Table 58 Histological classification

Histological classification	Cases (%)	
Not examined	6	(0.2%)
SCC	2337	(89.3%)
SCC	352	(13.5%)
Well diff.	517	(19.8%)
Moderately diff.	1067	(40.8%)
Poorly diff.	401	(15.3%)
Adenocarcinoma	73	(2.8%)
Barrett's adenocarcinoma	32	(1.2%)
Adenosquamous cell carcinoma	11	(0.4%)
(Co-existing)	3	(0.1%)
(Mucoepidermoid carcinoma)	1	(0.0%)
Adenoid cystic carcinoma	0	
Basaloid carcinoma	40	(1.5%)
Undiff. carcinoma (small cell)	9	(0.3%)
Undiff. carcinoma	2	(0.1%)
Other carcinoma	3	(0.1%)
Sarcoma	5	(0.2%)
Carcinosarcoma	17	(0.6%)
Malignant melanoma	10	(0.4%)
Dysplasia	10	(0.4%)
Other	24	(0.9%)
Unkown	33	(1.3%)
Total	2616	
Missing	53	

SCC: Squamous cell carcinoma

Table 59 Depth of tumor invasion

pT-category	Cases (%)	
pXT	16	(0.6%)
pT0	36	(1.4%)
pTis	47	(1.8%)
pT1a	231	(8.9%)
pT1b	601	(23.1%)
pT2	317	(12.2%)
pT3	1132	(43.5%)
pT4	184	(7.1%)
Other	0	
Unknown	36	(1.4%)
Total	2600	
Missing	69	

Table 60 Subclassification of superficial carcinoma

Subclassification	Cases (%)	
Not superficial carcinoma	1679	(65.4%)
m1 (ep)	43	(1.7%)
m2 (lpm)	73	(2.8%)
m3 (mm)	137	(5.3%)
sm1	86	(3.3%)
sm2	136	(5.3%)
sm3	242	(9.4%)
Unknown	172	(6.7%)
Total	2568	
Missing	101	

ep: epithelium

lpm: lamina propria mucosa mm: muscularis mucosa

Table 61 Pathological grading of lymph node metastasis

Lymph node metastasis	Cases (%)	
n (-)	1262	(49.1%)
n1 (+)	334	(13.0%)
n2 (+)	601	(23.4%)
n3 (+)	189	(7.4%)
n4 (+)	160	(6.2%)
Unknown	25	(1.0%)
Total	2571	
Missing	98	

Table 62 Numbers of the metastatic nodes

Numbers of lymph node metastasis	Cases (%)	
0	1181	(44.2%)
1-3	886	(33.2%)
4-7	351	(13.2%)
8-	216	(8.1%)
Unknown	35	(1.3%)
Total	2669	
Missing	0	

Table 63 Pathological findings of distant organ metastasis

Distant metastasias (M)	Cases (%)	
MX	44	(1.7%)
M0	2546	(96.0%)
M1	62	(2.3%)
Total	2652	
Missing	17	

Table 64 Residual tumor

Residual tumor (R)	Cases (%)	
RX	149	(5.7%)
R0	2138	(82.4%)
R1	170	(6.5%)
R2	139	(5.4%)
Unknown	0	
Total	2596	
Missing	73	

Table 75 Causes of death

Cause of death	Cases (%)	
Death due to recurrence	933	(73.5%)
Death due to other cancer	63	(5.0%)
Death due to other disease (rec+)	32	(2.5%)
Death due to other disease (rec-)	129	(10.2%)
Death due to other disease (rec?)	15	(1.2%)
Operative death*	35	(2.8%)
Hospital death**	57	(4.5%)
Unknown	5	(0.4%)
Total of death cases	1269	
Missing	6	

rec: recurrence

* **Operative death means death within 30 days after operation in or out of hospital.**

Operative mortality : 1.3%

** **Hospital death is defined as death during the same hospitalization, regardless of department at time of death.**

Hospital mortality : 2.1%

Follow-up period (years)	
Median (min - max)	3.25 (0.00 - 7.50)

Table 76 Initial recurrent lesion

Initial recurrence lesion of fatal cases	Cases (%)	
Lymph node	580	(35.0%)
Lung	242	(14.6%)
Liver	199	(12.0%)
Bone	119	(7.2%)
Brain	31	(1.9%)
Primary lesion	141	(8.5%)
Dissemination	92	(5.5%)
Anastomotic region	10	(0.6%)
Others	90	(5.4%)
Unknown	155	(9.3%)
Total of recurrence lesion	1659	
Total	1230	
Missing	47	

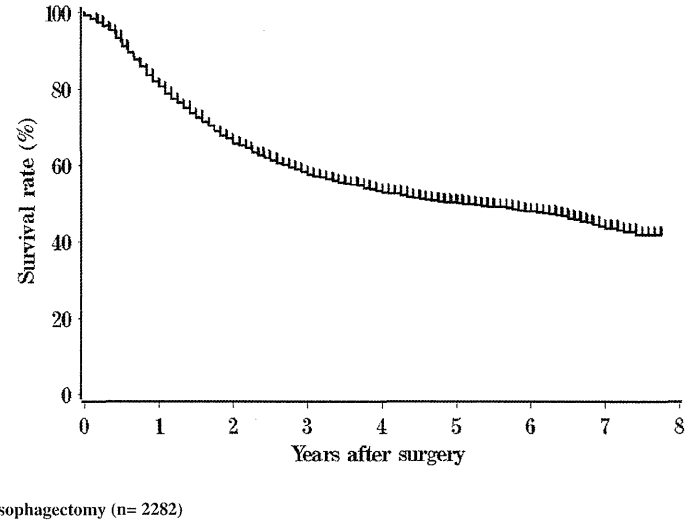

Fig. 8 Survival of patients treated by esophagectomy

	Years after surgery							
	1	2	3	4	5	6	7	8
Esophagectomy	80.7%	66.1%	57.7%	53.1%	50.2%	48.1%	43.8%	42.0%

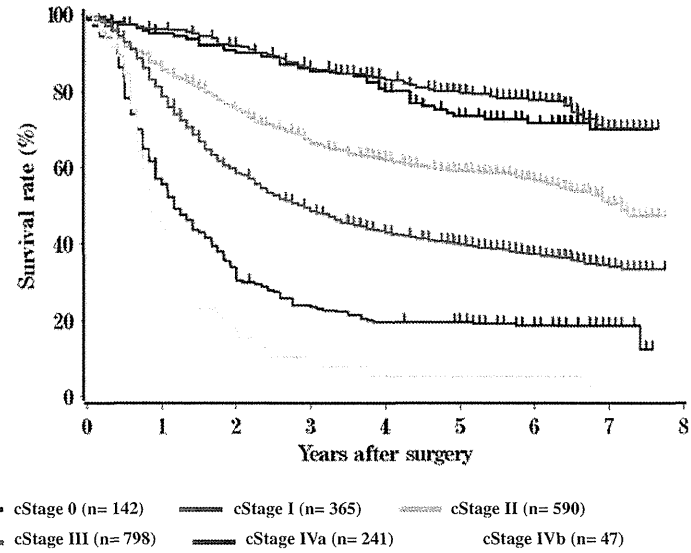

Fig. 9 Survival of patients treated by esophagectomy in relation to clinical stage (JSED-cTNM 9th)

	Years after surgery							
	1	2	3	4	5	6	7	8
cStage 0	95.0%	89.7%	85.3%	79.9%	73.4%	71.4%	69.8%	69.8%
cStage I	96.0%	91.7%	85.7%	83.0%	79.5%	77.7%	70.2%	70.2%
cStage II	85.5%	75.0%	66.3%	61.9%	58.9%	56.6%	50.4%	47.2%
cStage III	79.0%	58.9%	48.5%	42.8%	39.8%	37.3%	34.1%	33.3%
cStage IVa	55.6%	30.8%	23.4%	19.5%	19.5%	18.5%	18.5%	12.3%
cStage IVb	43.5%	17.8%	10.2%	5.1%	5.1%	5.1%	0.0%	-

