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Comparative Analysis of Patterns of Care Study of Radiotherapy for Esophageal Cancer among Three Countries: South Korea, Japan and the United States

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Purpose: For the first time, a nationwide survey of the Patterns of Care Study (PCS) for the various radiotherapy treatments of esophageal cancer was carried out in South Korea. In order to observe the different parameters, as well as offer a solid cooperative system, we compared the Korean results with those observed in the United States (US) and Japan.

Materials and Methods: Two hundreds forty-six esophageal cancer patients from 21 institutions were enrolled in the South Korean study. The patients received radiation theraphy (RT) from 1998 to 1999. In order to compare these results with those from the United States, a published study by Suntharalingam, which included 414 patients [treated by Radiotherapy (RT)] from 59 institutions between 1996 and 1999 was chosen. In order to compare the South Korean with the Japanese data, we choose two different studies. The results published by Gomi were selected as the surgery group, in which 220 esophageal cancer patients were analyzed from 76 facilities. The patients underwent surgery and received RT with or without chemotherapy between 1998 and 2001. The non-surgery group originated from a study by Murakami, in which 385 patients were treated either by RT alone or RT with chemotherapy, but no surgery, between 1999 and 2001.

Results: The median age of enrolled patients was highest in the Japanese non-surgery group (71 years old). The gender ratio was approximately 9 : 1 (male : female) in both the Korean and Japanese studies, whereas females made up 23.1% of the study population in the US study. Adenocarcinoma outnumbered squamous cell carcinoma in the US study, whereas squamous cell carcinoma was more prevalent both the Korean and Japanese studies (Korea 96.3%, Japan 98%). An esophagogram, endoscopy, and chest CT scan were the main modalities of diagnostic evaluation used in all three countries. The US and Japan used the abdominal CT scan more frequently than the abdominal ultrasonography. Radiotherapy alone treatment was most rarely used in the US study (9.5%), compared to the Korean (23.2%) and Japanese (39%) studies. The combination of the three modalities (Surgery+RT+Chemotherapy) was performed least often in Korea (11.8%) compared to the Japanese (49.5%) and US (32.8%) studies. Chemotherapy (89%) and chemotherapy with concurrent chemoradiotherapy (97%) was most frequently used in the US study. Fluorouracil (5-FU) and Cisplatin were the most preferred drug treatments used in all three countries. The median radiation dose was 50.4 Gy in the US study, as compared to 55.8 Gy in the Korean study regardless of whether an operation was performed. However, in Japan, different median doses were delivered for the surgery (48 Gy) and non-surgery groups (60 Gy).

Conclusion: Although some aspects of the evaluation of esophageal cancer and its various treatment modalities were heterogeneous among the three countries surveyed, we found no remarkable differences in the RT dose or technique, which includes the number of portals and energy beams.

Key Words: Esophageal cancer, Radiotherapy, Patterns of Care Study

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Introduction

In the United States, the Patterns of Care Study (PCS) was first established by Simon Kramer in 1971 for the purposes of improving the quality and accessibility of radiation oncology.[1] Throughout the past few decades, PCS has helped to offer

national standards of radiation oncology practice and solid cooperative systems among institutions.[2,3] The results of esophageal PCS in the US were published in 2000 by Coia[4] and 2003 by Suntharalingam.[5] The PCS was first introduced to Japan in 19966) and to South Korea in 2002.[7] The first Japanese PCS results of esophageal cancer have been published in 1998 by Teshima[8] which was followed by Tanisada, Gomi, and Murakami subsequently in 2000, 2003, and 2007.[9~11] An organization for Korean PCS was first established in early 2003 to meet the need for the systematic data of nation-wide patterns of radiotherapy structure, process, and results. The web-based Korean PCS system was developed and launched, and since then, the results of several disease sites[12~14] and the preliminary results of esophageal cancers have been published in 2007.[15] To make this results useful for international standards, we compared the Korean results with those of the US and Japan by analyzing the different parameters used for PCS, possibly to offer a solid cooperative system for the diagnostic tool and treatment strategy among the three countries. The summary of these results was presented at the 2007 ASTRO meeting.

