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Patterns of Care Study of Radiation Therapy for Cervix Cancer in Japan: The Influence of the Stratification of Institution on the Process

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Background: To improve the quality of radiation oncology in Japan, Patterns of Care Study (PCS), a widely known quality assurance (QA) program in the USA, was introduced. The feasibility was tested by collecting nationwide data by extramural audit for cervix cancer.

Methods: From July 1996 through February 1997, PCS audits were performed for 29 institutions nationwide. On the basis of the facility survey by Tsunemoto, 13 institutions were classified as A1 (university hospital/cancer center), 10 as B1 (other institutions treating ≥120 patients/year) and six as B2 (other institutions treating <120 patients/year). Medical charts for the patients treated for cervix cancer between 1992 and 1994 were reviewed based on the data format of the US PCS. The total number of patients surveyed was 432.

Results: Simulation was used for >90% of the patients in both A1 and B1–2 institutions. However, in B1–2, planning for 5% of the patients was performed with only a clinical set-up ($p = 0.0287$). A daily fraction with a size of 200 cGy was given to >65% of patients in A1 and to <47% in B1–2. On the other hand, >50% of those in B1–2 were treated with daily fractions of 180 cGy and less compared with 25% in A1 institutions ($p < 0.0001$). Brachytherapy was utilized more frequently for patients in Stages II ($p = 0.0365$), III ($p = 0.0015$) and IV ($p = 0.0483$) in A1 than in B1–2. As for external beam equipment, linear accelerators with 10 MV or more were used for 83% of the patients in A1. However, in B1–2 institutions, machines with lower energy were used for 38% of the patients ($p < 0.0001$). The median number of full-time-equivalent (FTE) radiation oncologists was 2.7 in A1, 0.65 in B1 and 0.2 in B2.

Conclusions: Institutional stratification, including equipment and personnel, was found to affect significantly the patterns of care for cervix cancer. Therefore, to improve the quality of radiation therapy nationwide, improvements in equipment and in supply of FTE personnel are extremely important. PCS was found to have great potential for a practical evaluation of how much improvement will be required in Japan.

Key words: Patterns of Care Study – cervix cancer – radiation therapy – quality assurance – process survey – structure of facility

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Abbreviations: PCS, Patterns of Care Study; QA, quality assurance; FTE, full-time equivalent; KPS, Karnofsky performance status; FIGO, Fédération Internationale de Gynécologie et d'Obstétrique; HDR, high dose rate; LDR, low dose rate; MDR, mid dose rate; A1, university hospital/cancer center treating ≥300 patients/year; B1, other institutions treating ≥120 patients/year; B2, other institutions treating <120 patients/year.

INTRODUCTION

Radiation therapy is expected to play an important role in cancer management in the next century because of a rapid increase in the number of elderly people in Japan. These patients are generally not suitable candidates for aggressive surgery or chemotherapy. In the field of radiation oncology, many innovative techniques, such as conformal therapy, intraoperative radiation therapy, and heavy ion medical accelerator therapy, have been developed by many pioneers.

However, the basic treatment with photons that is currently used to treat 99% of the candidates for radiation therapy is still not sophisticated enough. The structure survey of radiation oncology in 1990 by Tsunemoto et al. (1), and the subsequent comparative study between the USA and Japan (2), showed that >60% of the institutions in Japan were staffed by part-time radiation oncologists, and that their structure was immature and still developing.

To improve the quality of radiation oncology throughout Japan, Patterns of Care Study (PCS), a well-known quality assurance (QA) program for radiation oncology (3–5), was introduced to Japan with the strong support and courtesy of one of the authors: Gerald E. Hanks, MD, Principal Investigator of the original PCS in the USA and Chairman of the Department of Radiation Oncology, Fox Chase Cancer Center, Philadelphia. The feasibility of this study for Japan was tested by collecting data by extramural audit for cervix cancer patients nationwide. In the current study, the effect of institutional stratification, including equipment and personnel, on the process of work-up and treatment was also investigated.

MATERIALS AND METHODS

Official requests for an extramural PCS audit by the principal investigators of two different cancer research groups (M.A. and H.I.), and supported by the Ministry of Health and Welfare in Japan, were mailed to 22 staff members of four different radiation oncology research groups supported by this ministry. Fifteen members (72%) agreed to participate in this audit. Furthermore, the directors or chairmen of 14 affiliated hospitals of four academic institutions (Osaka University, Kyoto University, Hiroshima University and Shinshu University) approved PCS audits. From July 1996 through February 1997, audits were performed for 29 institutions (Table 1) by one of the authors (T.T.), and medical charts and treatment records were reviewed based on the same data format as that used for PCS in the USA. This format was provided courtesy of two of the authors: Gerald E. Hanks, MD and Jean B. Owen, PhD, Director of PCS, American College of Radiology, Philadelphia. Actual audits for the survey took ~590 h in total. Eligibility criteria were the same as those for PCS in the USA, and are listed below.

