the anticancer law actively supports improvements in quality assurance/quality control specialization for RT. However, the validity of this education and training system remains unsatisfactory, because we are still in the trial-and-error stage.

The distribution of the primary site for RT showed that more lung cancer patients were treated in B1 or B2 nonacademic institutions and more head-and-neck cancer patients were treated in A1 or A2 academic institutions. These findings might be because more curative patients were referred to academic institutions and more palliative patients with lung cancer were treated in nonacademic institution in Japan. In addition, more patients with bone metastasis were treated in nonacademic institutions. The use of specific treatments and the number of patients treated with these modalities were significantly affected by institutional stratification, with more specific treatments performed at academic institutions. These findings indicate that significant differences in the patterns of care, as reflected in the structure, process, and, possibly, outcomes for cancer patients still exist in Ja-

pan. These differences point to opportunities for improvement. We, therefore, based the Japanese Blue Book guidelines on this stratification by the PCS data (16) and are now in preparing to revise them accordingly.

The geographic patterns demonstrated significant differences among the prefectures in the use of RT, ranging from 0.9 to 2.1 patients/1,000 population. Furthermore, the number of JASTRO-certified physicians/population might be associated with the use of RT, so that a shortage of ROs or medical physicists on a regional basis will remain a major concern in Japan. The JASTRO has been making every effort to recruit and educate ROs and medical physicists through public relations, training courses, involvement in the national examination for physicians, and seeking to increase the reimbursement by the government-controlled insurance program, and other actions.

CONCLUSION

The Japanese structure of radiation oncology has clearly improved during the past 15 years in terms of equipment and its functions, although a shortage of manpower and differences in maturity by type of institution and caseload remain. Structural immaturity is an immediate target for improvement, and, for improvements in process and outcome, the PCS or National Cancer Database, which are currently operational and being closely examined, can be expected to play an important role in the future.

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CLINICAL INVESTIGATION

EXTERNAL BEAM RADIOTHERAPY FOR CLINICALLY LOCALIZED HORMONE-REFRACTORY PROSTATE CANCER: CLINICAL SIGNIFICANCE OF NADIR PROSTATE-SPECIFIC ANTIGEN VALUE WITHIN 12 MONTHS

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SUBGROUP OF PROSTATE CANCER

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Purpose: To analyze retrospectively the results of external beam radiotherapy for clinically localized hormone-refractory prostate cancer and investigate the clinical significance of nadir prostate-specific antigen (PSA) value within 12 months (nPSA12) as an early estimate of clinical outcomes after radiotherapy.

Methods and Materials: Eighty-four patients with localized hormone-refractory prostate cancer treated with external beam radiotherapy were retrospectively reviewed. The total radiation doses ranged from 30 to 76 Gy (median, 66 Gy), and the median follow-up period for all 84 patients was 26.9 months (range, 2.7-77.3 months). **Results:** The 3-year actuarial overall survival, progression-free survival (PFS), and local control rates in all 84 patients after radiotherapy were 67%, 61%, and 93%, respectively. Although distant metastases and/or regional lymph node metastases developed in 34 patients (40%) after radiotherapy, local progression was observed in only 5 patients (6%). Of all 84 patients, the median nPSA12 in patients with clinical failure and in patients without clinical failure was 3.1 ng/mL and 0.5 ng/mL, respectively. When dividing patients according to low (<0.5 ng/mL) and high (≥0.5 ng/mL) nPSA12 levels, the 3-year PFS rate in patients with low nPSA12 and in those with high nPSA12 was 96% and 44%, respectively ($p < 0.0001$). In univariate analysis, nPSA12 and pretreatment PSA value had a significant impact on PFS, and in multivariate analysis nPSA12 alone was an independent prognostic factor for PFS after radiotherapy.

Conclusions: External beam radiotherapy had an excellent local control rate for clinically localized hormone-refractory prostate cancer, and nPSA12 was predictive of clinical outcomes after radiotherapy. © 2008 Elsevier Inc.

Hormone-refractory, Prostate cancer, nPSA12, Radiotherapy, Prognostic factor.

INTRODUCTION

Androgen ablation is an effective treatment approach for prostate cancer and has been used as one of the primary treatments for localized disease or palliative treatment for systemic disease (1, 2). In Japan in particular, androgen abla-

tion has frequently been used because most Japanese patients with prostate cancer have had high-risk disease and hormonal therapy is frequently preferred as the primary therapy (3, 4). Although almost all prostate cancers initially respond well to hormonal therapy, the majority eventually lose their hormone

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Table 1. Patient characteristics

Age (y) (median, 73.3)	
<75	51
≥75	33
KPS (%)	
≤80	45
>80	35
Unknown	4
T stage (1997 UICC)	
T0-2	18
T3-4	56
N stage (1997 UICC)	
N0	58
N1	10
Unknown	16
Pretreatment PSA (ng/mL)	
Median (range)	9.7 (0.06-760.3)
<4	14
≥4	62
Unknown	1
Gleason combined score	
≤6	5
>6	13
Unknown	66
Differentiation	
Well/moderately	38
Poorly	51
Unknown	15

Abbreviations: KPS = Karnofsky performance status; UICC = International Union Against Cancer; PSA = prostate-specific antigen.

sensitivity and progress (5). In the absence of an effective therapy for hormone-refractory prostate cancer, patients will die within approximately 12-18 months after the diagnosis of hormone-refractory prostate cancer (6). Among these patients, however, some will develop local progression without systemic diseases. Although the optimal treatment approach for clinically localized hormone-refractory prostate cancer has not yet been established, radiotherapy may be considered the treatment of choice to treat local progression with curative intent or to release urinary obstructive symptoms as a palliative treatment (7-9). However, little information exists on the efficacy of radiotherapy for localized hormone-refractory disease. Moreover, there is also minimal information regarding the clinically useful markers of recurrence risk for localized hormone-refractory prostate cancer treated with radiotherapy.

For patients with untreated prostate cancer, prostate-specific antigen (PSA) has been used as an important tool for prostate cancer screening and as a marker for treatment response and disease recurrence (10, 11). The PSA nadir (nPSA) after radiotherapy has been shown to predict biochemical failure (12, 13), distant metastases (14, 15), cause-specific mortality (16, 17), and overall mortality (17). 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 value achieved during a well-defined, relatively short 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 metastases, and mortality that is independent of radiotherapy dose and other determinants of outcome after radiotherapy for previously untreated localized prostate cancer (10, 11).

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 hormone-refractory prostate cancer treated with radiotherapy. In the present study we analyzed the treatment results of external beam radiotherapy for localized hormone-refractory prostate cancer. Next, we examined the nPSA12 in patients with hormone-refractory prostate cancer treated with radiotherapy and investigated whether nPSA12 could be a prognostic factor of clinical outcomes for these patients.

METHODS AND MATERIALS

We used detailed data from patients with clinically localized hormone-refractory 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 (18). 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 external beam radiotherapy for prostate cancer patients (19-24).