Materials and Methods

Two hundred and forty six biopsy-confirmed esophageal cancer patients who received radiotherapy during 1998~1999 were enrolled from 23 different institutions in South Korea. They were confirmed as having epithelial cancer with no distant metastasis or double primary. These exclusion criteria were almost the same among the three countries. Random sampling was based on the power allocation method. Patient parameters and specific information regarding tumor characteristics and treatment methods were collected and registered through the web-based PCS system. The data was analyzed by the use of the Chi-squared test. We compared this data with the results of Suntharalingam in the United States where 414 patients who received RT between 1996~1999 were chosen from 59 institutions. We also compared Korean and US results with those of two different Japanese studies. The first one was by Gomi in 2003, where 220 patients from 76 facilities who had undergone surgery and received RT between 1998 and 2001 and the other study,

Table 1. Patients Characteristics

	South Korea	Japan		U.S.
Period	1998~1999	1995~1997	1999~2001	1996~1999
		Surgery group	Non-surgery group	
No. of patients	246	220	385	414
No. of institutions	23	76	76	59
Age (year)				
Median (range)	62	62.3 (31~89)	71	64 (25~91)
Sex (%)				
Male	91.1	88.1	85	76.9
Female	8.9	11.9	15	23.1
Performance (%)				
KPS* 60~70	ECOG 4 : 0.4	17.5	25.3	14.5
80	ECOG 3 : 3.7	47.5	35.8	29.8
90	ECOG 2 : 13.4	30.4	26.2	54.9
100	ECOG 1 : 74.0	4.6		0.7
Unknown	ECOG 0 : 8.5	1.4	12.7	0.1
Eligibility				
Location	Any	Thoracic	Thoracic & abdominal	Thoracic
Performance	Any	KPS ≥60	Any	KPS >60
Histology	Any	Any	Squamous cell ca 99%	Squamous cell or adenocarcinoma

*Karnofsky performance status

published by Murakami in 2007, where 385 patients from the same facility received RT without surgery between 1999 and 2001 (Table 1). We analyzed patient characteristics, pathologic prevalence, different diagnostic tools and treatment strategies among the three countries.

Results

1. Characteristics of the patients

The median age of esophageal cancer in the 3 countries were 62 years old in Korea, 64 in US, 62.3 for the Japanese surgery group and 71 for non-surgery group, subsequently. Gender ratio was approximately 9:1 in both Korea and Japan with male predominance, whereas females comprised 23.1% of the sample from the US. As regarding the performance status, ECOG 0 and 1 occupied 82.5% of Korean patients, and KPS of more than 90 comprised 55.7% of the total in the US study. In the surgery group of the Japanese study, KPS of more than 90 comprised 34% of the total while it was 30% for the non-surgery group (Table 1).

2. Diagnostic evaluation

The pretreatment evaluation was compared in the three countries (not obtained in the Japanese surgery group). Esophagogram, endoscopy, and chest CT scan were the main modalities of diagnostic evaluation. Among these tools, endoscopic examination was most frequently used in all three countries (more than 90% of patients). The esophagogram was also checked very frequently both in Korea and Japan (more than 90% of patients), but its use has been decreasing in US (from 70.5% in 1999 to 64.0% in the 2003 study). More than 90% of patients both in Korea and Japan obtained a chest CT scan, and this rate is slightly higher than the US result (86.8%). However, the United States and Japan used

Table 2. Diagnostic Methods

Period	South Korea	Japan		U.S.
	1998~1999	1995~1997	1999~2001	1996~1999
		Surgery group	Non-surgery group	
Esophagogram (%)	92.7	97.2	94	64.0
Endoscopy (%)	91.9	88.7	96	95.6
EUS* (%)	17.5	23.6	29	17.8
Chest CT (%)	96.7	97.0	97	86.8