Table 1. List of institutions audited and responsible person and staff who collaborated in this study (the sequence is based on the dates when audits were actually performed)

Institution	Location	Responsible person and staff
Sakai Municipal Hosp.	Sakai	Hiroyasu Yoshioka
Suita Municipal Hosp.	Suita	Masayuki Sato
Sumitomo Hosp.	Osaka	Jun Ueda
National Sapporo Hosp.	Sapporo	Masamichi Nishio
Aomori Prefectural Central Hosp.	Aomori	Sadao Watanabe and Yosinao Abe
Tohoku Univ. Hosp.	Sendai	Shogo Yamada and Yoshihiro Takai
Niigata Univ. Hosp.	Niigata	Kunio Sakai and Tadashi Sugita
National Kyoto Hosp.	Kyoto	Mitsuyuki Abe and Tohru Shibata
Kyoto Univ. Hosp.	Kyoto	Masahiro Hiraoka, Yasumasa Nishimura and Yasushi Nagata
Kyushu Univ. Hosp.	Fukuoka	Kouji Masuda, Satoru Uehara and Junichi Omagari
Hiroshima Univ. Hosp.	Hiroshima	Yutaka Hirokawa and Yukio Akagi
Hamamatsu Univ. Hosp.	Hamamatsu	Masao Kaneko and Tetsuo Nishimura
Shinshu Univ. Hosp.	Matsumoto	Shusuke Sone and Masahiko Oguchi
Gunma Univ. Hosp.	Maebashi	Hideo Niibe, Norio Mitsuhashi and Michitaka Yamakawa
National Cancer Center Hosp.	Tokyo	Hiroshi Ikeda, Yoshikazu Kagami and Minako Sumi
Tokai Univ. Hosp.	Isehara	Tomoyuki Mori and Yukio Ooizumi
Osaka Univ. Hosp.	Osaka	Toshihiko Inoue and Takehiro Inoue
Cancer Institute Hosp.	Tokyo	Takashi Yamashita, Masahiko Furukawa, Masao Kobayashi and Hiroshi Igaki
National Osaka Hosp.	Osaka	Masanori Mitomo and Masatoshi Ohtani
Osaka Rosai Hosp.	Sakai	Isao Tsukaguchi
Osaka Red Cross Hosp.	Osaka	Giro Todo
Kansai Denryoku Hosp.	Osaka	Daizaburo Hamanaka
Kyoto City Hosp.	Kyoto	Katsumi Hayakawa and Mototsugu Koishi
Hiroshima Red Cross Hosp. and Atomic-Bomb Survivors Hosp.	Hiroshima	Masaki Mori and Kazuki Kashimoto
Chuden Hosp.	Hiroshima	Akira Naito
Onomichi General Hosp.	Onomichi	Tetsuji Kiso
Chugoku Rosai Hosp.	Kure	Katsuro Hanaguri
Nagano Red Cross Hosp.	Nagano	Yoichi Okazaki
Hokushin General Hosp.	Nakano	Kiyonobu Itoh

Hosp., Hospital; Univ., University.

Table 2. Stratification of institutions by facility master survey in Japan by Tsunemoto et al. in 1990 (1)

Strata	Total no. of patients a year	No. of institutions	No. of patients
A1 Univ/CC	≥300	39	19 434
A2 Univ/CC	<300	51	10 365
B1 others	≥120	87	20 250
B2 others	<120	194	11 817
Total		371	61 866

Univ, University Hospital; CC, Cancer Center Hospital.

Treatment period: 1 January 1992 to 31 December 1994. The start of treatment refers to radiation therapy, regardless of any treatment which may have preceded it. The patient's treatment should have started during the period under investigation. Patients with distant metastasis are ineligible, but those with positive para-aortic lymph nodes are eligible. Prior or concurrent malignancies are ineligible, except for non-melanoma skin cancer. Only squamous cell carcinoma is eligible; adenosquamous carcinoma is therefore ineligible. Hysterectomy cases are ineligible, unless done at failure; however, if it can be determined that surgery was for a bulky central disease, i.e. a barrel-shaped cervix, the patient is eligible, but other types of bulky disease are not included. Cancer of the cervical stump following hysterectomy is ineligible. If the patient had surgery in lieu of an implant, due to some problem with os, the case is eligible. Patients with prior pelvic irradiation are not eligible, but patients need not complete the course of radiation therapy to be eligible. There are no eligibility criteria for institutions for data sampling in terms of equipment for radiation therapy, because national data are required as they are.