The PCS methodology has been described previously (18, 25, 26). In brief, the PCS surveys were extramural audits that used a stratified two-stage cluster sampling design. The PCS surveyors consisted of 20 radiation oncologists from academic institutions, and one radiation oncologist collected data by reviewing patients' charts from each 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: evidence of distant metastasis, concurrent or prior diagnosis of any other malignancy, or prior radiotherapy. The PCS data used in the present 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 constituting the 1996-1998 and 1999-2001 PCS survey populations, a total of 154 patients with regionally localized hormone-refractory prostate cancer were identified. Of these, 70 patients with insufficient nPSA12 data were excluded; a total of 84 patients with measurable nPSA12 were subjected to this analysis. The disease characteristics of these 84 patients, such as tumor stage and pretreatment PSA levels, were not significantly different compared with those of the 70 patients having insufficient data for nPSA12. All 84 patients received androgen ablation alone initially, followed by radiotherapy for local or biological progression in the absence of distant metastases.

Table 1 shows the patient characteristics for all 84 patients. Most patients had advanced disease at initial treatment. Pretreatment PSA value was defined as the PSA value before initial hormonal

Table 2. Treatment characteristics

Treatment	n (%)
Hormonal therapy	
Orchiectomy	19 (12)
Estrogen agent	24 (28)
LHRH agonist	78 (92)
Antiandrogen	60 (71)
Chemotherapy	
Yes	23 (27)
No	58 (69)
Unknown	3 (4)
Radiotherapy	
Radiation field	
WP plus boost	34 (40)
Prostate only	50 (60)
Total radiation dose (Gy)	
<60	12 (14)
>60	72 (86)
CT-based treatment planning	
Yes	17 (20)
No	49 (59)
Unknown	18 (21)
Conformal therapy	
Yes	23 (27)
No	44 (53)
Unknown	17 (20)

Abbreviations: LHRH = luteinizing hormone-releasing hormone; WP = whole pelvis.

treatment, and preradiotherapy PSA value was defined as the PSA value just before radiotherapy.

Methods of treatment are shown in Table 2. Hormonal therapy was administered alone or in combination with orchiectomy, estrogen agent, luteinizing hormone-releasing hormone agonist, or antiandrogen. The median duration of hormonal therapy before radiotherapy was 34.4 months (range, 0.2–164.8 months). Regarding chemotherapy, 23 patients (28%) were also treated with chemotherapy, such as estramustine and 5-fluorouracil, but no patients received docetaxel or paclitaxel-containing chemotherapy.

Regarding radiotherapy, most of the patients were treated with ≥ 10 MV linear accelerator and also treated with four or more portals. The median radiation dose delivered to the prostate was 66 Gy (range, 30–76 Gy), and the median dose per fraction was 2.0 Gy (range, 1.5–3.0 Gy). In the present study there were no definitive treatment policies for hormone-refractory prostate cancer, and radiation field was determined by the respective physicians at each institution. Thirty-four patients (40%) received treatment to the pelvic nodes in addition to prostate, and the remaining 50 patients (60%) received irradiation only to the prostate. Regarding lymph node status, 8 of 10 patients (80%) with clinically positive lymph nodes received treatment to the pelvic nodes in addition to prostate.

The 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 (range, 1–12) in all 84 patients. Median follow-up of all patients was 26.9 months (range, 2.7–77.3 months), and all patients without clinical failure had at least 1 year of follow-up. Patients were categorized as having progression after radiotherapy if they developed local, pelvic nodal, or distant failure.

Statistical analyses were performed using the Statistical Analysis System (SAS Institute, Tokyo, Japan) at the PCS statistical center (27). Overall and progression-free survival (PFS) rates were calcu-

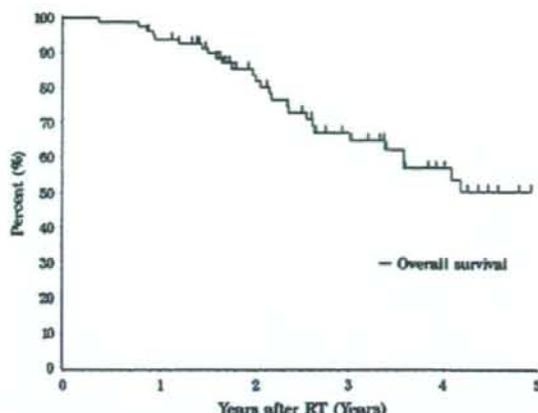


Fig. 1. Actuarial overall survival curves for 84 patients with clinically localized hormone-refractory prostate cancer treated with radiotherapy (RT).

lated actuarially according to the Kaplan-Meier method (28) and were measured from the start of radiotherapy. Differences between groups were estimated using the χ^2 test, the Student's *t* test, and the log-rank test (29). Multivariate analysis was performed using the Cox regression model (30). 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 (31).

RESULTS

Of 84 patients, 27 (32%) died during the period of this analysis. Of these 27 patients, 24 died of prostate cancer, and the remaining 3 died without any sign of clinical recurrence (2 died of intercurrent disease, 1 died of unknown cause). The 3-year actuarial overall survival rate for all 84 patients was 67% (Fig. 1). With regard to the site of recurrence, 37 patients had clinical failure (local only in 3 patients, local with regional in 1 patient, local with distant metastases in 1 patient, regional in 3 patients, distant metastases in 24 patients, and regional and distant metastases in 5 patients). The 3-year actuarial PFS and local control rates in all 84 patients after radiotherapy were 61% and 93%, respectively (Figs. 2 and 3). Although distant metastases and/or regional lymph node metastases were seen in 34 patients (40%), local progression was observed in only 5 patients (6%), including 2 patients with simultaneous regional/distant metastases. The total dose and radiation field treated were tested for correlation with local control (Table 3). Ten of 12 patients (83%) treated with <60 Gy achieved local control, whereas 54 of 55 patients (98%) treated with ≥ 66 Gy achieved local control ($p = 0.024$). Thirty-three of 34 patients (97%) treated with whole-pelvis irradiation with boost and 46 of 50 patients (92%) treated with local-field irradiation achieved local control; this difference was not statistically significant ($p = 0.34$). Table 4 indicates regional control according to N stage and radiation field. Twenty-eight of 34 patients (82%) treated

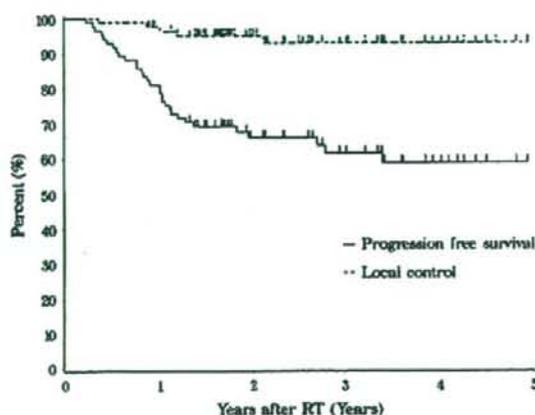


Fig. 2. Actuarial progression-free survival and local control curves for 84 patients with clinically localized hormone-refractory prostate cancer treated with radiotherapy (RT).

with whole-pelvis irradiation with boost and 47 of 50 patients (94%) treated with local-field irradiation achieved regional control; this difference was not statistically significant ($p = 0.09$).