*endoscopic ultrasonography

Table 3. Histologies and Clinical Stagings

Period	South Korea	Japan		U.S.
	1998~1999	1995~1997	1999~2001	1996~1999
		Surgery group	Non-surgery group	
Histology (%)				
Squamous cell	96.3	99.0	99	48.7
Adenocarcinoma	1.2	0.5	0	49.6
Adenosquamous	0.8	0	1	0.9
Unknown	1.6	0.5		0.8
Clinical stage (%)				
I	6.5	19.6	16	15.8
II	38.6	34.1	29	39.1
III	54.9	40.1	55 (III&IV)	33.1
Unknown & missing	0	6.2		11.9

abdominal CT scan more frequently (75.4% and 87% respectively) than abdominal ultrasonography. Abdominal ultrasonography was carried out with relatively higher frequency in Korea (62.2%). The frequency of using EUS was 38.6% in Japan and 17.5% in Korea. Its use has increased in the US study (17.8%)(Table 2).

3. Characteristics of tumor at diagnosis

The histologic type was mainly squamous cell carcinoma both in Korea and Japan (Korea 96.3%, Japan 98%) but in the United States adenocarcinoma outnumbered squamous cell carcinoma, 49.6% to 48.7% (Table 3). The location of the primary tumor was mostly middle thoracic both in Korea (44.7%) and Japan (56% for the non-surgery group) but this was not studied in the US (Table 1).

4. Clinical stage at diagnosis

In both Korea and Japan, clinical stage III was distributed in the largest scale (Korea 54.9%, Japan 51%) whereas in the United States, stage II was most prevalent (stage II 54.9%, stage III 33.1%)(Table 3).

5. Treatment strategy

In all three countries, the most common treatment was using radiation in combination with chemotherapy with the exception of the Japanese 2003 study where a survey was conducted with special reference to the patients who had undergone surgery. In the United States, radiation alone was very infrequently used (9.5%) when compared to radiation in combination with chemotherapy (56.4%). In both Korea and Japan, the use of radiation alone was relatively higher than in the US (23.2% in Korea, 39% in Japan). In the 2003 study of

Table 4. Treatment Strategy

	South Korea	Japan		U.S.
Period	1998~1999	1995~1997	1999~2001	1996~1999
		Surgery group	Non-surgery group	
RT* alone (%)	23.2	0	39	9.5
RT+Surgery (%)	15.0	45.0	0	1.4
RT+CT† (%)	50.0	0	61	56.4
RT+CT+Surgery (%)	11.8	49.5	0	32.8
Unknown	0	5.5		0

*radiation therapy, †chemotherapy

Table 5. Chemotherapy Characteristics

	South Korea	Japan		U.S.
Period	1998~1999	1995~1997	1999~2001	1996~1999
		Surgery group	Non-surgery group	
Yes (%)	61.8	54.1	61	89
Concurrent (%)	69.1	59.7	73	97
Anticancer agent				
5-FU*	92.1	78.2	97	82
Cisplatin	78.3	76.5	82	67
Carboplatin	1.3	4.2	3	22 (paclitaxel)
		12.5 (Vindesine)		

*5-Fluorouracil

Table 6. Radiotherapy Characteristics

Period	South Korea	Japan		U.S.
	1998～1999	1995～1997	1999～2001	1996～1999
		Surgery group	Non-surgery group	
Radiation dose (Gy)				
Median dose	55.8	48	60	50.4
RT* alone / postop RT	59.4 / 50.4			
Median dose / fraction	1.8		2.0	1.8
Energy ≥10 MV (%)	46.3	83.6 (≥6 MV)		39
Brachytherapy (%)	13.8		10	6

*radiation therapy

the Japanese surgery group, radiation was only combined with surgery in 45% of patients, while surgery was combined with chemoradiotherpy in 49.5% of the patients. The frequency of using chemotherapy was highest in the US (89%), followed by Korea (61.8%), and Japanese non-surgery group (61%). In the study of the Japanese surgery group, chemotherapy was still used in more than half of the patients (54.1%)(Table 4). In all three countries, the pattern of using chemotherapy was mostly in conjunction with RT. The concurrent rate was highest in the US (97%), followed by the Japanese non-surgery group (73%), and Korea (69.1%), respectively. Cispaltin and 5-FU are the most favoured agents in all three countries,; however, the use of paclitaxel has been increasing in the US (Table 5).