Japanese institutions of radiation oncology were stratified into four categories on the basis of the facility master survey by Tsunemoto et al. (Table 2) (1) as shown in a previous report (6). Based on this stratification, 13 institutions were classified as A1 (university hospital/cancer center treating ≥300 patients/year), 10 as B1 (other institutions treating ≥120 patients/year) and six as B2 (other institutions treating <120 patients/year) in the current series. The total number of cervix cancer patients surveyed was 432. In some of the institutions, Karnofsky performance status (KPS) was not routinely recorded in the medical chart of radiation oncology section only. Thus, the data from the patient's record by nurse were frequently used to evaluate the KPS. The dose to point A by external irradiation was counted only from whole pelvic field, because accurate dosimetry to point A was difficult after placement of the central shield.

Statistical significance was tested by means of χ^2 test.

RESULTS

Background

The median age (minimum–maximum) was 69 years (29–92) for A1 institutions and 68.5 years (31–88) for B1–2 institutions (Fig. 1, $p = 0.1751$). There was a tendency for the ratio of 80-year-old or older patients to be higher in B1–2 institutions than in A1. The KPS of the patients in A1 institutions was better than that of those in B1–2 institutions (Fig. 2, $p < 0.0001$).

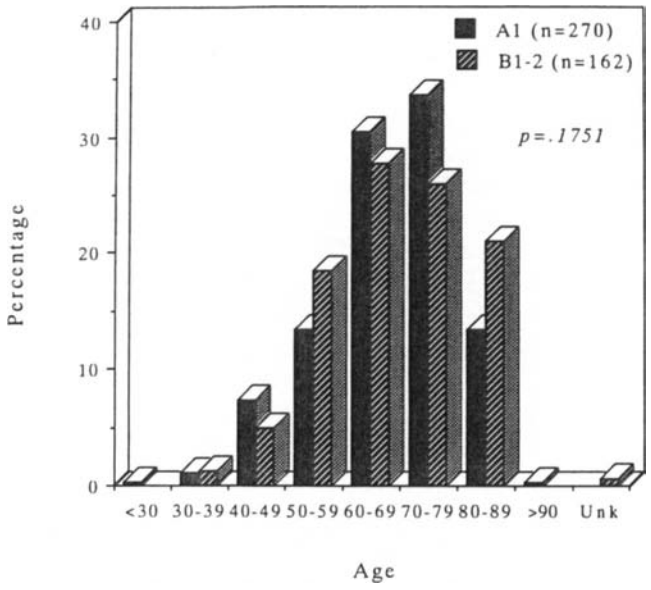

Figure 1. Age distribution of cervix cancer patients treated from 1992 to 1994 by stratification of institutions. Unk, unknown.

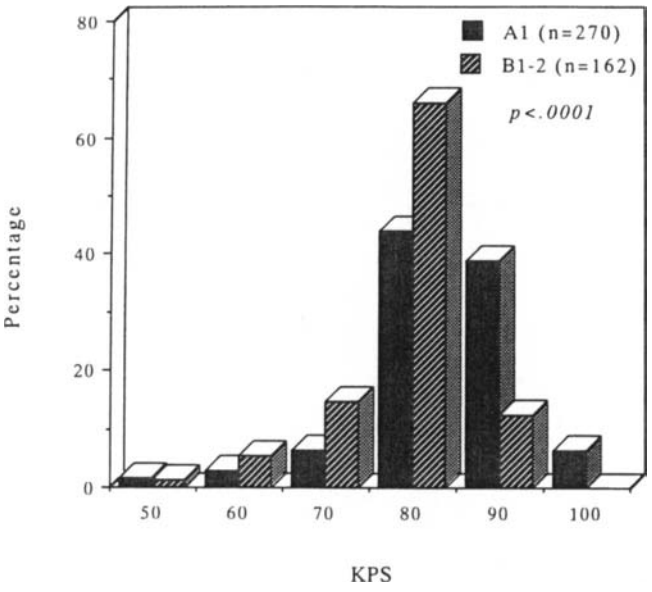

Figure 2. Karnofsky performance status distribution of cervix cancer patients treated from 1992 to 1994 by stratification of institutions.

Work-up

Histologically, nearly 50% of the patients had non-keratinizing large-cell-type squamous cell carcinoma, 10–15% had keratinizing squamous cell carcinoma, 6–8% had non-keratinizing small-cell-type squamous cell carcinoma, and the remaining patients had unknown differentiation of squamous cell carcinoma. There was no significant difference in type between the two kinds of institutions (Table 3, $p = 0.2714$), but there was a significant difference in stage distribution (Table 3, $p = 0.0161$). More Stage II patients were found in A1 institutions than in B1–2 institutions, and the reverse held true for Stage III patients.