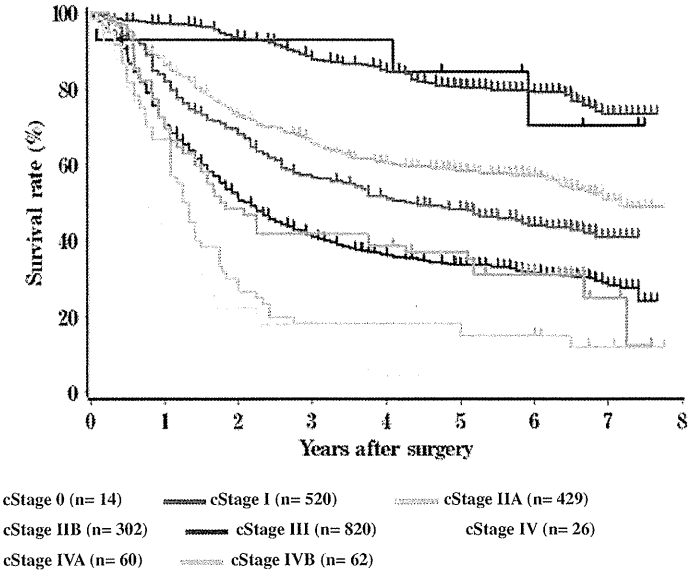

Fig. 10 Survival of patients treated by esophagectomy in relation to clinical stage (UICC-cTNM 5th)

	Years after surgery							
	1	2	3	4	5	6	7	8
cStage 0	92.9%	92.9%	92.9%	92.9%	84.4%	70.3%	70.3%	70.3%
cStage I	97.2%	93.4%	87.8%	84.6%	80.5%	79.2%	73.4%	73.4%
cStage IIA	86.8%	72.7%	65.4%	60.5%	58.3%	57.3%	50.7%	48.8%
cStage IIB	82.1%	68.0%	56.9%	50.9%	48.3%	44.0%	41.1%	41.1%
cStage III	70.6%	51.1%	40.9%	36.0%	33.5%	31.6%	28.2%	24.1%
cStage IV	44.2%	22.1%	17.7%	4.4%	4.4%	-	-	-
cStage IVA	66.7%	28.3%	18.3%	18.3%	15.0%	15.0%	12.0%	12.0%
cStage IVB	69.4%	48.4%	41.9%	38.7%	37.0%	31.1%	24.9%	12.4%

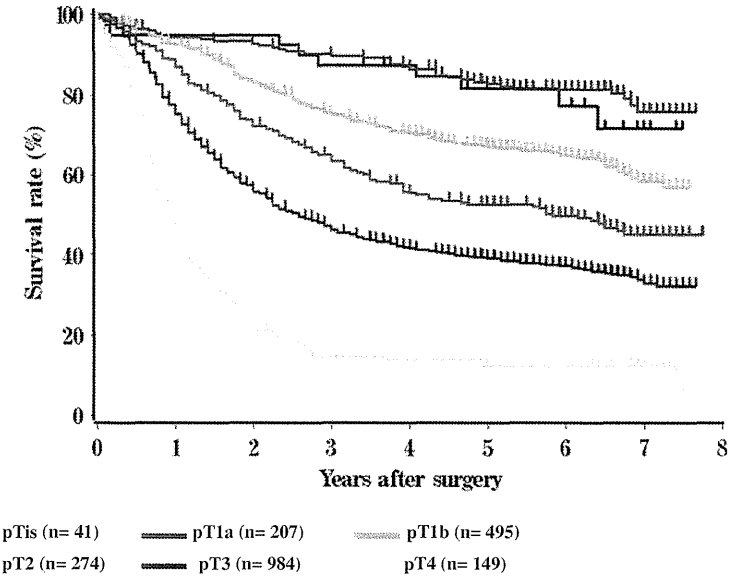

Fig. 11 Survival of patients treated by esophagectomy in relation to the depth of tumor invasion (JSED-pTNM 9th: pT)

	Years after surgery							
	1	2	3	4	5	6	7	8
pTis	95.1%	95.1%	87.6%	87.6%	81.8%	77.3%	71.7%	71.7%
pT1a	94.5%	93.0%	89.8%	86.7%	82.8%	81.5%	75.9%	75.9%
pT1b	92.7%	83.1%	75.3%	70.5%	67.3%	64.9%	58.6%	57.0%
pT2	87.0%	72.2%	63.8%	55.5%	52.6%	49.8%	45.2%	45.2%
pT3	75.5%	56.2%	46.3%	41.7%	39.2%	37.3%	32.9%	32.2%
pT4	45.0%	21.8%	14.6%	13.8%	12.3%	12.3%	12.3%	6.1%

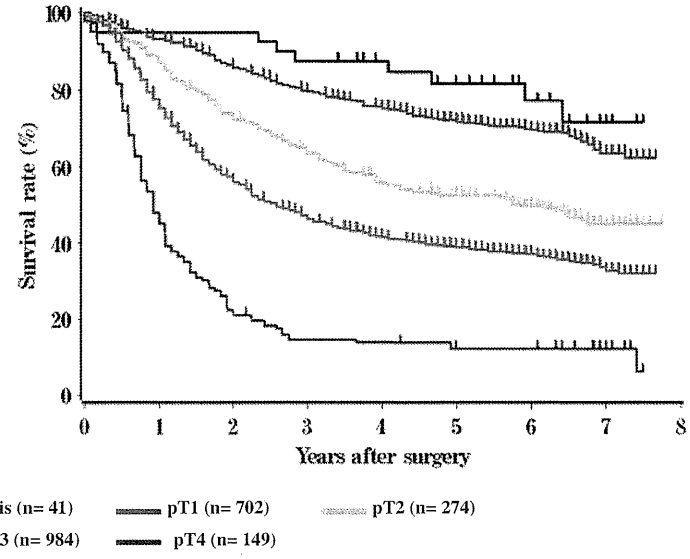

Fig. 12 Survival of patients treated by esophagectomy in relation to the depth of tumor invasion (UICC-pTNM 5th: pT)

	Years after surgery							
	1	2	3	4	5	6	7	8
pTis	95.1%	95.1%	87.6%	87.6%	81.8%	77.3%	71.7%	71.7%
pT1	93.2%	86.0%	79.6%	75.2%	71.8%	69.8%	63.7%	62.6%
pT2	87.0%	72.2%	63.8%	55.5%	52.6%	49.8%	45.2%	45.2%
pT3	75.5%	56.2%	46.3%	41.7%	39.2%	37.3%	32.9%	32.2%
pT4	45.0%	21.8%	14.6%	13.8%	12.3%	12.3%	12.3%	6.1%

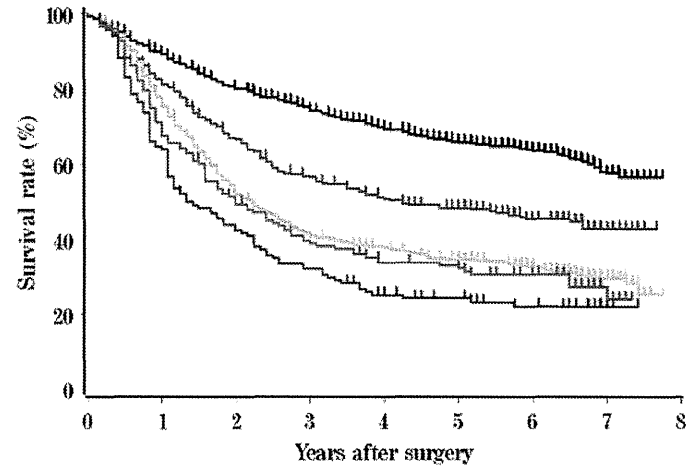

Fig. 13 Survival of patients treated by esophagectomy in relation to lymph node metastasis (JSED-pTNM 9th: pN)