6. Technical aspect of radiotherapy

The median doses of radiation used are 50.4 Gy in the US, 55.8 Gy in Korea , regardless of operation, and in Japan the delivered doses between the surgery group (48 Gy) and non-surgery group (60 Gy) differed greatly. The median dose per fraction was similar in all three countries (1.8～2.0 Gy). The type of beam, number of portals, three dimensional radiation technique , and application of brachytherapy did not differ greatly in three countries (Table 6).

Discussion and Conclusion

The patterns of care study was first carried out in 1971 by Dr. Simon Kramer and Herring of the United States in an attempt to increase the quality and accessibility of radiation therapy.[1,2] The National Cancer Institute funded the American College of Radiology (ACR) to perform PCS in 1974 and they applied Donabedian's model of quality assessment for PCS.[16] It is in general classified into 3 categories : the "structure study" which investigates facilities, human resources and equipments resulting in the establishment of facility master list (FML) that have been updated every five years; the "study of processing" which studies treatment related facts comprising actions to evaluate and treat patients; and the "outcome study" which analyzes the survival, treatment results and complications that set in. In US, PCS uses two-stage cluster sampling of institutions and patients according to institutional stratification. This is the basic mechanism that renders PCS data useful for the improvement of nationwide structure and make it possible to analyze the structure in close correlation with process and outcome. PCS has helped to identify the national standards of radiation oncology practice for multiple disease sites in the United States. The PCS of esophageal cancer was first published by Coia in 1999 with results between 1992 and 1994.[4] In 2003, Suntharalingam[5] published the results obtained between 1996 and1999 where the actual two stages of cluster sampling of patients were applied. The site visits to collect data took place at 20 large academic centers, 2 small academic, 19 large nonacademic and 18 small academic facilities. Cases were randomly selected for review and data abstraction, based on lists generated by the facility according to eligibility criteria. Data were collected from 2000 to 2002 by PCS research associates who performed on-site chart reviews at each facility participating in the study. Data items on the survey form were determined by the PCS

Esophageal Committee, which met before national site visits to identify key evaluation, management, and treatment issues in esophageal cancer. Data collected included demographics, symptoms at presentation, extent of workup (including study results), staging, treatment (planned and delivered), toxicities encountered and outcomes.

PCS was first introduced to Japan from USA in July 1996.[6] So far, four Japanese PCS (JPCS) surveys for esophageal cancer patients receiving RT have been performed. The first preliminary study was published in 1998 by Teshima[8] to observe the influence of stratification of institutions on the PCS process. The second survey was conducted from 1996 to 1998, collecting data from 1992 to 1994 which was published in 2000 by Tanisada.[9] It was a study of a non-surgery group with special reference to age, where the feasibility of Japanese PCS was confirmed. In this study, they concluded that age was not a significant prognostic or risk factor for esophageal cancer patients, particularly in the non-surgery group treated with radiation therapy. They also concluded that institutional stratification including equipment and personnel had significantly affected the patterns of care for esophageal cancer. The third Japanese survey was carried out from 1998 to 2001,[10] collecting data from 220 patients from 78 facilities who had undergone preoperative and postoperative RT between 1995 and 1997. This time the participating institutions were classified into three groups by type and number of patients treated annually: academic institutions (main cancer centers and university hospitals) treating more than 300 patients annually were designated as A1, academic institutions treating less than 300 patients as A2, and non-academic institutions (national hospitals, public general hospitals, and private hospitals) as B. The results were published in 2003 by Gomi who concluded that there are still important issues regarding RT for esophageal cancer that should be solved immediately, namely treatment strategy, timing of RT, photon energy level, and dose applied to the spinal cord. In 2007, Murakami[11] published the results of esophageal cancer treated between 1999 and 2001 receiving definitive radiation therapy without surgery. At this time, the institutions were divided into four large groups. University hospitals and any hospital having more than 430 new patients per year were designated as A1:, less than 430 patients as A2:, and non academic hospitals having new cases of more than 130 patients as B1:, and hospitals having less than 130 patients as B2. For this survey, 76 facilities were selected (20 from A1, 18 from A2, 20 from B1 and 18 from B2). The clinical data of 621 esophageal cancer patients receiving RT with or without surgery were accumulated. Of these, 385 patients (62%) who received RT without surgery were analyzed (106 patients from A1, 88 from A2, 142 from B1 and 49 from B2). The inclusion criteria were thoracic and abdominal esophageal cancer treated RT from 1999 to 2001 with KPS of 60 or more. It is very noteworthy that they excluded patients of cervical esophageal cancer because of its different treatment strategy and various RT parameters from thoracic and abdominal esophageal patients. Statistical analyses were performed using the statistical analysis system (SAS) at the JPCS statistical center. Statistical significance was tested using the x2 test and Student's t-test.