Table 3. Characteristics of cervix cancer patients treated from 1992 to 1994 in Patterns of Care Study by stratification of institutions

Variable		Stratification of institutions		*p* value
		A1 (n = 270)	B1–2 (n = 162)	
Work-up				
Histology	Squamous cell carcinoma			
	Keratinizing	35 (13%)	24 (15%)	0.2714
	Non-keratinizing large cell	123 (46)	86 (53)	
	Non-keratinizing small cell	21 (8)	11 (7)	
	Unknown subtype	91 (34)	41 (25)	
Stage/FIGO	I	23 (9)	8 (5)	0.0161
	II	84 (31)	34 (21)	
	III	127 (47)	101 (62)	
	IV	36 (13)	19 (12)	
Treatment				
Simulation	Yes	261 (98)	152 (95)	0.0287
	Clinical set-up only	3 (1)	8 (5)	
	Unknown	2	0	
Daily fraction	<180 cGy	14 (5)	2 (1)	<0.0001
size	180	66 (25)	81 (51)	
	181–199	2	0	
	200	174 (65)	75 (47)	
	>200	20 (8)	2 (1)	

FIGO, Fédération Internationale de Gynécologie et d'Obstétrique.

Treatment

Simulation was done for >90% of the patients in both institutions. However, in B1–2 institutions, treatment of 5% of patients was still planned with a clinical set-up only (Table 3, $p = 0.0287$). Daily fractions of 200 cGy were given to >65% of the patients in A1 institutions and to <47% of the patients in B1 institutions. On the other hand, 51% of the patients in B1–2 institutions were treated with daily fractions of 180 cGy compared with <25% of patients in A1 institutions (Table 3, $p < 0.0001$).

Distributions of dose to point A by whole pelvic irradiation for patients who received brachytherapy by stage (early stage: ≤Stage II; late stage: ≥Stage III) are shown in Figs 3a and b, respectively. In the early stage, >35% of the patients received an external dose of 20–24 Gy at point A and >20% a dose of 30–34 Gy, with no significant difference between A1 and B1–2 institutions (Fig. 3a, $p = 0.0710$). In the late stage, nearly 40% of the patients received 30–34 Gy for the whole pelvic field. In A1 institutions, 25% of the patients received higher doses, such as 40–44 or 50–54 Gy. In B1–2 institutions, 21% of the patients received lower doses, such as 20–24 Gy. There was a significant difference in the dose range between A1 and B1–2 institutions (Fig. 3b, $p = 0.0096$). Corresponding figures for doses for the pelvic wall (point B) by stage are shown in Figs 4a and b. In the early stage, >75% of the patients received doses of 50–54 Gy, with no significant difference in the dose range between A1 and B1–2 institutions (Fig. 4a, $p = 0.3827$). In the late stage, >90% of the patients received doses of 50–54 Gy in B1–2 institutions, as did 75% of those in A1 institutions. In A1 institutions, both higher doses, such as 55–59 Gy, and lower doses, such as 40–49 Gy, were delivered. There was a significant difference in the dose range between A1 and B1–2 institutions (Fig. 4b, $p = 0.0035$).

Brachytherapy was utilized more frequently in A1 institutions than in B1–2 institutions for the patients in Stage II ($p = 0.0365$), Stage III ($p = 0.0015$) and Stage IV ($p = 0.0483$) (Fig. 5). Brachytherapy was administered with high dose rate (HDR) for 312 patients, with low dose rate (LDR) for 60 patients and with mid dose rate (MDR) for eight patients. In the HDR group, the dose for point A for the early stage ranged from 15 to 34 Gy, as shown in Fig. 6a, and there were two peaks, around 20–24 and 30–34 Gy. There was no significant difference between A1 and B1–2 institutions. For the late stage, there were two peaks, around 15–19 and 20–24 Gy, in A1 institutions. In B1–2 institutions, the peak was found around 20–34 Gy. Again, there was a significant difference in the dose range between A1 and B1–2 institutions (Fig. 6b, $p < 0.0001$). In the LDR group, doses with a wide range from 25 to 60 Gy were administered, but there was no significant difference between A1 and B1–2 institutions because of the small number of patients in B1–2 (Fig. 7a, $p = 0.3616$ and Fig. 7b, $p = 0.630$). The dose of brachytherapy administered with MDR for point A ranged from 20 to 40 Gy in A1 institutions, but no patients were treated with MDR in B1–2 institutions.