Of all 84 patients, the median nPSA12 in patients with clinical failure after radiotherapy and in those without clinical failure was 3.10 ng/mL (range, 0.36–1400 ng/mL) and 0.50 ng/mL (range, 0–50.39 ng/mL), respectively. Figure 4 shows the distribution of nPSA12 according to the achievement of clinical control. More than half of patients with clinical control (27 of 52 patients, 52%) had nPSA12 of <0.5 ng/mL, whereas only 1 of 32 patients (3%) with clinical failure had nPSA of <0.5 ng/mL ($p < 0.0001$). For the 27 patients who achieved an nPSA12 <0.5 ng/mL and who did not experience clinical failure, the median time from the completion of radiotherapy to achievement of nPSA12 <0.5 ng/mL was 6.4 months (range, 0.07–11.7 months).

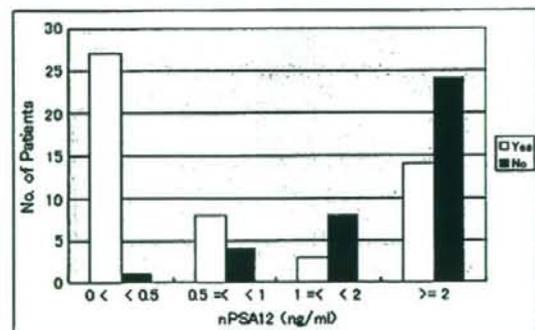


Fig. 3. Distribution of nPSA12 according to clinical control. More than half of patients with clinical control had a prostate-specific antigen nadir at 12 months (nPSA12) <0.5 ng/mL, whereas only 1 of 32 patients who experienced clinical failure had an nPSA12 <0.5 ng/mL.

Table 3. Local control according to radiation dose and field

Total dose (Gy)	n	Patients with LC	Incidence of LC	
			WP + B	Local
<60	12	10 (83)	5/5	5/7
60–<62	15	15 (100)	10/10	5/5
62–<64	2	0	0	0/2
64–<66	2	2	1/1	1/1
66–<68	17	16 (94)	7/8	9/9
68–<70	14	14 (100)	2/2	12/12
≥70	22	22 (100)	8/8	14/14
Total	84	79 (94)	33/34 (97)	46/50 (92)

Abbreviations: LC = local control; WP = whole pelvis; B = boost. Values in parentheses are percentages.

In the present study, patients with nPSA12 <0.5 ng/mL were assigned to the low nPSA12 group ($n = 28$), whereas those with nPSA12 ≥0.5 ng/mL were assigned to the high nPSA12 group ($n = 56$). The 3-year actuarial PFS rate in patients with high nPSA12 and in patients with low nPSA12 was 96.4% and 43.9%, respectively (Fig. 5). The difference between these two groups was statistically significant ($p < 0.0001$). In a univariate analysis, nPSA12 and pretreatment PSA value had a statistically significant impact on PFS (Table 5). No significant differences in PFS were seen with respect to other factors. In a multivariate analysis, nPSA12 alone was a significant prognostic factor for PFS (Table 6).

Late morbidity of RTOG Grade 2–3 was observed in 11 patients (13%). A total of 8 patients experienced late rectal toxicity, 3 patients had late urinary toxicity, and 1 patient had multiple late rectal and urinary toxicities (Grade 3 rectal stricture, Grade 2 incontinence, and Grade 2 urethral stricture). There were no cases of Grade 4 toxicity (Table 7). Regarding 7 patients who had Grade 3 late complications, CT-based treatment planning was done in only 1 patient (14%), and conformal therapy was supplemented in 2 patients (29%).

DISCUSSION

The present study indicated that external beam radiotherapy had an excellent local control rate for clinically localized hormone-refractory prostate cancer. Several reports have also indicated that radical radiotherapy had an excellent local control rate for these tumors (20, 32). Akimoto *et al.* (32) treated

Table 4. Regional control according to N stage and radiation field

N stage	n	Patients with LC	Incidence of LC	
			WP + B	Local
N0	74	68 (92)	23/26	45/48
N1	10	7 (70)	5/8	2/2
Total	84	75 (89)	28/34 (82)	47/50 (94)

Abbreviations as in Table 3. Values in parentheses are percentages.

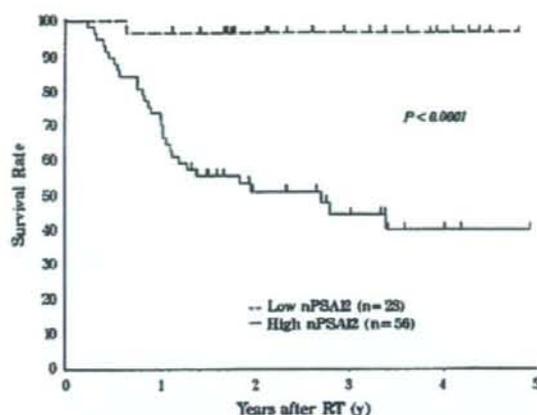


Fig. 4. Actuarial progression-free survival (PFS) curves according to the level of prostate-specific antigen nadir at 12 months (nPSA12). There were significant differences in PFS between patients with a low nPSA12 (<0.5 ng/mL) and those with a high nPSA12 (≥ 0.5 ng/mL).

53 patients with localized hormone-refractory prostate cancer with external beam radiotherapy, and only 2 patients (4%) had local failure as the first site of recurrence (32). Similarly, our initial report indicated that local progression was observed in only 1.6% of patients with hormone-refractory prostate cancer when treated with radiotherapy (20). In the present study, only 5 of 84 patients (6%) developed local failure after radiotherapy. These results indicate that external beam radiotherapy is effective in preventing local recurrence of these tumors.