	Years after surgery							
	1	2	3	4	5	6	7	8
pN0	89.2%	80.1%	74.3%	69.5%	65.9%	63.9%	57.8%	56.6%
pN1	81.5%	67.2%	56.6%	50.9%	48.6%	45.6%	43.0%	43.0%
pN2	75.2%	52.5%	41.0%	37.7%	34.8%	33.0%	29.9%	25.3%
pN3	68.3%	50.8%	38.9%	33.9%	32.3%	30.7%	24.1%	24.1%
pN4	64.0%	42.5%	32.1%	25.2%	24.3%	22.2%	22.2%	22.2%

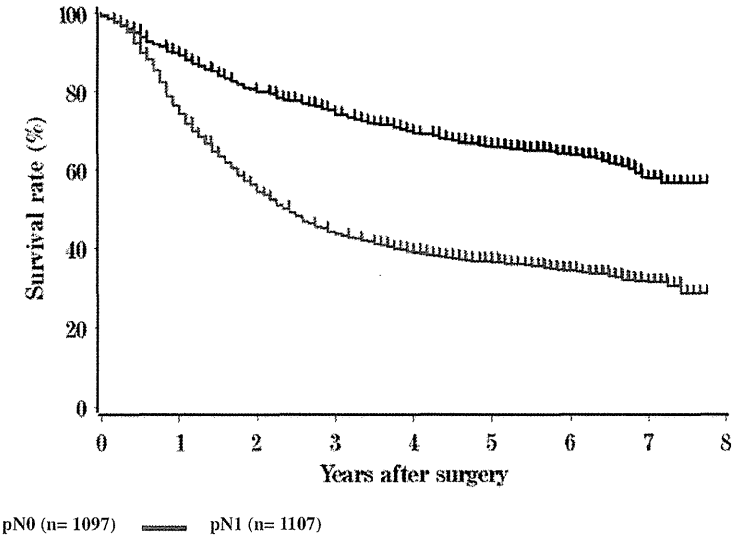

Fig. 14 Survival of patients treated by esophagectomy in relation to lymph node metastasis (UICC-pTNM 5th: pN)

	Years after surgery							
	1	2	3	4	5	6	7	8
pN0	89.2%	80.1%	74.3%	69.5%	65.9%	63.9%	57.8%	56.6%
pN1	74.5%	54.8%	43.6%	39.1%	36.7%	34.6%	31.7%	28.8%

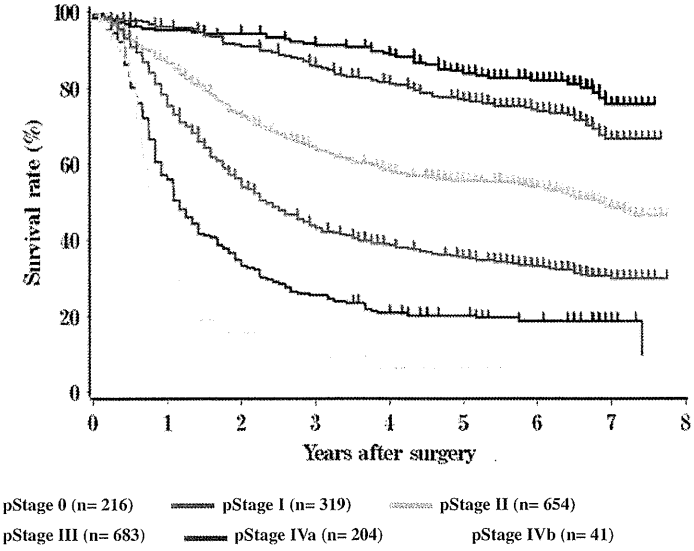

Fig. 15 Survival of patients treated by esophagectomy in relation to pathological stage (JSED-pTNM 9th)

	Years after surgery							
	1	2	3	4	5	6	7	8
pStage 0	95.2%	94.2%	91.2%	88.7%	83.9%	82.0%	75.7%	75.7%
pStage I	96.1%	91.1%	85.7%	81.2%	76.8%	73.9%	66.6%	66.6%
pStage II	86.5%	72.4%	63.5%	57.7%	55.6%	53.9%	48.4%	46.4%
pStage III	75.6%	54.3%	43.0%	38.5%	35.4%	33.1%	29.9%	29.9%
pStage IVa	55.9%	33.6%	25.5%	20.8%	20.2%	18.8%	18.8%	9.4%
pStage IVb	34.6%	15.5%	9.3%	6.2%	6.2%	6.2%	0.0%	-

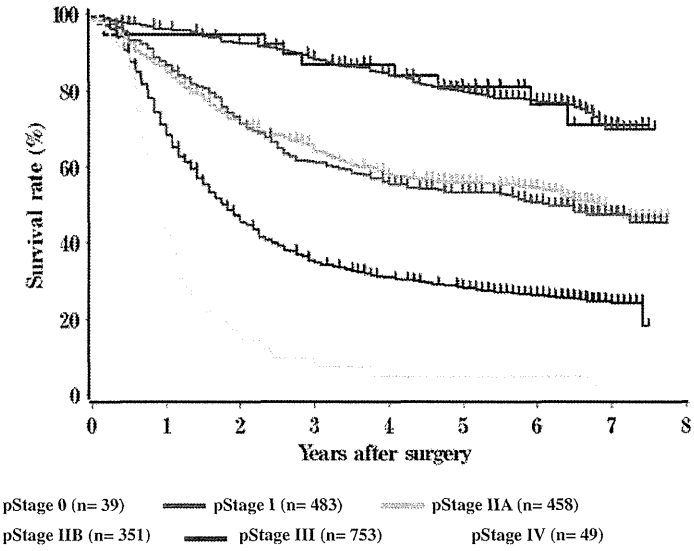

Fig. 16 Survival of patients treated by esophagectomy in relation to pathological stage (UICC-pTNM 5th)

	Years after surgery							
	1	2	3	4	5	6	7	8
pStage 0	94.8%	94.8%	86.9%	86.9%	81.0%	76.5%	71.0%	71.0%
pStage I	96.1%	92.4%	88.3%	84.2%	79.6%	77.2%	70.0%	70.0%
pStage IIA	85.2%	71.6%	64.1%	57.9%	55.9%	54.6%	48.0%	46.8%
pStage IIB	86.7%	71.4%	61.1%	55.4%	53.2%	50.6%	47.5%	45.4%
pStage III	68.6%	46.0%	34.9%	31.0%	28.3%	26.4%	24.3%	18.2%
pStage IV	41.6%	17.0%	9.7%	4.9%	4.9%	4.9%	0.0%	-

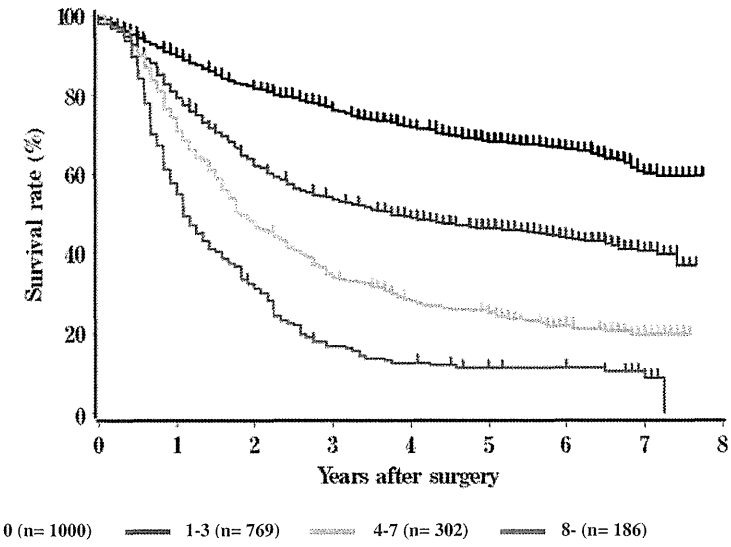

Fig. 17 Survival of patients treated by esophagectomy in relation to number of metastatic node