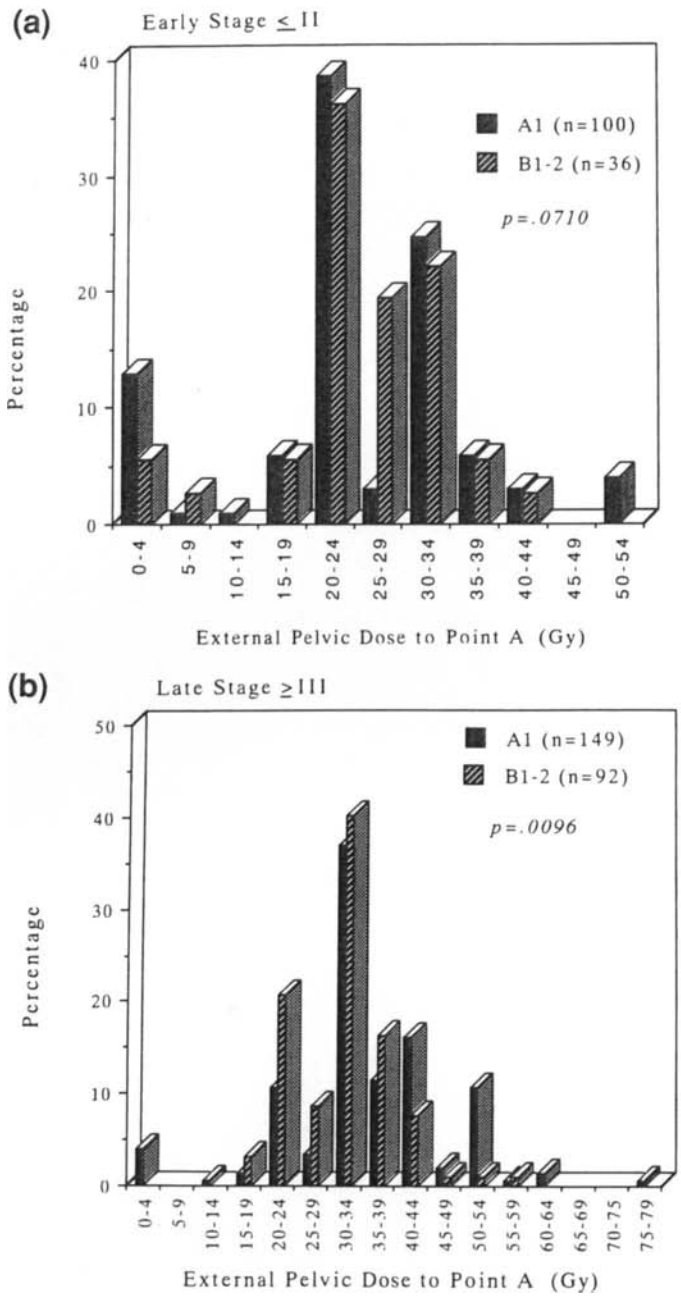

Figure 3. Distribution of dose to point A by external radiotherapy for cervix cancer patients who received brachytherapy from 1992 to 1994 by stratification of institutions and stage [early stage ≤ II (a) and late stage ≥ III (b)].

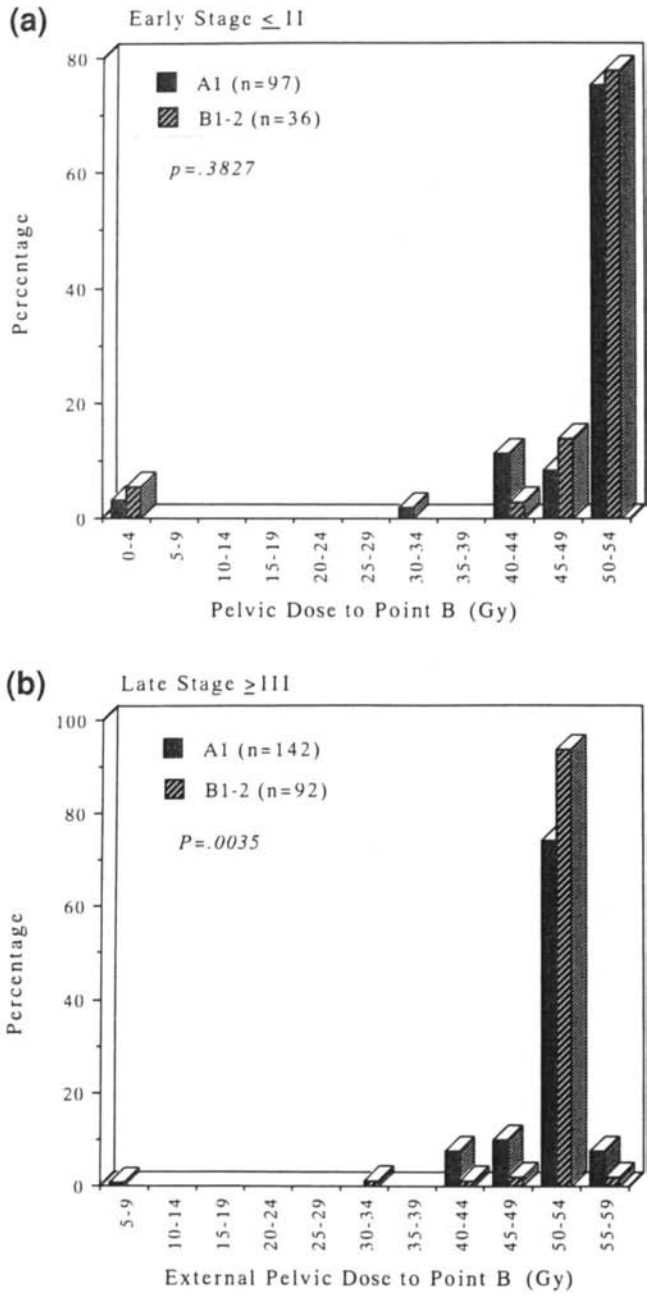

Figure 4. Distribution of dose to point B by external radiotherapy for cervix cancer patients who received brachytherapy from 1992 to 1994 by stratification of institutions and stage [early stage ≤ II (a) and late stage ≥ III (b)].