Although the dose-response relationship in patients who undergo irradiation for localized hormone-refractory prostate cancer has not yet been clearly established, higher doses with curative intent can result in fairly prolonged survival in some patients. Furuya *et al.* (8) treated 11 patients with local progression by external radiotherapy at a dose of 50–66.6 Gy, and no patients suffered from local progression. Lankford *et al.* (9) examined 29 patients with localized hormone-refractory prostate cancer treated with radiotherapy and showed that the 3-year local control rate after irradiation of >60 Gy was 90%, compared with only 29% for those receiving ≤ 60 Gy. In the present study, the 3-year local control in 84 patients treated with a median dose of 66 Gy was 93%, and 52 of 53 patients (98%) treated with ≥ 66 Gy achieved local control. Therefore, radiation doses of ≥ 66 Gy seem to be appropriate for localized hormone-refractory prostate cancer patients when treated with external beam radiotherapy. However, it is important to note that in the present study almost all patients who had 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 late complications. Concerning radiation field, we did not find significant differences in both local and regional control between patients treated with whole-pelvis irradiation with boost and localized

Table 5. Univariate analysis of various potential prognostic factors for PFS in patients with hormone-refractory prostate cancer treated with external beam radiotherapy

Variable	n	Univariate analysis	
		3-y PFS (%)	p
nPSA12 (ng/mL)			0.0029*
<0.5	28	96	
≥ 0.5	56	44	
Pretreatment PSA (ng/mL)			0.0260*
<5	19	93	
≥ 5	62	47	
N stage			0.0737
N0	58	67	
N1	10	50	
Preradiotherapy PSA (ng/mL)			0.0997
<4	14	86	
≥ 4	69	57	
Age (y)			0.1102
<75	51	54	
≥ 75	33	74	
Differentiation			0.1398
Well/moderately	38	51	
Poor	31	70	
KPS (%)			0.4603
≤ 80	45	60	
>80	35	62	
Pelvic irradiation			0.6006
Yes	34	60	
No	50	63	
T stage			0.6886
T0–2	18	60	
T3–4	56	63	
Total radiation dose (Gy)			0.6939
<60	12	53	
≥ 60	72	62	
Use of chemotherapy			0.7089
Yes	23	64	
No	58	62	
Gleason combined score			0.9972
≤ 6	5	100	
>6	13	69	

Abbreviation: PFS = progression-free survival; nPSA12 = prostate-specific antigen nadir within 12 months. Other abbreviations as in Table 1.

* $p < 0.05$.

field only. Therefore, localized field irradiation may be sufficient in this patient population. Further studies are required to determine whether localized field irradiation can be sufficient for these patients.

The present study also indicated that patients with a high nPSA12 had a significantly lower PFS rate than patients with a low nPSA12. Moreover, nPSA12 was an independent prognostic factor for PFS in patients with localized hormone-refractory prostate cancer treated with radiotherapy. To our knowledge, this is the first report to demonstrate the utility of nPSA12 in determining prognosis in patients with localized hormone-refractory prostate cancer treated with radiotherapy. Concerning previously untreated prostate cancer, Alcabare *et al.* (10) indicate that nPSA12 is independent of radiation dose, T stage, Gleason score, pretreatment initial

Table 6. Multivariate analysis of potential prognostic factors for PFS in patients with hormone-refractory prostate cancer treated with external beam radiotherapy

Variable	RR (95% CI)	p
nPSA12 (<0.5 vs. ≥ 0.5 ng/mL)	10.965 (1.454–82.671)	0.0202*
Pretreatment PSA (<5 vs. ≥ 5 ng/mL)	6.489 (0.854–49.430)	0.0706

Abbreviations: RR = relative risk; CI = confidence interval. Other abbreviations as in Tables 1 and 5.

* $p < 0.05$.

PSA value, age, and PSA doubling time, and dichotomized nPSA12 (≤ 2 vs. > 2 ng/mL) was independently related to distant metastases and cause-specific mortality. Ray *et al.* (11) indicated that patients with nPSA12 ≤ 2.0 ng/mL had significantly higher 8-year PSA failure-free survival and overall survival rates than patients with nPSA12 > 2.0 ng/mL, and nPSA12 was an independent prognostic factor for prostate cancer patients treated with radiotherapy alone. These results suggest that nPSA12 may be a useful marker for localized hormone-refractory prostate cancer patients treated with radiotherapy, as well as for patients with previously untreated prostate cancer treated with radiotherapy. Because nearly all of the patients in the present study achieved local control, nPSA12 levels may largely reflect the recurrence risk for both regional and distant metastases.

Several previous studies have suggested other potential factors associated with the risk of prostate cancer recurrence, such as preradiotherapy PSA value, PSA doubling time, and Gleason score (9, 32, 33). Our results indicated that pretreatment PSA value has a significant impact on PFS, although multivariate analyses failed to confirm the significance (Table 4). Further studies are required to evaluate the influence of additional factors, such as pretreatment PSA value, on clinical outcomes for localized hormone-refractory patients treated with radiotherapy.

Patients with hormone-refractory prostate cancer generally have poor prognoses, even if the disease is regionally localized. The most common cause of failure in patients treated with radiotherapy is distant metastases (9, 20, 32). Akimoto *et al.* (32) indicated that 15 of 53 patients (28%) showed

Table 7. Late complications ($n = 84$)

Complication	Toxicity grade			Total dose (Gy) (Grade 3)
	2	3	4	
Rectal				
Bleeding	3	5	0	60–71*
Stricture	0	1	0	66
Urinary				
Incontinence	1	0	0	
Stricture	2	1	0	50

* Median total dose, 70 Gy.

locoregional and/or distant metastases; the sites of the first recurrence were bone metastasis in 10, lymph node in 3, and local failure in 2 patients (32). Lankford *et al.* (9) demonstrated that there were 6 local and 14 regional or distant failures after locoregional radiotherapy in 29 patients with localized hormone-refractory prostate cancer, with a 4-year survival rate of 39%. In the present study, 34 of 84 patients (40%) developed distant metastases with or without local/regional recurrence after radiotherapy. Therefore, new treatment approaches for preventing distant metastases should be explored. Recently, a survival benefit of treatment with docetaxel-containing chemotherapy for patients with advanced prostate cancer was demonstrated in two large Phase III clinical trials (34, 35). Therefore, optimal adjuvant chemotherapy combined with radiotherapy may be a treatment of choice for high-risk patients.

In conclusion, our results indicated that external beam radiotherapy had an excellent local control rate for localized hormone-refractory prostate cancer and should be considered the treatment of choice for these tumors. Our results also indicate that nPSA12 is an early predictor of clinical failure that is independent of radiotherapy dose and other determinants of outcome after radiotherapy for patients with localized hormone-refractory prostate cancer. Because the majority of clinical failures are distant metastases, nPSA12 could potentially help identify patients at high risk who might benefit from earlier application of adjuvant 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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米国に学ぶ医学物理士の養成・活用法

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はじめに

放射線治療を必要とするがん患者の増加、治療装置の高精度化による複雑な業務、頻発する医療事故、欧米に遅れる医療機器開発等のために放射線治療現場に放射線腫瘍医、診療放射線技師に加えた新たな職種として医学物理士の参入が強く要望されている。がん対策基本法と同基本計画でもその職種の必要性が明記されている。本稿では医学物理士の現在および将来の需要を分析し、日米比較データも参考にして将来の医学物理士の需要を算定する。さらに、日米の医学物理士教育を比較して、これからわが国で整備する養成の参考とする。同時に、医学物理を担う高等教育には研究が含まれないとうまく機能しないであろう。最近の欧米の医学物理関係の研究の傾向を概観する。最後に、医学物理士の活用法について考案する。

