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Role of Radiotherapy for Squamous Cell Carcinoma of the External Auditory Canal and Middle Ear

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Purpose: To investigate the role of radiotherapy for squamous cell carcinomas of the external auditory canal and middle ear.

Materials and Methods: A series of 35 patients who were treated at a single institution from 1981 through 2007 were retrospectively analyzed. Thirteen patients were treated by radiotherapy alone; four by surgery only and 18 by a combination of surgery and radiotherapy. The total radiation dose ranged from 39~70 Gy (median, 66 Gy) in 13~35 fractions for radiotherapy alone and 44~70 Gy (median, 61.2 Gy) in 22~37 fractions for the combined therapy. Clinical end-points were the cause of specific survival (CSS) and local relapse-free survival (LRFS). The median follow-up time was 2.8 years (range, 0.2~14.6 years).

Results: The 3-year CSS and LRFS rate was 80% and 63%, respectively. Based on a univariate analysis, performance status and residual disease after treatment had a significant impact on CSS; performance status and histologic grade for LRFS. Patients treated by radiotherapy alone had more residual disease following the course of treatment compared to patients treated with the combined therapy; 69% vs. 28%, respectively.

Conclusion: Our results suggest that radiation alone was not an inferior treatment modality for CSS compared to the combined therapy for squamous cell carcinoma of the external auditory canal and middle ear. However, local failure after radiotherapy is the main issue that will require further improvement to gain optimal local control.

Key Words: Ear canal, Middle ear, Squamous cell carcinoma, Radiotherapy

Introduction

Cancer of the external auditory canal (EAC) and middle ear (ME) is a rare malignancy, accounting for less than 1% of all head-and-neck malignancies.[1,2] Squamous cell carcinoma (SCC) in this region is the most common histologic type, occurring in more than 80% of cases.[3,4] The reported 5-year survival rate of SCC of the EAC and ME varies between 33% and 55%.[1,5~8] Because of the relatively small number of patients in most of the reported series, together with the difficulty of pretreatment radiological evaluation, there is no universally accepted standard staging system.

Although surgery is considered as the primary treatment in general, some controversy exists regarding the best options for the treatment of SCC in the EAC and ME. Radiotherapy (RT) has been usually used postoperatively for gross residual disease or for a high risk of recurrence. Preoperative RT combined with chemotherapy can be one of the options to obtain a negative margin during surgery to enhance disease control and survival.[9,10] Comparable outcomes of primary RT have been reported recently,[7,8,11] but the role of RT in a definitive setting has not been clearly defined. In this study, we present the clinical characteristics and the results of treatment outcome of 35 patients with SCC of the EAC and ME. A comparison of the treatment outcome for the use of RT and combined modality treatment using surgery with RT

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was performed. We also investigated the prognostic factors for local relapse and cancer specific death.

Materials and Methods

1. Patients

We retrospectively reviewed the medical records of 51 patients who presented at our institution with cancer of the EAC and ME, not skin cancer invading EAC, from July 1981 through January 2007. In the study, patients with SCC who had completed planned treatment were analyzed. Thus 16 patients were excluded from the analysis because of a non-SCC histology (n=12), incomplete treatment (n=2) and early follow-up loss (n=2). The median follow-up was 2.8 years (range, 0.2 to 14.6 years) from the date of diagnosis to the date of the last follow-up or death. Seven patients were followed only for short duration, less than six months, because the patients who were dead at the time of analysis were included in the data. Permission to perform the study was obtained from our institutional review board.

The median age of the 35 patients was 55 years (range, 35 to 79 years) and 23 males and 12 females were included. Most of the patients had good performance status (ECOG scale 0 or 1). A pathologic diagnosis was obtained for all patients. Thirteen patients underwent a biopsy (37%), two patient underwent wide excision (6%), 12 patients underwent partial temporal bone resection (34%) and eight patients underwent subtotal temporal bone resection (23%). All operable patients were considered to be treated with radical or cyto-reductive surgery and patients with residual disease or suspicious resection margin were treated with postoperative radiotherapy. Seven patients (20%) had disease at a ME location. A preoperative computed tomography (CT) or magnetic resonance (MR) scan was performed in all patients. An MR scan was performed before treatment in 22 patients (63%). Patient disease was restaged according to the classification described by Stell and McCormack[12] (Table 1) using images, surgical records and pathologic reports. Most of the patients had T1 or T2 (60%) stage disease and regional node involvement was 6%. Thirty-one patients (89%) had received RT and five patients (14%) had received chemotherapy. After planned treatment all patients were examined using initial image modalities at 2～3 months from end of treatment. Unless patients have progressed, regular work-ups were performed with 3～6 months interval, untill at least 5 years after end of treatment.