Structure Including Equipment and Personnel

For external beam equipment, accelerators with 10 MV or more were generally used in A1 institutions, but in B1–2 institutions machines with lower energy were used, while 5% of the patients were still treated with a ^{60}Co machine (Fig. 8, $p < 0.0001$). The median value of the number of full-time-equivalent (FTE) radiation oncologists (40 h/week for the radiation oncology service) was 2.7 in A1 institutions, 0.65 in B1 and 0.2 in B2, as shown in Table 5 of our previous report (6).

DISCUSSION

The median ages of the patients in both A1 and B1–2 institutions were almost the same. However, there was a tendency for the population of 80-year-old or older patients to be larger in B1–2 than in A1 institutions. This finding suggests that patients who are 80 years old or older tend to be treated in a local community hospital near their home or B1–2 institutions. KPS was markedly lower in B1–2 institutions than in A1 institutions, indicating that weaker patients tend to be referred to the B1–2 institutions.

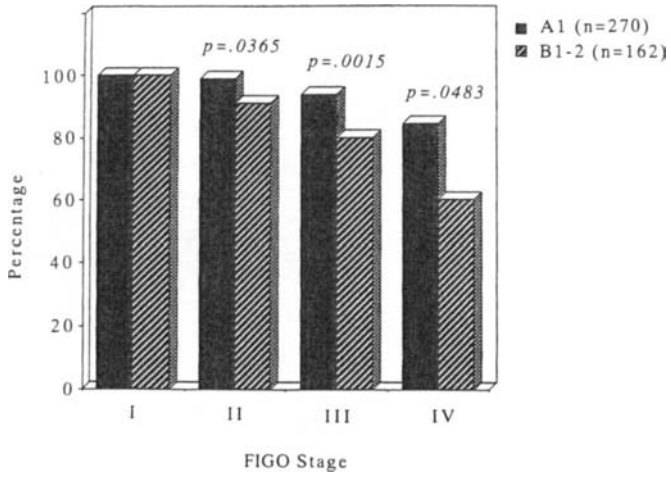

Figure 5. Brachytherapy utilization for cervix cancer patients treated from 1992 to 1994 by stratification of institutions.