医学物理士の需要

放射線治療患者数推移と将来予測：日本放射線腫瘍学会(JASTRO)の定期構造調査によると、2005年で16万2千人の新規がん患者、約20万人の総がん患者(新患+再患)が放射線治療を受けていた。この時点で、新規がん患者に対する放射線治療の適用率は25%である。欧米の60-70%に比べるとかなり低い(表1)¹⁾。がん診療体系、保険制度の違いも影響しているが、放射線腫瘍医数の人口比での少なさ(欧米の1/2)である証拠がある。現在、JASTROでも放射線腫瘍医育成を急いでいる。がんプロフェッショナル養成プラン(がんプロ)による支援によりさらに加速しなければならない。現在の患者数の伸び率から外挿すると、2015年には36万人の患者が放射線治療を必要とする。欧米並みの60-70%の適用率に到達すると仮定すれば、50万人と推定される。

表1 日米の放射線治療の構造比較

	日本 ¹⁾	米国*
調査年	2005	2004
人口(X 10 ⁶)	127.7	293.9
施設数	735	293.9
新規患者数	約162,000	700,000
全がん患者に対する放射線治療適用率	約25%	60%
放射線腫瘍医数	774 FTE	約4,000
医学物理士	117**	約4,000

*米国データはASTRO 2004 Fact Sheetによる。現在、AAPM Directoryでは医学物理士数は約5,000人いるといわれている。 **日本の構造データでは医学物理士は診療放射線技師との兼任は除外できていない。

日米の構造比較とブルーブックガイドライン²⁾での需要の推定：2005年で米国では約5,000人の医学物理士が病院、研究機関、企業で活躍している。日本では117名である。多くが診療放射線技師との兼任業務である。ブルーブックガイドラインではがん患者総数400名に1名(専任)必要としている。現時点でも約500名の専任医学物理士(20万/400)が必要である。一方、上記2015年の需要を考慮すると総患者数は新患の1.2倍と仮定すると1,080名(36万×1.2/400)、欧米並みに増加した場合は1,500名(50万×1.2/400)の専任物理士が必要である。さらに研究開発を担う人材を考慮すると2,000人規模の人材が必要と推定される。

医学物理士の基礎教育

医学物理士教育システムの日米比較：図1に日本のシステムと米国との比較を示す。米国では一般的な理工系の物理コースを受講したものが修士から物理・医学物理コース並びに研究を行うケースが多い。その後、レジデントプログラム(日本の研修医制度のように病院より給料を得られる)を受けて臨床現場のトレーニングを積み、American Board of Radiology (ABR)の試験を得る。ポストドクプログラムの中には、研究に加えて臨床トレーニングを盛り込んでいる大学もある。現在の教育機関数を表2に示している。米国では2012年を目指して全員にレジデンシープログラムを課すため体制を整備している。さらに各施設の教育プログラム

に査察を加える予定である。

一方、大阪大学は学部教育で放射線技術科学を学び、卒業時に診療放射線技師の国家試験を受ける。その後、主に放射線腫瘍学を目指した保健学修士に医学物理の研究を通して教育を行っている。修士最終年度で日本医学放射線学会(JRS)の医学物理士認定試験を受ける。その後、多くは診療放射線技師としての2年間の臨床経験を経てJRSの最終認定を受ける。この際に臨床経験の内容は細かく規定されていない。実はこの部分の経験内容、所属機関と指導体制が医学物理士のキャリア形成に大きな影響を及ぼす。わが国での整備には臨床現場での放射線腫瘍医からの忍耐強い教育と指導が必須である。十分な症例数も必要である。臨床現場の多忙さから、教育を嫌う放射線腫瘍医は多い。米国の医学物理士の黎明期には優れた放射線腫瘍医が彼らの職種の重要性を認識し、傍にいてその教育、研究、職域の確保を全面的に支援してきた。わが国の混沌とした状況下でも医学物理士の教育・育成に自助努力と同時に医師の懐深さが必須である。

既存カリキュラム+がんプロカリキュラムの比較：表3に現在の大阪大学におけるカリキュラムに今春、開始されたがんプロフェッショナル養成プラン(がんプロ)のカリキュラム(太字)を重ねたものを示している。既存の学部教育の不足分をこのがんプロで補ってきている。特に放射線基礎物理学として大阪大学核物理センター専任教員に詳細な講義を依頼している。後期には加速器測定実習を予定している。臨床実習は後述のレ

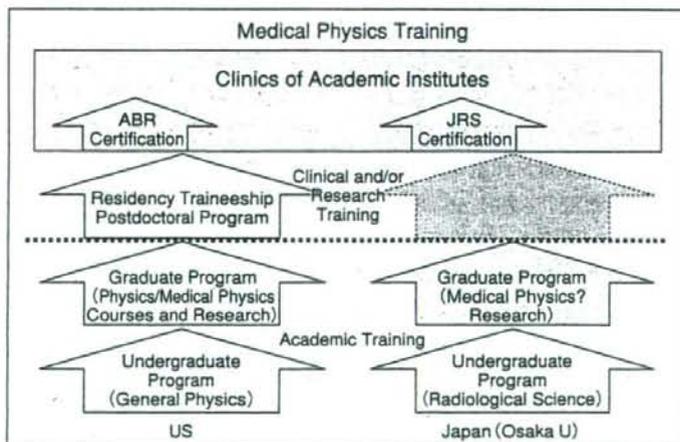


図1 日米の医学物理教育の比較(日本は大阪大学の場合である。がんプロの新規プログラムはこの図には盛り込んでいない。)

表2 米国 CAMPEP 認定施設と非認定施設における大学院とレジデント教育と今後

<p>1) CAMPEP 認定施設</p> <p>大学院教育 17 施設 (MS だけ: 3, PhD だけ: 1, MS と PhD 両方: 13)</p> <p>レジデント教育 19 施設</p> <ul style="list-style-type: none"> ・ 5 年毎の認定施設を見直し ・ シニア医学物理士グループによる調査団体が施設基準を満たすか判断 (REPRC: Residency Education Program Review Committee) <p>2) CAMPEP 非認定施設、AAPM 認定施設</p> <p>大学院教育 31 施設</p> <p>レジデント教育 9 施設</p> <p>3) 米国における医学物理士試験資格の今後</p> <p>ABR の方針として 2012 年以降、医学物理の修士 (博士) 課程を修了すること、あるいは他の修士 (博士) 修了者 (主に工学系) でも、CAMPEP 認定 (非認定) 施設でのレジデンシープログラム*を修了することを義務付ける予定。</p> <p>*レジデンシープログラム</p> <ul style="list-style-type: none"> ・ 2 年のコース (6 ローターション: 4 か月/ローテーション) ・ 臨床トレーニングが主 ・ ローターション毎の試験 ・ 最後の 2 ローターションは、外病院にて研修医学物理士として働く