In Korea, an organization for Korean PCS was first established in 2002 to meet the need for the systematic data that shows nation-wide patterns of radiotherapy structure, process, and results. The web-based Korean PCS system, which was developed for the first time in the radiation oncology field enables clinical quality assurance and offers a useful standard for comparison with other nations.[7] Since then, the results of several disease sites were published one after another.[12~14] We published the results of esophageal cancer PCS in 2007, where 246 esophageal cancer patients who received RT between 1998 and 1999 from 23 different hospitals were collected.[15] In Korea, where most radiation therapies are carried out in university hospitals, the hospitals were assorted into three groups based only on the number of new incidences per year, where less than 400 patients was designated as group A, between 400~900 as B, and more than 900 as C respectively. Data items and survey forms were determined by a consensus committee. The random sampling of patient distribution was based on the power allocation method. Patient parameters and specific information regarding tumor characteristics and treatment methods were collected and registered through the web-based PCS system. PCS research associates performed site visits and chart reviews for the external audits of input data. By reviewing Korean data to be published, we have reached the conclusion that to obtain result that meet international standards, it is essential to compare the results with those of the US and Japan. For this

purpose, we have chosen one US[5] and two Japanese studies[10,11] where the survey of collected data was performed during a similar period with ours. For the Japanese occasion, two studies were chosen because each study had been executed with special reference to different treatment modalities, namely, the surgery and non-surgery groups. By doing this comparing analysis, we could see several differences in tumor characteristics, diagnostic tools and treatment strategy but comparing of survival rates was very challenging due to the different staging criteria of the three countries. Regarding the patients and tumor characteristics, although a higher proportion of female patients and the predominance of adenocarcinoma in the US study were not surprising, the median age of the Japanese study of the non-surgery group was much higher than expected (71 years old), indicating not only the longer life-span of Japanese, but also that younger patients are more apt to receive surgery than older ones. This result implies that there should be a certain consensus among the three countries that a special age reference must be included according to the different treatment modalities in future studies. The high proportion of ECOG1 (74.0%) and large scale of clinical stage III (54.9%) in the Korean result is comparable to other countries, which can be possibly explained as the relative short interval between the initial symptom and final diagnosis of Korean patients. This was not issued in the US and Japanese studies. Reviewing the diagnostic tools, we could see no specific or remarkable differences among the three countries. Esophagogram, endoscopy and chest CT scan were performed as the main modalities of diagnostic evaluations in all three countries. The endoscopic ultrasonography was not used frequently, but its use has increased in the US and Japan. Abdominal ultrasonography was used more frequently in Korea (62.2%) than abdominal CT scan, on the contrary in the US and Japan, it was checked as much as chest CT scan. In most Korean institutions, when a chest CT scan is performed, the scan usually includes the upper abdomen as well, making a separate abdominal CT scan unnecessary. Concerning treatment modalities, the rate of RT alone was not very high in any of the three countries indicating that local therapy alone is not appropriate to control esophageal cancer regardless of its staging. When chemoradiotherapy is used it is usually performed concurrently in the US, suggesting that a different rate of tolerance among races exists, particularly when the most toxic treatment is applied. The median dose of RT was quite similar in Korea and the US studies, where it was not analyzed according to the performance of surgery, while in the Japanese studies, the different median dose for the surgery and non-surgery groups seems to be very reasonable,; this aspects should be taken into considerations in future studies of Korean and US esophageal PCS.