	Years after surgery							
	1	2	3	4	5	6	7	8
0	89.7%	81.5%	75.9%	71.7%	68.2%	66.3%	60.3%	59.5%
1-3	79.4%	62.3%	53.6%	48.8%	46.4%	44.0%	40.6%	36.9%
4-7	71.3%	47.1%	33.9%	28.0%	25.2%	21.7%	19.7%	19.7%
8-	54.9%	31.8%	16.7%	12.5%	11.2%	11.2%	8.8%	0.0%

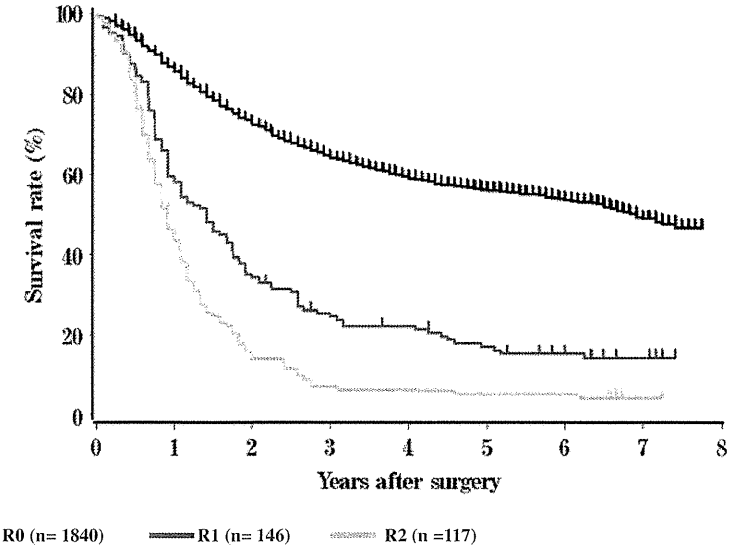

Fig. 18 Survival of patients treated by esophagectomy in relation to residual tumor (R)

	Years after surgery							
	1	2	3	4	5	6	7	8
R0	85.8%	72.7%	64.2%	59.1%	56.1%	53.8%	49.0%	46.8%
R1	58.1%	34.4%	24.6%	22.3%	17.2%	15.4%	14.3%	14.3%
R2	43.5%	14.2%	7.1%	6.2%	5.3%	5.3%	4.4%	-

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Clinical Investigation: Gynecologic Cancer

Patterns of Radiotherapy Practice for Patients With Cervical Cancer in Japan, 2003–2005: Changing Trends in the Pattern of Care Process

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Summary

This study reports changes in the patterns of practice of definitive radiotherapy for cervical cancer in Japan since 1995 by comparing 3 patterns of care surveys. There has been a significant trend toward use of concurrent chemotherapy consistent with randomized trial data. External beam radiation has became progressively more standardized. Intracavitary brachytherapy, however, still has not reached consistent levels of quality.

Purpose: The patterns of care study (PCS) of radiotherapy for cervical cancer in Japan over the last 10 years was reviewed.

Methods and Materials: The Japanese PCS working group analyzed data from 1,200 patients (1995–1997, 591 patients; 1999–2001, 324 patients; 2003–2005, 285 patients) with cervical cancer treated with definitive radiotherapy in Japan.

Results: Patients in the 2001–2003 survey were significantly younger than those in the 1999–2001 study ($p < 0.0001$). Histology, performance status, and International Federation of Gynecology and Obstetrics stage were not significantly different among the three survey periods. Use of combinations of chemotherapy has increased significantly during those periods (1995–1997, 24%; 1999–2001, 33%; 2003–2005, 54%; $p < 0.0001$). The ratio of patients receiving concurrent chemotherapy has also dramatically increased (1995–1997, 20%; 1999–2001, 54%; 2003–2005, 83%; $p < 0.0001$). As for external beam radiotherapy (EBRT), the application rate of four-field portals has greatly increased over the three survey periods (1995–1997, 2%; 1999–2001, 7%; 2003–2005, 21%; $p < 0.0001$). In addition, the use of an appropriate beam energy for EBRT has shown an increase (1995–1997, 67%; 1999–2001, 74%; 2003–2005, 81%; $p = 0.064$). As for intracavitary brachytherapy (ICBT), an iridium source has become increasingly popular (1995–1997, 27%; 1999–2001, 42%; 2003–2005, 84%; $p < 0.0001$). Among the three surveys, the ratio of patients receiving ICBT (1995–1997, 77%; 1999–2001, 82%; 2003–2005, 78%) has not changed. Although

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Conflict of interest: none.

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follow-up was inadequate in each survey, no significant survival differences were observed ($p = 0.36$), and rates of late Grade 3 or higher toxicity were significantly different ($p = 0.016$).
Conclusions: The Japanese PCS has monitored consistent improvements over the past 10 years in the application of chemotherapy, timing of chemotherapy, and EBRT methods. However, there is still room for improvement, especially in the clinical practice of ICBT.

Keywords: Cervix, Chemotherapy, Japan, Patterns of care study, Radiotherapy

Introduction

In Japan, the number of uterine cervical cancers decreased from the 1980s to 2000 but has been steadily increasing since then (1). The age-adjusted mortality rate due to cervical cancer has also shown an increase, especially in the younger generation in Japan (3). Radiation therapy is established as an integral component for cervical cancer. Over the past 10 years, some changes have occurred in the cervical cancer radiotherapy policy in Japan. Given the increases in cervical cancer and age-adjusted mortality rates, to optimally treat Japanese cervical cancer patients, it is important to accurately delineate intrinsic changes taking place in the national practice process of radiotherapy for cervical cancer in Japan. The patterns of care study (PCS) (2) initially surveyed radiotherapy practice in the United States. In the United States, PCS has been conducted for more than 30 years, and the structure, process, and outcomes of radiotherapy, as well as various problems in clinical practice, have been identified for cervical cancer (4, 5). The Japanese PCS began in 1996 and used the same methods (6). We previously reported Japanese PCS results for radiotherapy practice in cervical cancer patients treated in 1995–1997 and 1999–2001 (7, 8). We report here the corresponding results for 2003–2005, and the changes in radiotherapy practice that occurred over the years from the 1995–1997, 1999–2001, and 2003–2005 survey periods are also examined.

Methods and Materials

Between 2006 and 2008, the Japanese PCS working group conducted a third national survey of patients with uterine cervical cancer treated with radiotherapy. Patients who were eligible for the survey (*1*) had carcinoma, (*2*) were treated between January 2003 and December 2005, and (*3*) had no distant metastasis, (*4*) no prior or concurrent malignancy, (*5*) no gross para-aortic lymph node metastasis, and (*6*) no previous pelvic radiotherapy. Sixty-one of 640 institutions were selected for this survey by using a stratified two-staged cluster sampling method. Before the random sampling, all institutions were divided into four groups. Institutions were classified by type and number of patients treated with radiotherapy. The Japanese PCS working group stratified Japanese institutions as A1, academic institutions treating $\geq$430 patients annually; A2, academic institutions treating <430 patients; B1, nonacademic institutions treating $\geq$130 patients annually; and B2, nonacademic institutions treating <130 patients. Detailed criteria for stratification have been shown elsewhere (6). The Japanese PCS surveyors performed on-site chart reviews at each participating facility, using an originally developed database format for cervical cancer. Data collection included patient characteristics, details of the pretreatment workup, therapeutic information, and treatment outcome. The Japanese PCS collected clinical data for 487 patients with cervical cancer, who were treated with radiotherapy from 61 institutions. In this study, 285 patients treated with radiotherapy without planned surgery were analyzed. These included 114 patients from A1 institutions, 87 patients from A2 institutions, 50 patients from B1 institutions, and 34 patients from B2 institutions. There were unknown and missing data in the tables because no valid data were found in the given resources.

In addition, the current study compared data for three Japanese PCS surveys of 1,200 patients (1995–1997, 591 patients; 1999–2001, 324 patients; 2003–2005, 285 patients) with cervical cancer treated with radiotherapy with curative intent. Methods for the 1995–1997 and 1999–2001 PCS were the same as those for the 2003–2005 study. Ratios were calculated without unknown or missing data. Statistical significance was tested using the chi-square test.