(隅田伊織博士の好意による)

CAMPEP: Commission on Accreditation of Medical Physics Educational Program

レジデントプログラムとも絡むのだが、On the job training(OJT)に重点を置き、約 1 年間の訓練を課す計画である。しかし、がんプロの修士課程 2 年間では臨床研修期間としては不足している。既存の博士後期課程(保健学博士、医学博士)での訓練も視野に入れている。大阪大学ではその他として生物系教科が多い。一見、マイナス面のように見えるが、米国の医学物理研究チームの中に最近、少数ながら Biologist を参加させており、先取りしている面はあるかもしれない。

米国 Stanford 大学の Dosimetry Training Tool (DTT)¹⁾: 日本は短期間に欧米のレベルに到達し、凌駕しなければならぬ。本年 2 月に米国の医学物理士教育を視察した。Stanford 大学ではインターネットを介した教育ツールである DTT を紹介された(表 4)。年間 1,000 ドルで約 5 名の学生に Dosimetry に関する基礎から臨床の Web 教育を行うことができる。病理学、解剖学、放射線計測学、医学物理学、放射線生物学に分類され、テキスト表示で視覚的にも分かり易い図や動画が豊富で、理解の促進を図れる。プレテスト、本テストにより、理解度を受講生自身が評価でき、指導教員(チューター)が学生の理解状況を把握できる。大阪大学では今春より試験運用を始めている。当然、すべて英語なので学生に対する負担は大きい。英語教育も兼ねており、

有効な教育ツールと評価している。

医学物理士の臨床教育 (レジデントプログラム)

大阪大学で想定される臨床研修: 大阪大学では今春、附属病院のオンコロジーセンターのもとに医学物理室が設置された。MD 教員 1 名、PhD を有する医学物理士資格を持つ教員 2 名、同修士 1 名について放射線治療計画(高精度ならびに小線源治療)の OJT を行うことを想定している。試行錯誤で、現場の需要に沿う形で徐々に整備していく予定である。がんプロコースでは約 1 年間課す予定だが、十分とは考えていない。医師研修に近いもので、医師とペアで行動させることが重要と考えている。放射線治療の患者さんへの適用の最前線、すなわち共通の責任を理解させることが重要である。ただこのプログラムへの経済的な裏付けがないのが、問題である。診療放射線技師職を有している場合は医療職としての裏付けがあるが、十分ではない。理工系の場合は大学や研究機関での研究職や教職しかない。

理工系コースの場合: 医学的知識の背景のない理工系出身者に対する医学教育をがんプロの 2 年間のみで行うことには無理がある。しかし、不可能ではない。

表3 米国医学物理学会 AAPM 推奨カリキュラムと大阪大学カリキュラム(学部課程) + がんプロカリキュラム(修士課程)*

米国	日本(大阪大学)
<u>1) Core topics</u>	
Radiation Physics and Dosimetry	Radiation Physics
Health Physics/Radiation Safety	Radiation Measurement
Radiation Biology	Radiation Biology
Anatomy and Physiology	Radiology, Introduction, Physiology
Computational Skills	Imaging Anatomy
Professional Ethics/Conflicts of Interest/Scientific Misconduct	Medical Ethics/Law/Economics
Statistical Methods in Medical Science	Radiation Safety Control
Safety: Electrical/Chemical/Biological/Elementary Radiation	
<u>2) Imaging Science</u>	
Conventional Planar Imaging	Medical Imaging
Digital X-ray Imaging and Computed Tomography	Radiographic Image Theory
Ultrasound Imaging	Image Information Science
Magnetic Resonance Imaging	Nuclear Magnetic Resonance
Nuclear Medicine	Nuclear Medicine
<u>3) Radiation Therapy</u>	
Radiation Oncology	Radiation Oncology I, II
External Beam Radiation Therapy	Radiotherapy Physics I, II
Brachytherapy	High Precision Radiotherapy, DTT
Treatment Planning	Brachytherapy, DTT
Radiation Therapy Device	Basic Radiation Physics
Special Technique in Radiotherapy	Particle Therapy, DTT
Radiation Therapy with Neutrons, Protons & Heavy Ions	Imaging Physics
Radiation Protection in Radiotherapy	Basic Radiation Physics Practice
	High Precision Radiotherapy Practice
	Brachytherapy Practice
	Particle Therapy Practice
<u>4) Miscellaneous (Osaka University only)</u>	
Medical Physics, Introduction	Biomedical Molecular Engineering
Medical Electronics Engineering	Medical Instrument Control
Clinical Pharmacology	Medical Instrument Engineering
System Control Engineering	Related Regulations
Allied Health Sciences, Introduction	Imaging Techniques
Medical Sociology	Electric Engineering
Biochemistry	Nursing
Radiochemistry and Radiopharmacology	Cardiovascular Technology
Biomedical Optics	Medical Informatics

太字はがんプロの新カリキュラムにて2008年4月より追加された教科

良く整備された詰め込み教育を行うことが必要となる。医師の忍耐強い関与は必須となる。レジデントプログラムでのOJTにおける補充教育も必要になる。病院医学物理士を目指す場合は医師によって臨床での資質を見極める必要がある。医学物理士の場合、研究機関、企業での活躍の場もあるので、適正に合った職を提供できれば良い。

医学物理研究の動向

教育システムだけ確立すればわが国でも優れた医学

物理士が育成されて精度高い医療が可能になるという考えは短絡的である。高等教育において教育と研究は車の両輪である。2008年のASTROの医学物理関係の教育講演、パネルを分析した。計(Educational session + Panels)76のうちMedical Physics関連は11(14.4%)ある。その内訳は、RTP 1、Brachy 1、SRS 1、IMRT 2、IGRT 5、Particle 1である。この比率が現在、米国の医学物理士が勢力を注いでいる分野を反映している。一方、日本では、加速器開発、IGRT、ATC、QA/QC、モンテカルロシミュレーション、Biological targeting、電子情報、粒子線関連で新規アイデア

表4 米国Stanford大学のDosimetry Training Tool(DTT)の章目³⁾

Fundamental of Cancer Management
Anatomy for Medical Dosimetrist
Radiobiology for Medical Dosimetrist
Fundamentals of Radiation Safety
Physics Fundamentals for Radiation Therapy
Production of Teletherapy Radiation
Radiation Sources for Brachytherapy
Radiological Imaging
Introduction to Dosimetry Instrumentation
Measurement of Dose in Radiation Oncology
Introduction to Teletherapy Dose Calculations
Brachytherapy Dose Calculations
Teletherapy Treatment Planning
Practice Dosimetry Problems
Radographic and Virtual Simulation
Three-Dimensional Conformal Radiotherapy
High-Dose-Brachytherapy
Introduction to Radiotherapy by Permanent Seed Implants
Treatment Planning for Stereotactic Radiosurgery
Treatment Planning for Intensity-Modulated Radiotherapy
Dosimetric Quality Assurance for Radiation Oncology
Professional Issues for Medical Dosimetrists
Math Skills