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국문초록

한국, 미국, 일본의 식도암 방사선 치료에 대한 PCS (1998～1999) 결과의 비교 분석

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목 적: 식도암의 방사선 치료에 대해 최초로 시행한 한국의 PCS의 결과를 토대로 미국, 일본에서 시행한 결과와 비교 분석하여 식도암 환자들의 특징, 진단 및 치료방침의 차이를 파악해 향후 범 국가적으로 활용할 시스템의 구축에 응용하고자 하였다.

대상 및 방법: 국내의 21개 병원의 방사선 종양학과에서 1998-1999년 동안 식도암으로 확진 된 후 방사선 치료를 받은 총 246명을 대상으로 하였다. 이 결과를 미국 59개 병원에서 식도암 환자 414명을 연구한 PCS 결과(Suntharalingam)와 비교 하였다. 또 일본의 76개 병원에서 수술과 방사선치료를 받았거나 수술, 방사선 치료, 항암제 치료를 함께 받은 수술 군 환자 220명(Gomi), 수술을 받지 않고 방사선 치료만 시행하였거나 방사선 치료와 항암제치료를 함께 시행한 비 수술 군 환자 385명(Murakami)을 대상으로 시행한 PCS 결과와 비교 분석하였다.

결 과: 환자들의 평균 연령은 일본의 비 수술 군이 가장 높았다(71세). 한국과 일본은 남성의 발생 빈도가 월등히 높았지만(9:1) 미국은 여성의 발생률이 23.1%였다. 한국과 일본은 편평상피세포암이 압도적으로 많았지만(한국 96.3%, 일본 98%) 미국은 선암이 더 많은 양상을 보였다(49.6%). 병기결정을 위한 검사는 식도 내시경, 흉부 컴퓨터 단층촬영, 식도조영술을 가장 많이 사용하였고 미국과 일본은 복부 컴퓨터단층촬영을 복부 초음파보다 더 자주 시행하였다. 치료방침을 분석한 결과 방사선 단독치료의 비율은 한국이 23.2%, 일본이 39%인데 반해 미국은 9.5%에 불과하였다. 수술과 방사선 및 항암치료를 병용한 빈도는 미국(32.8%)과 일본 (49.5%)이 한국(11.8%)보다 높았다. 식도암 치료에 있어서 항암제 치료는 미국이 가장 높은 빈도로 사용되어졌고(89%) 동시항암방사선 치료도의 빈도도 미국이 가장 높았다(97%). 항암치료제는 3개국 모두에서 cisplatin과 5-FU를 가장 선호하였다. 방사선 조사량은 한국 55.8 Gy, 미국 50.4 Gy였고 일본은 수술 군(48 Gy)과 비 수술 군(60 Gy)이 현격한 차이를 보였다.

결 론: 한국, 미국, 일본에서 시행된 식도암 환자의 PCS 결과를 분석하여 환자 및 종양의 특징, 진단 및 치료 방침에 다소간의 상이점을 발견하였다. 그러나 방사선 조사량과 조사야 수, 방사선치료 에너지의 종류 등 방사선 기술적인 부분은 3개국 모두에서 큰 차이를 보이지 않았다.

핵심용어: 식도암, 방사선치료, Patterns of Care Study