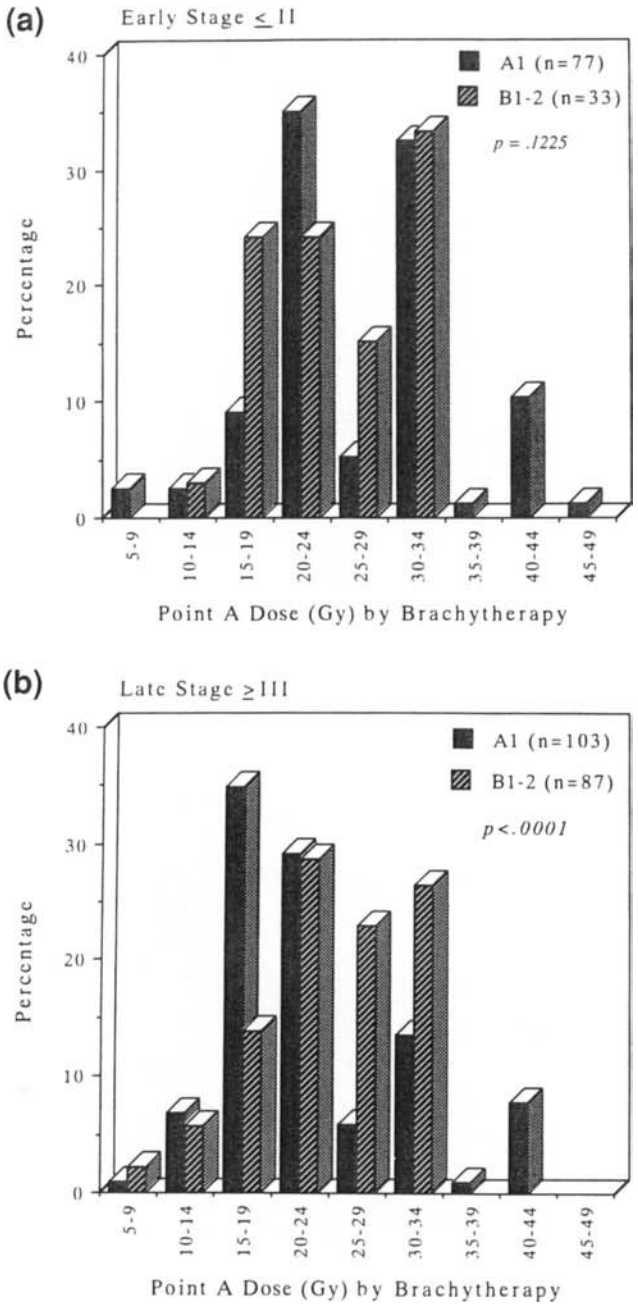

Figure 6. Distribution of dose to point A by brachytherapy for cervix cancer patients treated with HDR from 1992 to 1994 by stratification of institutions and stage [early stage ≤ II (a) and late stage ≥ III (b)].

Histological analysis showed that all patients in this study had squamous cell carcinomas, with the most common subtype being non-keratinizing large cell type, the keratinizing type was second and the non-keratinizing small cell type was third. This distribution of histological subtypes was almost similar to that described in the annual report from the Japanese Gynecological Society (7). Stage distribution by stratification of institution showed a significant difference between A1 and B1–2 institutions. In A1 institutions, the ratio of the Stage III population was 15% lower than that in B1–2 institutions, while the ratio of the Stage II population in A1 institutions was 10% higher than that in B1–2 institutions. Our other PCS of radiotherapy for esophageal cancer showed a higher rate of combination of surgery for the patients in A1 institutions (6). Although we lack direct evidence in the current study, this suggests that in A1 institutions even small populations of Stage III patients might undergo aggressive surgical treatment after intensive intra-arterial chemotherapy, and that in B1–2 institutions patients with an advanced stage are referred to radiation therapy.

Simulation was used for planning in the case of >90% of the patients in both types of institutions. This percentage was higher than that reported in 1990 in the Japanese Structure Survey by Tsunemoto et al. (1), who showed that 78% of institutions had an X-ray simulator. This discrepancy suggests that the current data might contain a selection bias for higher treatment scores, compared with the actual national average in Japan. However, compared with the data of a structure survey carried out in the USA in the 1970s, planning with simulation was used for a higher percentage of patients in B1–2 institutions in Japan (5). This finding indicates that basic treatment equipment, such as X-ray simulators, had already spread in Japan in the 1990s.

Brachytherapy was commonly used for patients in every stage in A1 institutions. Even among Stage IV patients, >80% received brachytherapy. However, in B1–2 institutions, this utilization decreased significantly for Stages II, III and IV. This suggests that in B1–2 institutions, brachytherapy cannot be administered sufficiently because of a shortage of FTE radiation oncology staff and of brachytherapy equipment, or because of the occurrence of more advanced tumors within the same stage and of lower KPS. The overall utilization of brachytherapy was higher than the national average for the USA in 1983 and 1989 (8).

Examination of the fraction size of the daily external dose showed that more patients in A1 institutions received 200 cGy than in B1–2 institutions, and more patients in B1 institutions received 180 cGy than in A1 institutions. This significant difference in fraction size means that the patients with a lower KPS or who were 80 years or older were treated in B1–2