アが生まれてきている。国民に貢献できる医学物理士の育成を図るために、以上の研究を高等教育に最初から組み込むべきで、資格の取得のみを最終目標とすべきではない。臨床、教育、研究をバランス良く実績をあげることは医者養成と同様のことであろう。

医学物理士の活用法

放射線腫瘍医である医師は患者の直接ケアに関わり、発生する臨床情報について責任がある。一方、医学物理士は装置と発生ビームなどの物理的要因すべてに責任を持つ。放射線腫瘍医と診療放射線技師のイコール・パートナーである。放射線治療は医療のなかにあつて特殊な領域かもしれない。外科でメスを振るのは医師であるが、放射線治療領域でメスを振るのは診療放射線技師であり、手術方法を指示するのは医師であり、それをより確実にするのが医学物理士である。3者のチームワークが必須で、データに基づいて論理的に進める上で要となるのが医学物理士である。これから放射線治療分野で3職種を揃えることの意味は大きい。従来の医師と診療放射線技師の1対1の関係では上下関係が生じたり、逆に一方に甘えが生じたりしていた。3者が独立して相互に刺激を与え、和の精神で臨めば、

欧米を凌駕する優れたシステムを構築できる可能性がある。この和がもたれあいにならないためには、常に客観データが重要で、医学物理士は情報管理においてもキー・プレイヤーを務めなくてはならない。

考案

日本の放射線治療のシステムで医学物理士教育が難しいという議論はそろそろ止めにして、何を次世代に残すか、果敢に行動しなければならぬ。明るい面は今のところ日本の臨床成績は欧米に決して劣っていないことである。また米国の1/2の医療コストで達成してきた事実もある。国際比較成績の検証結果を先ず国民に示しておくことが重要であろう。現場を担う臨床医が努力と犠牲も払っている事実を国民に示した上で、今後の患者への安心で質の高い治療を提供するためのインフラ補充の必要性についてデータに基づいた議論を展開しなければならない。

確かに米国の医学物理教育はシステム化され、優れている。個々の研究者のレベルも高い。それには待遇の良さもあり、優秀な人材が集まる仕組みができていく。日本でも医学物理士が臨床現場に出たときにやりがいのある環境を整えなければならない。医師に近い待遇と責任を与えるべきである。医学物理士の仕事に誇りを持たなければならない。そのためには後述の国家資格化も避けて通れない問題である。

日本の放射線治療現場の高精度化が従来の医師と診療放射線技師だけの体制では使いこなせなくなり、限界に近づいている。日本の医学物理士はDosimetrist levelを第一段階の到達目標とするものの、次の研究開発も想定して早期にギアをシフトさせなければならない。研究開発の素養を引き継ぎながら医学知識、臨床技量によるグレードアップを図るべきである。そこには技術系と理工系との明確な境界はないと思う。国民のがん治療を担う上での志と多層的アプローチが必要である。

文献

- 1) 手島昭樹, 渋谷均, 西尾正道, 他, JASTRO データベース委員会, 全国放射線治療施設の2005年定期構造調査報告(第1報), 日放腫誌19: 181-192, 2007.
- 2) 日本PCS作業部会(厚生労働省がん研究助成金計画研究班14-6)がんの集学治療における放射線腫瘍学-医療実態調査研究に基づく放射線治療の品質確保に必要とされる基準構造-2005.
- 3) <http://www.dosimetrytrainingtool.com/dtt/portal/portal>

4. PCS (Patterns of Care Study) による日米間の放射線治療の比較

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放射線治療は全国的にはインフラ（装備、人員）や診療内容の面で不備があるが、がん対策基本法の強力な支援を得て、整備が進められている。これらを具体的に測定・分析する方法として PCS (Patterns of Care Study) がある。1996年に厚生労働省がん研究助成金と米国 PCS の支援を得て導入した。施設規模による構造、過程、結果に顕著な差を観察した。放射線治療の現状と問題点を米国との比較のもとに考察する。

はじめに

PCS (Patterns of Care Study) は米国にて開発された放射線治療の診療の質保証プログラムである^{1, 2)}。日本では医療実態調査研究と訳している。文字通り、ある年度の医療実態 (= 診療の質) をありのまま観察研究する。短期間に適行的に行う。診療の質とは Donabedian の質の評価モデルにあるように、構造 structure, 過程 process, 結果 outcome の 3 要素によって構成される。構造は装備や人員を含む。過程は患者評価や治療行為を示す。結果は患者の生存率や副作用発生率である。「十分な装備があり、正しく診療を行えば、良い治療結果が得られる」という仮説のもと、PCS では短期間にこの 3 要素を国全体でモニタし、相互関係を分析し、問題点を特定して改善のため

の道筋をつける。国の「がん医療均てん化」施策を進める上で放射線治療分野についての必要な具体的なデータを提供できる強力なツールともいえる。1996年に厚生労働省がん研究助成金と米国 PCS グループの支援を得て初導入した。本稿では、得られた PCS データからわが国の放射線治療の現状と問題点を米国 PCS データとの比較のもとに考察する。

I. PCS の方法

放射線治療の診療の質を評価するために上記 3 要素をモニタし分析することが重要である。過程と結果については治療症例の診療内容を具体的に調べるのが医療供給側、受益者(患者)双方にとって最大の関心事なので測定する。PCS では以下の手順で調査を進め

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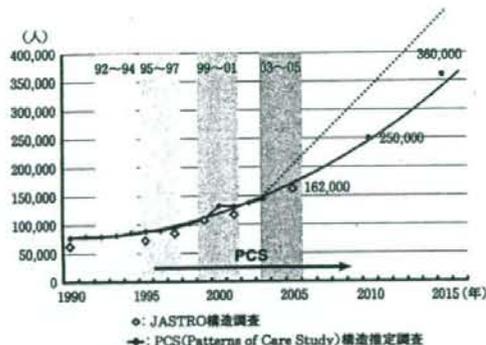


図1 PCSとJASTRO構造調査による患者数増加実態と予測曲線ならびにPCS施行対象年

放射線治療を要する新規患者数は今後10年で2倍以上に増加すると推定される(実線)。欧米並みに全がん患者への適応率50%が達成されると仮定するとさらに急峻な増加が予測される(破線)。

(文献1, 2, 4より引用)