Results

Patient characteristics in the 2003–2005 survey and trends in the 1995–1997, 1999–2001, and 2003–2005 surveys

Table 1 shows characteristics of the 285 patients in the 2003–2005 survey and changes in radiotherapy practice over the 1995–1997, 1999–2001, and 2003–2005 survey periods. The ages of the analyzed cohorts were significantly different among the three survey periods ($p < 0.0001$). The ages of the analyzed cohort were not different between the 1995–1997 and 1999–2001 surveys ($p = 0.34$) but were significantly different between the 1999–2001 and 2003–2005 surveys ($p < 0.0001$). Karnofsky performance status (KPS), histology, and International Federation of Gynecology and Obstetrics (FIGO) stages were not significantly different among the three survey periods, as shown in Table 1.

EBRT in the 2003–2005 survey and trends in the 1995–1997, 1999–2001, and 2003–2005 surveys

In the 2003–2005 survey, EBRT was performed in 283 patients (99%). Major treatment parameters for pelvic EBRT in the 2003–2005 survey are shown in Table 2. Treatment parameters in the 2003–2005 survey other than those shown in Table 2 are as follows. In 220 cases (78%), multileaf collimators were used to shape the portals. For 265 patients (94%), the planning target volume included the whole pelvic region. The upper border of the pelvic field was at level of the L4–L5 interspace in 245 of the 265 patients (92%). Only 6 patients (2%) received extended field radiotherapy that included the para-aortic region. The median radiation treatment time was 6.0 weeks (range, 1.1–13.0 weeks). The median radiation treatment time exceeded 8 weeks in 7 patients (3%).

Table 1 Patient and tumor characteristics of patients with uterine cervical cancer treated with radiotherapy in each surveillance period

Characteristic	No. of patients (%) 1995–1997 (n = 591)	1999–2001 (n = 324)	2003–2005 (n = 285)	p
Age (years)				<0.0001
Range	28–94	26–100	25–95	
Median	70	71	67	
KPS				0.21
≤70	133 (23)	64 (21)	52 (18)	
80–90	421 (72)	217 (72)	193 (68)	
100	28 (5)	21 (7)	40 (14)	
Unknown/missing	9 (–)	22 (–)	0 (–)	
Histology				0.99
Squamous cell	554 (95)	300 (94)	257 (92)	
Adenocarcinoma	23 (4)	14 (4)	14 (5)	
Adenosquamous cell	4 (1)	4 (1)	5 (2)	
Other	4 (1)	2 (1)	3 (1)	
Unknown/missing	6 (–)	4 (–)	6 (–)	
FIGO stage				0.89
I	57 (10)	43 (14)	27 (10)	
II	171 (29)	102 (34)	85 (30)	
III	280 (48)	122 (40)	132 (46)	
IVA	75 (13)	35 (12)	41 (14)	
Other	5 (1)	0 (0)	0 (0)	
Unknown/missing	3 (–)	22 (–)	1 (–)	

Abbreviations: FIGO = International Federation of Gynecology and Obstetrics; KPS = Karnofsky performance status.

Changes in radiotherapy practice over the 1995–1997, 1999–2001, and 2003–2005 survey periods are also shown in Table 2. The ratio of appropriate EBRT beam energy levels of more than or equal to 10 MV showed a tendency to increase over the three surveys (1995–1997, 67%; 1999–2001, 74%; 2003–2005, 81%; $p = 0.064$). In addition, application of four-field portals greatly increased over the three surveys ($p < 0.0001$). Use of a midline block, single-daily fraction doses, and total point A doses were not significantly different among the three survey periods.

ICBT in the 2003–2005 survey and trends in the 1995–1997, 1999–2001, and 2003–2005 surveys

No patient surveyed received interstitial brachytherapy in the 2003–2005 survey. Fifty-nine patients (27%) received ICBT at another facility. Details of ICBT in the 2003–2005 survey are shown in Table 3. In most patients, all high-dose-rate ICBT (HDR-ICBT) procedures (applicator insertion, radiograph generation, and treatment) were performed in the same room, but these data for dose calculations for the rectum and bladder and the ICBT method showed a considerable rate of unknown or missing data.

Changes in ICBT practice over the years are also shown in Table 3. A ratio of Ir-192 source showed a significant increase among the three surveys ($p < 0.0001$). The number of patients who received no supportive medication before or during the applicator insertion significantly decreased over the three survey periods ($p < 0.0001$), but conscious sedation was still used for a few patients. The use of ICBT, dose rate, method of ICBT, and single-daily fraction dose were not different among the three survey periods. The use of *in vivo* dosimetry and International Commission on Radiation Units and Measurements (ICRU) report 38 calculations for bladder and rectum were not different among the three survey periods, although these data also showed an appreciable rate of unknown or missing data.

Chemotherapy in the 2003–2005 survey and trends in the 1995–1997, 1999–2001, and 2003–2005 surveys

In the 2003–2005 survey, chemotherapy was given to 149 patients (54%), as shown in Table 4. Neoadjuvant chemotherapy was given to 16 patients before they received radiation therapy (11%), and 124 patients (83%) were treated with concurrent chemoradiation (CCRT). Weekly cisplatin was the agent most frequently used with CCRT (45%), and cisplatin was the most common agent in CCRT (55%) regimens.

Changes in chemotherapy practice over the years are also shown in Table 4. Application of chemotherapy significantly increased over the three survey periods ($p < 0.0001$). In addition, concurrent use of chemotherapy with radiotherapy has dramatically increased ($p < 0.0001$). On the other hand, the ratio of neoadjuvant chemotherapy in the most recent survey (2003–2005, 11%) decreased compared to those of 1995–1997 (58%) and 1999–2001 (50%).

Comparison of outcomes and toxicity between the 1995–1997, 1999–2001, and 2003–2005 surveys

Overall survival rates of patients in each survey are shown in Figure 1. Two-year survival rates in the 1995–1997, 1999–2001,

Table 2 Treatment parameters of pelvic external beam radiotherapy in the 1995–1997, 1999–2001, and 2003–2005 survey periods

	No. of patients (%)			
Parameters	1995–1997 (n = 591)	1999–2001 (n = 324)	2003–2005 (n = 285)	p
Beam energy				0.064
Co-60 and 3–5 MV	96 (17)	32 (11)	20 (7)	
6–9 MV	82 (14)	45 (15)	30 (11)	
10–14 MV	338 (59)	220 (71)	191 (70)	
≥15 MV	45 (8)	9 (3)	31 (11)	
Other	10 (2)	0 (0)	1 (0)	
Unknown/ missing	20 (–)	2 (–)	12 (–)	
Technique				<0.0001
AP-PA	560 (98)	269 (87)	205 (75)	
Four-field box	11 (2)	21 (7)	57 (21)	
Other	1 (0)	17 (6)	11 (4)	
Unknown/ missing	19 (–)	1 (–)	12 (–)	
Midline block				0.56
Yes	386 (69)	215 (75)	186 (69)	
No	171 (31)	72 (25)	82 (31)	
Unknown/ missing	34 (–)	1 (–)	17 (–)	
Daily fraction size (Gy)				0.10
<1.8	13 (2)	25 (8)	3 (1)	
1.8	259 (45)	135 (44)	142 (51)	
>1.8 to <2	0 (0)	2 (1)	8 (3)	
2	299 (52)	137 (45)	120 (43)	
>2	3 (1)	6 (2)	4 (2)	
Unknown/ missing	17 (–)	3 (–)	8 (–)	
Total point A dose (Gy)				0.39
0–20	23 (8)	13 (5)	23 (9)	
20–30	42 (14)	40 (14)	58 (21)	
30–40	119 (38)	121 (42)	128 (47)	
40–50	57 (18)	62 (22)	46 (11)	
>50	69 (22)	49 (17)	17 (17)	
Unknown/ missing	17 (–)	39 (–)	12 (–)	
Median	32.2	32.4	32.4	

Abbreviations: AP-PA = opposing anteroposterior-posteroanterior; EBRT = external beam radiotherapy.

and 2003–2005 surveys were 83.4%, 78.4%, and 80.5%, respectively, with a median follow-up of only 2.4, 1.4, and 1.7 years, respectively, in the three studies. These differences did not reach a statistically significant level (p = 0.36).