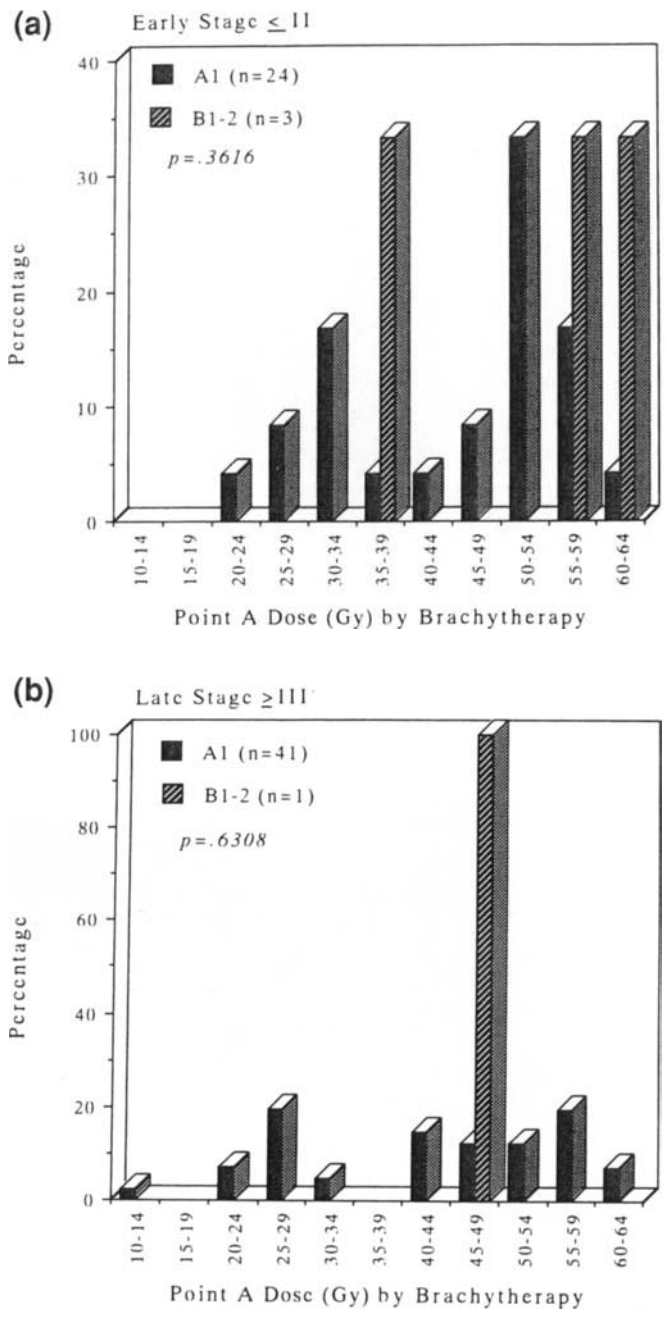

Figure 7. Distribution of dose to point A by brachytherapy for cervix cancer patients treated with LDR from 1992 to 1994 by stratification of institutions and stage [early stage ≤ II (a) and late stage ≥ III (b)].

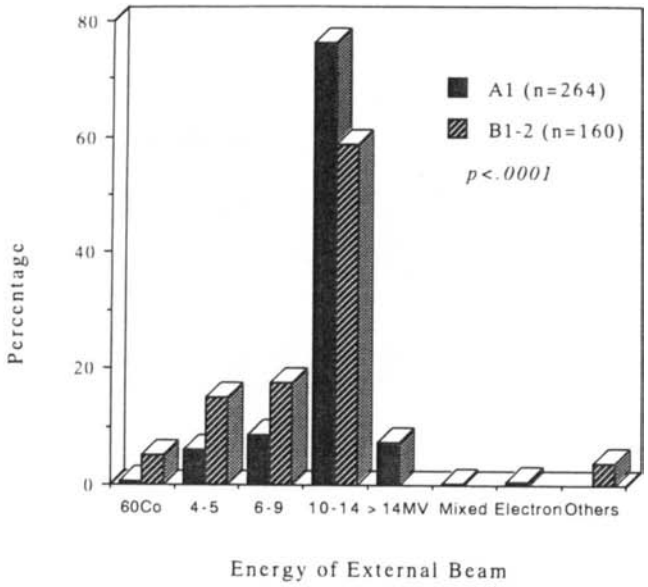

Figure 8. External beam equipment distribution of cervix cancer patients treated from 1992 to 1994 by stratification of institutions.

institutions, and that safer and/or smaller treatment fractions were used for these patients. In the late Stages III and IV, there was a significant difference in the dose range for external irradiation of the whole pelvic field, pelvic wall and intracavitary dose with HDR. In A1 institutions, the external dose for the whole pelvic field was significantly larger than that used in B1–2 institutions, indicating that a relatively larger number of Stage IV patients are treated in A1 institutions. In the early Stages I and II, there was no significant difference in the dose range for the whole pelvic field, pelvic wall and intracavitary dose administered with HDR. The clinical implications of these differences should be clarified by future outcome surveys.

Machines with a higher energy more suitable for the treatment of gynecological cancer were used in A1 rather than in B1–2 institutions. Although even in B1–2 institutions nearly 60% of patients were treated with 10–14 MV X-rays, lower energy machines were still used for the remaining 40%. Thus, flexibility in appropriate beam selection for cervix patients in B1–2 institutions was restricted.

Pure randomization for data sampling was not used because this study was the first trial in Japan due to budget restrictions, so that one of its main purposes was to examine its applicability. Our data may be biased in terms of selection of institutions and patients from each institution. Thus, there might be a potential risk of overestimation compared with actual national averages in Japan.

This study was shown to be applicable to Japan if resources and personnel are efficiently invested even during a short time. Detailed information on the process of the work-up and treatment for cervix cancer patients can be obtained through active collection of accurate data from extramural audits. That stratification of institutions, including equipment and personnel, has a significant effect on several important processes for cervix cancer patients was shown in this study, and first demonstrated by the findings for radiation oncology practice with the original PCS in the USA by Hanks et al. (9). Adequate and appropriate structure ensures better patient care. To improve the quality of radiation therapy for cervix cancer patients in all of Japan, improvement of equipment and personnel is extremely important. This PCS has great potential for a practical evaluation of how much equipment and personnel will be required if the relationship between process and outcome can be clearly identified by a future outcome study.

Acknowledgments

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