る。①放射線治療が重要な役割を果たし、十分な症例数が確保されている5疾患：乳癌、子宮頸癌、食道癌、肺癌、前立腺癌を対象とする。②現時点での標準治療、最新のガイドラインの内容を追跡できる調査項目を策定してコンピュータ化データベースDBを開発する。③構造は2年毎に行われている日本放射線腫瘍学会(JASTRO)の定期的構造調査結果を利用する。④各施設での治療症例の過程、結果に主力を注いで調査する。対象施設は構造に準拠した4施設層(A1:大学病院/がんセンターで年間430例以上治療, A2:同未満, B1:その他の国公立病院130例以上, B2:同未満)から無作為抽出し、その施設の該年度の症例についてさらに無作為抽出を行う(2段階クラスタサンプリング)。DBを用いた訪問調査入力講習会で若手放射線腫瘍医を訓練して訪問調査auditを行う。全国700強の放射線治療施設があるが、そのうち約1割である70~80施設を抽出する。⑤集積データに統計補正をかけて診療実態の各調査項目の国全体の平均値national averageを求める。これを基準として各施設のデータと比較する。診療の質の定量評価を可能にする。

PCS (Patterns of Care Study)

FTE (full time equivalent; 週40時間放射線治療専任業務)

表1 日米の放射線治療の構造比較

	日本	米国
調査年	2005	2004
人口(×10 ⁶)	127.7	293.9
施設数	735	2,010
新規患者数	約162,000	700,000
がん患者への適用率	約25%	60%
放射線腫瘍医	776 FTE	約4,000
医学物理士	115	約4,000

FTE: full time equivalent (週40時間放射線治療専任業務=実質的マンパワーを示す。)

(文献4より引用)

現在までに4回のPCSを行ってきた(図1)。厚生労働省がん研究助成金の支援を得て1992~1994年(PCS92-94), 1995~1997年(PCS95-97), 1999~2001年(PCS99-01), 2003~2005年(PCS03-05)の実態を調査してきた。2001年と2003年に日米PCSワークショップ³⁾を開催し、以後も日米間の情報交換を行っている。

II. PCSの成果

1. 構造 structure

2005年時点で約16万2千人の新規がん患者(約19万6千人の新患+再患)に放射線治療を行っていた(表1)⁴⁾。過去15年間増加しており、さらに増加することが予測される(図1)。年間発生がん患者のうち約25%に放射線治療が行われている。米国は約70万人で放射線治療適用率は60%である。米国との差である約35%の患者が放射線治療の恩恵を受けていないことが示唆される。わが国のがん医療の構造問題とも言える。放射線腫瘍医776 full time equivalent (FTE; 週40時間放射線治療専任業務)人、医学物理士数115人は米国のそれぞれ約4,000人と比較して非常に少ない。

PCSでは既述のように全国の施設を規模と性格により4層に分類している。B施設層が全施設の81%、全患者の60%を占める⁵⁾。この4層で装置、人員に大

JASTRO (日本放射線腫瘍学会)

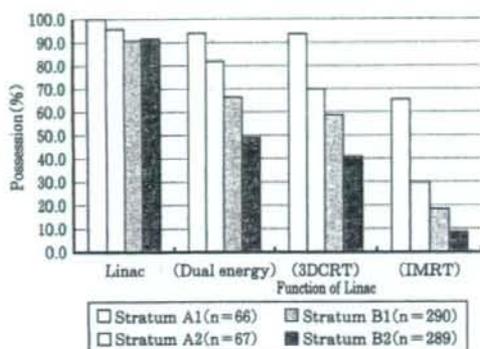


図2 2005年のPCS施設層毎のlinac保有率とその機能

Dual energy: 2つ以上のビームエネルギーが選択可能。3DCRT: 3 dimensional conformal radiotherapy, IMRT: intensity modulated radiotherapy (文献5より引用)

きな差がみられた。充実度はA1 → B2へと低下する。図2に外部放射線治療装置であるライナックとその機能を示している。患者の体表面、深部双方のガンにも対応できる dual energy 機能、腫瘍形状に応じて照射野を形成できる 3DCRT (3 dimensional conformal radiotherapy) 機能、照射野内の線量強度を調整させて腫瘍により高線量を、正常組織へは低線量を投与できる IMRT (intensity modulated radiotherapy) 機能はA施設の方が充実していた。幸いどの施設層も過去のPCS結果より有意に改善してきている。一方、米国の場合は装備について施設層間較差は日本程大きくない。1989年に米国の non-academic 施設 (日本のB施設相当) の患者数は409人で、Academic (同A施設相当) で1,022人であり、日本(2005年, 同130人, 430人) よりかなり成熟している⁶⁾。

1 FTE 放射線腫瘍医当たりの年間患者数負荷の全国平均値は246.8人であった。A1, A2, B1の1/4で1 FTE 放射線腫瘍医当たり300名以上(診療の質低下の改善警告値)治療していた(図3)⁷⁾。2005年の調査ではA1, A2施設の放射線腫瘍医が小規模のB2施設を支援している実態の重なりを排除できていない。

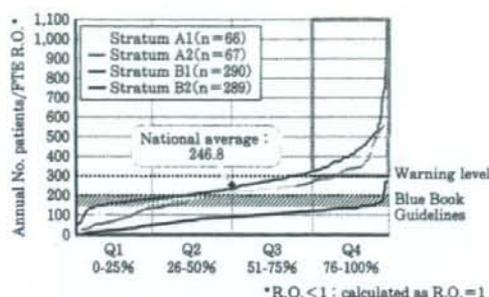


図3 2005年のPCS施設層別化による1 FTE放射線腫瘍医あたりの患者負荷の分布

FTE: full time equivalent (週40時間放射線治療専任業務)。横軸は各施設層において1 FTE放射線腫瘍医あたりの患者負荷数が低い施設から高い施設へと連続的に並べている。

Q1: 0 ~ 25%, Q2: 26 ~ 50%, Q3: 51 ~ 75%, Q4: 76 ~ 100%。

(文献7より引用)

日本では1名の放射線腫瘍医が日米のブルーブックガイドライン⁸⁾の推奨レベル(200人/1放射線腫瘍医)を凌駕した患者数を治療している。米国と比べて支援スタッフ寡少の日本では過酷な実態とも言える。図4に施設単位でみた一施設における年間患者数の分布と施設数(%)をみている。最も多い施設数は150 ~ 200人/FTE放射線腫瘍医であり、1989年の米国のデータに近似し改善してきている。しかし、不抜きパーで示すFTE < 1の施設の比率は6割以上あり、この比率は15年間、全く変わっていない⁹⁾。

がん診療連携拠点病院ではそれぞれの施設層の中ではより規模が大きい傾向にあったが、十分とはいえず、半数弱(124/266施設 = 48.1%, 2007年3月時点)で常勤放射線腫瘍医(> 1 FTE)が確保できていない⁷⁾。図5に人口100万人当たりのJASTRO認定数と1,000人当たりの放射線治療患者数を示す。後者は平均1.5人/1,000人であった。放射線治療の全がん患者への適用率が約25%であるので、欧米並みの約50%を仮定すると3.0人/1,000人ぐらゐが標準といえる。一方、このデータを地域的にJASTRO認定医数が低い方から並べて放射線治療適用率をみると有

3DCRT (3 dimensional conformal radiotherapy)

IMRT (intensity modulated radiotherapy)