Rates of developing late Grade 3 or higher toxicity of cervical cancer patients surveyed in each survey are shown in Figure 2. Two-year rates of developing late Grade 3 or higher toxicity in the 1995–1997, 1999–2001, and 2003–2005 surveys were 4.4%, 2.3%, and 8.5%, with a median follow-up of only 2.3, 1.4, and 1.7 years, respectively, in the three studies. Rates of late toxicity were significantly different (p = 0.016).

Discussion

The current study showed that, in Japan, a significant increase was observed in the rate of patients who received chemotherapy over the three periods of 1995–1997, 1999–2001, and 2003–2005. Several RCTs conducted in the 1990s demonstrated that CCRT reduced mortality risk in cervical cancer patients compared with radiotherapy alone (9). The current study showed that a combination of chemotherapy with radiotherapy has become widely used in Japan, similar to the change in the United States in the late 1990s. Concurrent use of chemotherapy also significantly increased over the three survey periods. Our study suggests that more appropriate management of uterine cervical cancer has been adopted in Japan. On the other hand, more than half of the patients (125 patients did not receive chemotherapy; and 25 of the patients who did receive chemotherapy did not receive CCRT) were not treated with CCRT in the 2003–2005 survey, although not all of these patients needed CCRT. Some Japanese physicians remain cautious about employing CCRT as a standard treatment for two reasons. The first reason concerns the feasibility of using the standard chemotherapy of weekly cisplatin concurrently with radiotherapy. Several reports have found Japanese cervical cancer patients frequently experienced severe toxicities, and investigators concluded that CCRT using weekly 40 mg/m^2 dosages of cisplatin might not be feasible for Japanese patients (10). The second reason is that there are limited data for CCRT using HDR-ICBT. A large amount of data concerning excellent outcomes and acceptable toxicity have been reported for patients treated with the Japanese standard schedules, but most of this information was derived from retrospective analyses, and CCRT data are limited (11). Therefore, a prospective study (Japanese Gynecologic Oncology Group study 1066) was undertaken to evaluate toxicities and outcomes in patients treated with CCRT by using the standard dosage/schedule of cisplatin and the standard Japanese radiotherapy dosage schedules for HDR-ICBT (12). On the other hand, whereas several RCTs revealed the negative therapeutic value of neoadjuvant chemotherapy in the mid-1990s, more than 10% of patients were still treated with this strategy during the most recent survey period. However, the current study showed that the ratio of neoadjuvant chemotherapy decreased in the recent survey (2003–2005, 11%) compared to those in the 1995–1997 (58%) and 1999–2001 (50%) surveys. Cisplatin was the agent most commonly used in CCRT (55%) in the 2003–2005 survey. Previous recommendations have been limited to platinum-based chemoradiotherapy, but a recently released individual patient data meta-analysis (13) has shown a significant benefit also associated with non-platinum regimens, specifically those containing 5-fluorouracil and/or mitomycin-C, although those results are not based on a direct comparison. Therefore, detailed information about chemotherapy regimens other than cisplatin will need to be evaluated in future PCS surveys of radiotherapy for cervical cancer.

The current study showed that the four-field technique was gradually applied more frequently over the three survey periods and that the ratio of the four-field technique during the 2003–2005 period was 21%. However, most patients were still treated with the opposing anteroposterior (AP-PA) technique in

Table 3 Details of intracavitary brachytherapy in the 1995–1997, 1999–2001, and 2003–2005 survey periods

Parameter	No. of patients (%) 1995–1997 (n = 591)	1999–2001 (n = 324)	2003–2005 (n = 285)	p
ICBT given				0.66
Yes	454 (77)	265 (82)	222 (78)	
No	132 (23)	58 (18)	63 (22)	
Unknown/missing	5 (–)	1 (–)	0 (–)	
Dose rate				0.47
HDR	386 (89)	215 (89)	205 (93)	
LDR	37 (9)	27 (11)	13 (6)	
Other	10 (2)	0 (0)	2 (1)	
Unknown/missing	21 (–)	23 (–)	65 (–)	
Source				<0.0001
Ir-192	113 (27)	102 (42)	183 (84)	
Co-60	269 (64)	112 (46)	23 (11)	
Cs-137	33 (8)	21 (9)	12 (5)	
Ra-226	9 (2)	7 (3)	0 (0)	
Unknown/missing	33 (–)	23 (–)	67 (–)	
Method of ICBT				0.65
Tandem plus vaginal applicator	352 (87)	202 (83)	190 (89)	
Tandem only	30 (8)	26 (11)	14 (7)	
Vaginal applicator	22 (5)	16 (6)	6 (3)	
Others	0 (0)	0 (0)	3 (1)	
Unknown/missing	50 (–)	21 (–)	9 (–)	
Applicator				0.025
Rigid	NA	166 (72)	158 (85)	
Nonrigid	NA	66 (28)	27 (15)	
Unknown/missing	NA	33 (–)	100 (–)	
In vivo dosimetry: bladder				0.73
Yes	NA	8 (4)	9 (5)	
No	NA	207 (96)	171 (95)	
Unknown/missing	NA	50 (–)	105 (–)	
In vivo dosimetry: rectum				0.24
Yes	NA	71 (33)	75 (41)	
No	NA	145 (67)	108 (59)	
Unknown/missing	NA	49 (–)	102 (–)	
ICRU 38: bladder				0.12
Yes	NA	48 (25)	57 (35)	
No	NA	146 (75)	106 (65)	
Unknown/missing	NA	71 (–)	122 (–)	
ICRU 38: rectum				0.38
Yes	NA	65 (34)	68 (40)	
No	NA	128 (66)	104 (60)	
Unknown/missing	NA	72 (–)	113 (–)	
Preparation				<0.0001
None	199 (53)	90 (54)	33 (19)	
NSAIDs administered orally/rectally	107 (28)	68 (41)	86 (49)	
IV conscious sedation	29 (8)	5 (3)	7 (4)	
Others	2 (1)	3 (2)	49 (28)	
Unknown/missing	117 (–)	99 (–)	110 (–)	
All procedures performed in the same room*				0.58
Yes	NA	167 (94)	157 (92)	
No	NA	11 (6)	13 (8)	
Unknown/missing	NA	37 (–)	115 (–)	
Each fraction was planned*				0.16
Yes	NA	159 (76)	157 (84)	
No	NA	49 (24)	30 (16)	
Unknown/missing	NA	7 (–)	98 (–)	

(*continued on next page*)

Table 3 (*continued*)

Parameter	No. of patients (%) 1995–1997 (n = 591)	1999–2001 (n = 324)	2003–2005 (n = 285)	p
Single-point A dose of HDR-ICBT (cGy)				<0.0001
0–499	16 (5)	43 (20)	14 (7)	
500–599	100 (33)	79 (37)	59 (29)	
600–699	145 (47)	48 (22)	123 (59)	
700–799	43 (14)	15 (7)	10 (5)	
>800	2 (1)	2 (1)	1 (1)	
Unknown/missing	21 (–)	28 (–)	65 (–)	
Median	600	524	600	
Total point A dose of HDR-ICBT (Gy)				<0.0001
0–10	4 (1)	5 (3)	6 (3)	
10–20	80 (26)	58 (31)	71 (34)	
20–30	145 (48)	113 (61)	127 (61)	
30–40	77 (25)	8 (4)	4 (2)	
>40	0 (0)	1 (0)	0 (0)	
Unknown/missing	21 (–)	24 (–)	64 (–)	
Median	24.0	20.3	24.0	

Abbreviations: HDR = high-dose rate; ICBT = intracavitary brachytherapy; ICRU = International Commission on Radiation Units and Measurements; LDR = low-dose rate; NA = not applicable; NSAIDs = nonsteroidal anti-inflammatory inflammatory drugs.

* A total of 222 patients were treated with HDR-ICBT.

Japan, and rates of the use of the four-field technique remained low during the latest period. According to a report of the status of Japanese radiation oncology, one of the problems for the national practice process of radiotherapy in Japan was structural immaturity, especially in terms of personnel (14). Results of our study indicated that radiotherapy characteristics are still developing in Japan. The current study also revealed a change in the beam energy used for radiotherapy in Japan over the three survey periods. Only 7% of the patients were treated with Co-60 and 3 to 5 MV in 2003–2005, whereas these energies were used in 17% of patients in 1995–1997 and 11% of patients in 1999–2001. In addition, the use of appropriate beam energies of 10 to 14 MV and ≥15 MV increased over the three survey periods. In conjunction with the increased numbers of full-time equivalent radiation oncologists in both academic and nonacademic institutions (15),

Table 4 Details of chemotherapy in the 1995–1997, 1999–2001, and 2003–2005 survey periods

Parameters	No. of patients (%) 1995–1997 (n = 591)	1999–2001 (n = 324)	2003–2005 (n = 285)	p
Chemotherapy given				<0.0001
Yes	140 (24)	104 (33)	149 (54)	
No	434 (76)	213 (67)	125 (46)	
Unknown/missing	17 (–)	7 (–)	11 (–)	
Timing*				<0.0001
Neoadjuvant	81 (58)	52 (50)	16 (11)	
Concurrent	28 (20)	56 (54)	124 (83)	
Adjuvant	31 (22)	15 (14)	34 (23)	
Agent†				NA
CDDP weekly	NA	NA	49 (45)	
CDDP daily	NA	NA	5 (5)	
CDDP plus 5-FU	NA	NA	6 (5)	
Others	NA	NA	49 (45)	
Unknown/missing	NA	NA	15 (–)	

Abbreviations: 5-FU = 5-fluorouracil; CDDP = cisplatin; NA = not applicable.

* Some patients overlap in the timing column.

† The indicated agent was used for patients who received concurrent chemotherapy.

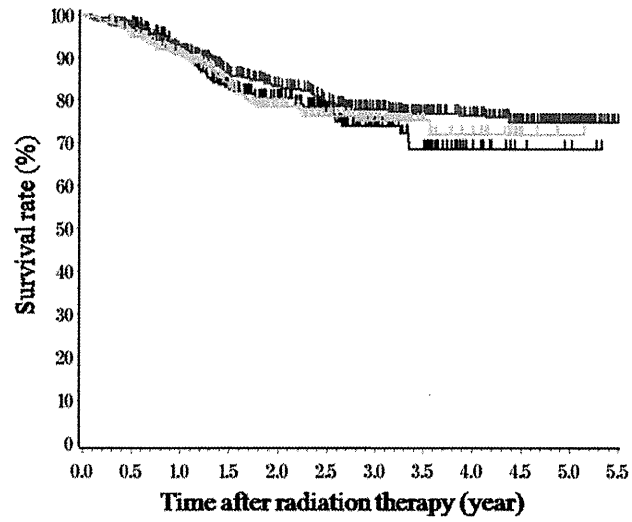

Fig. 1. Kaplan-Meier estimates of overall survival are shown for cervical cancer patients surveyed in the 1995–1997 (blue line, n = 573 patients), 1999–2001 (yellow line, n = 310 patients), and 2003–2005 (black line, n = 279 patients) patterns of care studies in Japan.

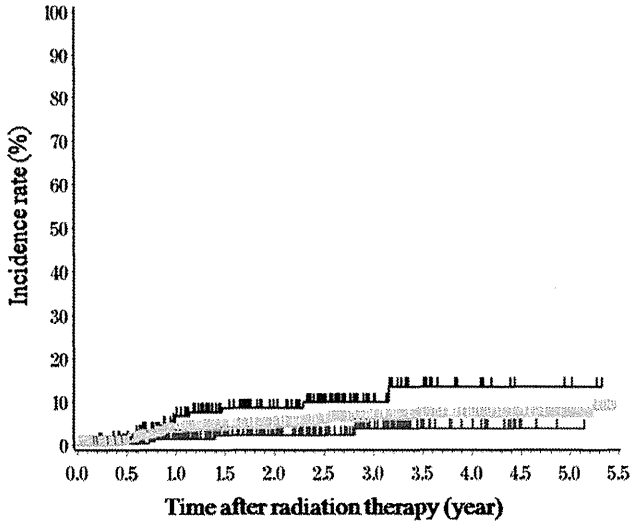

Fig. 2. The rate of developing late Grade 3 or higher toxicity are shown for cervical cancer patients surveyed in the 1995–1997 (blue, $n = 445$), 1999–2001 (yellow, $n = 224$), and 2003–2005 (black, $n = 166$) patterns of care studies in Japan.

Japanese cervical cancer patients are increasingly undergoing more appropriate methods.

The ratio of patients receiving ICBT did not increase over the three surveys. A considerable number of patients, 22%, were still not given ICBT during 2003–2005, and the application rate was lower in Japan than in the United States (4, 5). Therefore, ICBT should be applied more routinely for cervical cancer patients treated with definitive radiotherapy in Japan. One reason for the fact that some patients were not given ICBT might have been insufficient equipment, because 27% of patients received ICBT at another institution compared with 8.5% in the United States (16). The use of Ir-192 in 2003–2005 increased significantly compared with that in 1995–1997 and 1999–2001. The rapid increase in the use of Ir-192 might have been due to the result of the Japanese Society for Therapeutic Radiology and Oncology recommendation in the early 2000s that stated Co-60 should be avoided as a remote afterloading brachytherapy source in Japan because of source attenuation consistent with age. The American Brachytherapy Society (ABS) made a number of recommendations regarding HDR-ICBT techniques (17). Doses to the rectum were more often determined by using a dosimeter than by ICRU 38 reference point calculations. In fact, many studies showed that late rectal complications can be predicted by calculated doses at the ICRU 38 reference points (18). According to the ABS survey, rectal/bladder doses were evaluated in 80% or more patients at U.S. institutions, where HDR radiation was performed (19). However, our study showed that doses to the rectum and bladder in ICBT were evaluated, at most, in 40% of patients in Japan, and this status has significant scope for further improvement. Because accurate insertion can hardly be achieved if patients experience discomfort in ICBT, the ABS also recommends conscious sedation for HDR-ICBT applicator insertions (17). The current study showed that the number of patients who received no supportive medication before or during the applicator insertion significantly decreased, but conscious sedation was still used for a few patients. Although there are some limitations to the interpretation of these data due to an appreciable rate of unknown or missing data, we believe that additional improvements in the management of ICBT are still needed.

The current study also showed that patients' ages in the 1999–2001 survey were significantly different than those in the 2003–2005 survey, and the median age of 71 years old in the 2003–2005 survey was younger than that of the median age of 67 years old in the 1999–2001 survey. We think this may be due to the recent change in the age-specific incidence rate of cervical cancer in Japan. The age-specific incidence rate of cervical cancer in women over 40 years old has fallen gradually since the 1980s, while that in patients under 40 has gradually increased (21). Thus, the percentage of younger patients treated with radiotherapy may have increased. Konno *et al.* (22) organized the critical public health issues about cervical cancer in Japan in their cervical cancer working group report. In Japan, a national program for screening of cervical cancer was enacted in 1982. However, Organization for Economic Cooperation and Development data showed high rates of cervical cancer screening coverage in the United States and Europe but low coverage in Japan (23.4%) (20). With regard to cervical cancer prevention in Japan, in 1983, the government passed a Health and Medical Service Law for the Aged, leaving screening up to regional governments. A human papilloma virus vaccine was licensed in 2009 in Japan.

No significant survival improvement in patient outcome was observed among the three surveys. On the other hand, rates of late toxicity were significantly different in each study. One possible cause for these differences was the dramatic increase in the use of CCRT over the three survey periods. However, the current study has limitations in terms of outcome and toxicity analysis because of an inadequate follow-up time and significant variations in follow-up information according to institutional stratification (6). Therefore, we cannot draw any conclusions about Japanese radiotherapy practice in cervical cancer from these outcome and toxicity data.

Conclusions

In conclusion, we reported the status of definitive radiotherapy for uterine cervical cancer in Japan between 2003 and 2005 and examined the changes over the years in radiotherapy practice in the 1995–1997, 1999–2001, and 2003–2005 survey periods. By comparing the results of previous surveys with those of the 2003–2005 PCS survey, we delineated the changes in the process of care for cervical cancer patients treated with radiotherapy in Japan. Study data indicate a significant trend toward a combination of chemotherapy and concurrent use of chemotherapy and radiation therapy due to the adoption of recommendations found in RCTs. EBRT conditions such as beam energy and technique were gradually standardized to more appropriate methods over the three periods. Regarding ICBT, the patterns of both clinical procedure and quality assessment have still not reached sufficient quality. We believe that the three surveys of Japanese patterns of care for cervical cancer clearly show distinct improvements, while several problems remain to be resolved.

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CLINICAL INVESTIGATION **Education and Training**

NATIONAL MEDICAL CARE SYSTEM MAY IMPEDE FOSTERING OF TRUE SPECIALIZATION OF RADIATION ONCOLOGISTS: STUDY BASED ON STRUCTURE SURVEY IN JAPAN

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Purpose: To evaluate the actual work environment of radiation oncologists (ROs) in Japan in terms of working pattern, patient load, and quality of cancer care based on the relative time spent on patient care.

Methods and Materials: In 2008, the Japanese Society of Therapeutic Radiology and Oncology produced a questionnaire for a national structure survey of radiation oncology in 2007. Data for full-time ROs were crosschecked with data for part-time ROs by using their identification data. Data of 954 ROs were analyzed. The relative practice index for patients was calculated as the relative value of care time per patient on the basis of Japanese Blue Book guidelines (200 patients per RO).

Results: The working patterns of RO varied widely among facility categories. ROs working mainly at university hospitals treated 189.2 patients per year on average, with those working in university hospitals and their affiliated facilities treating 249.1 and those working in university hospitals only treating 144.0 patients per year on average. The corresponding data were 256.6 for cancer centers and 176.6 for other facilities. Geographically, the mean annual number of patients per RO per quarter was significantly associated with population size, varying from 143.1 to 203.4 ($p < 0.0001$). There were also significant differences in the average practice index for patients by ROs working mainly in university hospitals between those in main and affiliated facilities (1.07 vs 0.71: $p < 0.0001$).

Conclusions: ROs working in university hospitals and their affiliated facilities treated more patients than the other ROs. In terms of patient care time only, the quality of cancer care in affiliated facilities might be worse than that in university hospitals. Under the current national medical system, working patterns of ROs of academic facilities in Japan appear to be problematic for fostering true specialization of radiation oncologists. © 2012 Elsevier Inc.

Structure survey, Working pattern, Patient load, Quality of cancer care, Medical care system.

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INTRODUCTION

The medical care systems of the United States and Japan are very different, which influences the personnel cost of medical staff. In radiation oncology, too, there is thus a major difference in personnel distribution between the United States and Japan. Most radiotherapy facilities in the United States are supported by full-time radiation oncologists (ROs), whereas the majority of radiotherapy facilities in Japan still rely on part-time ROs. Radiotherapy facilities with less than one full-time equivalent (FTE) RO on their staff still account for 56% nationwide (1). The Cancer Control Act was implemented in Japan in 2007 in response to patients' urgent petitions to the government (2). This act strongly advocates the promotion of radiotherapy (RT) and an increase in the number of ROs and medical physicists. However, a shortage of ROs still remains a major concern in Japan and will remain so for the foreseeable future.

The Japanese Society of Therapeutic Radiology and Oncology (JASTRO) has conducted national structure surveys of RT facilities in Japan every 2 years since 1990 (1, 3). The structure of radiation oncology in Japan has improved in terms of equipment and its functions in response to the increasing number of cancer patients who require RT.

In this study, we used the data of the JASTRO structure survey of 2007 to evaluate the actual work environment of radiation oncologists in Japan in terms of working pattern, patient load, and the quality of cancer care based on the relative time spent on patient care.

MATERIALS AND METHODS

Between March and December 2008, JASTRO carried out a national structure survey of radiation oncology in the form of a questionnaire in 2007 (1). The questionnaire consisted of questions about the number of treatment machines and modality by type, the number of personnel by job category, the number of patients by type, and the site. The response rate was 721 of 765 (94.2%) from all actual RT facilities in Japan.

Table 1 shows the overview of radiation oncology in Japan. University hospitals accounted for 15.8% of all RT facilities and had 40.0% of the total full-time ROs and treated 29.5% of all patients. The corresponding data were 4.0%, 7.8%, and 10.2% for cancer centers, and 80.2%, 52.2%, and 60.3% for other RT hospitals, respectively. "Full-time/part-time" indicates the employment pattern of RO. In Japan, even full-time ROs must work part-time in smaller facilities such as other RT hospitals. We considered these numbers to be inappropriate for accurate assessment of personnel. For this survey, we therefore collected FTE (40 h/week for radiation oncology services only) data depending on hours worked in clinical RT of each RO. For example, if an RO works 3 days at a university hospital and 2 days at an affiliated hospital each week, FTE of the RO at the university hospital is 0.6 and at an affiliated hospital it is 0.4. The FTE of a facility that has three ROs with 0.8, 0.4, and 0.6 is calculated as 1.8 in total.

This survey collected the work situation data of a total of 1,007 full-time ROs and 534 part-time ROs. The data of full-time ROs were crosschecked with those of part-time ROs by using their identification data. Table 2 shows the result of crosschecking between data of full-time ROs and data of part-time ROs. In this study, data of 954 ROs were analyzed. Table 3 shows an overview of the analyzed data. In ROs working mainly in university hospitals, there are two ROs who worked at a maximum of six facilities (main facilities and five affiliated facilities) SAS 8.02 (SAS Institute Inc., Cary, NC) (4) was used for the statistical analysis, and the statistical significance was tested by means of the Student's *t*-test or analysis of variance.

The Japanese Blue Book guidelines (5, 6) for structure of radiation oncology in Japan based on Patterns of Care Study (PCS) data were used as the standard for comparison with the results of this study. PCS in Japan have been used since 1996 and have disclosed significant differences in the quality of RT by the type of facilities and their caseloads (7, 8). The standard guidelines for annual patient load per FTE RO have been set at 200 (warning level 300).

To evaluate quality of cancer care provided by ROs, the relative practice index for patients was calculated by the following expression.

$$\frac{\sum_{k=1}^{n} f_k}{\sum_{k=1}^{n} a_k} \times 200$$

in which n is the number of facilities that the RO works in ($n = 1, 2, 3, \ldots, k$), f_k is the FTE of the RO in facility k, and a_k is the annual number of patients per RO in facility k

Calculation method of coefficient "200:"

1) Number of weeks per year = (365–15)/7 = 50 weeks
   ※ Japan has 15 national holidays a year
2) 1.0 FTE = 40 h/week
3) Annual working hours of FTE 1.0 = 50 × 40 h = 2,000 h
4) Relative practice index for patients was normalized using the Blue Book guideline of 200 patients/FTE RO. For this guideline, care time per patient was set at 10 hours (2,000 h/200 patients).
5) Coefficient was 200 (2000/10).

RESULTS

Working patterns

Figure 1 shows working patterns of ROs working mainly in (a) university hospitals, (b) cancer centers, and (c) other

Table 1. Categorization of radiotherapy facilities in Japan

Facility category	Number of facilities	New patients	Total patients (new + repeat)	Full-time ROs		Part-time ROs	
				n	FTE	*n*	FTE
University hospital	114	50,351	60,555	403	293.0	70	21.6
Cancer center	29	16,794	20,968	78	73.7	14	2.5
Other radiotherapy hospital	578	103,084	123,564	526	351.8	450	83.7
Total	721	170,229	205,087	1,007	718.5	534	107.8

Abbreviations: RO = radiation oncologist; FTE = full-time equivalent (40 hours per week for radiation oncology services only).