2. Radiotherapy

RT was carried out 3～8 weeks after radical resection or a biopsy in most patients with megavoltage beams (Co-60 or 4 or 6 MV X-rays). Of the 31 patients who had received RT, 13 patients were treated with definitive aim (median dose, 66 Gy; range, 39 to 70 Gy) and 18 patients were treated with preoperative (n=1) or postoperative (n=17) aim (median dose, 61.2 Gy; range, 44 to 70 Gy) using a conventional fractionation schedule, that is, 2 Gy per fraction per day, five days a week in most patients. All patients were treated with curative aim, but two patients in definitive RT group fail to complete scheduled treatment and these were included in the analysis. To facilitate the comparison of the different fractionation schedules, we computed the biologically effective dose that is equivalent to 2 Gy/fraction (2 Gy-BED) according to the linear-quadratic model: $BED=nd\ \{1+[d/(\alpha/\beta)]\}$; where α/β is 10 for cancer; n is the number of fractions and d is the dose per fraction. The median 2 Gy-BED was 66 Gy for definitive RT and 60.2 Gy for combination therapy. The two oblique lateral field technique was used in most (n=24) patients. The RT field encompassed the tumor bed and periauricular lymph nodes. The boosted doses to residual disease or high-risk areas were generally delivered through reduced portals with either photon or electron beams. For node positive patients, the cervical region was also included in

Table 1. Stell and McCormack Staging System for the External Auditory Canal and Middle Ear

T1	Tumor limited to site of origin, with no facial nerve paralysis and no bone destruction on radiography
T2	Tumor extending beyond the site of origin indicated by facial paralysis or radiologic evidence of bone destruction, but no extension beyond the organ of origin
T3	Clinical or radiologic evidence of extension to surrounding structures (dura, base of the skull, parotid gland and temporomandibular joint)
TX	Patient with insufficient data for classification, including patients previously treated elsewhere

the fields but no patient had received elective neck RT. The three-dimensional conformal technique was used since 2004 and subsequently treatment plans were checked with multi-slice dose distribution. Recently, a total of 60～64.8 Gy had been prescribed in patients treated with surgery, and 70 Gy for the control of macroscopically residual disease or for the radical aim.

3. Statistical analysis

Statistical analysis was performed using SPSS ver. 12.0 (SPSS Inc., Chicago, IL USA). The endpoints of the study were local relapse-free survival (LRFS) and cause specific survival (CSS). LRFS was measured from the date of initial treatment to the date of first local failure or death from any cause. When there was any evidence of tumor growth at the primary site based on an imaging work-up, we defined the tumor growth as local relapse of tumor. At three months after planned treatment, it was regarded as 'residual' if residual disease was confirmed with an imaging work-up. CSS was defined from the date of initial treatment to the date of death of disease or treatment-related death. At the time of the last follow-up, data was censored. Survival rates were estimated using the Kaplan-Meier method. The log-rank test was used for univariate analysis and the Cox proportional hazard model

Table 2. Summary of Treatment Outcome

No.	Stage	Age/Sex	ECOG*	Treatment	OP† type	RT‡ dose (Gy)	Chemotherapy	F/U (yr)	Outcome
1	T1N0	43/M	1	OP	PTR‖	−	−	7.7	NED§§
2	T1N0	53/M	0	OP	PTR	−	−	1.2	LR‖‖
3	T1N0	56/F	1	OP	PTR	−	−	14.6	NED
4	T1N0	75/F	0	OP	PTR	−	−	3.6	DOD¶¶
5	T1N0	69/F	1	RT	Biopsy	70	−	1.1	NED
6	T1N0	53/F	1	RT	Biopsy	70	−	8.4	LR
7	T1N0	70/M	1	RT	Biopsy	70	−	1.6	DOD
8	T2N0	66/F	2	CT→RT	Biopsy	70	FP** #1	1.1	LR
9	T2N0	63/M	1	RT	Biopsy	66	−	4.0	NED
10	T2N0	57/F	1	RT	Biopsy	66	−	0.3	NED
11	T2N0	79/F	1	RT	Biopsy	70	−	1.8	NED
12	T3N0	49/M	1	RT	Biopsy	70	−	1.0	NED
13	T3N0	79/M	2	RT	Biopsy	64.8	−	0.4	DID##
14	T3N0	42/F	1	CCRT	Biopsy	60	CDDP†† #2	1.6	NED
15	T3N0	44/M	1	RT→CT	Biopsy	54	DFP‡‡ #4	4.5	LR
16	T3N0	65/M	2	CT→RT	Biopsy	39	FP #3	0.4	DOD
17	T3N0	53/F	2	CT→RT	Biopsy	39.6	FP #1	0.3	DOD
18	T1N0	49/M	1	RT→OP	PTR	44	−	0.6	RR***
19	T1N0	77/M	1	OP→RT	WE¶	70	−	2.8	NED
20	T1N0	46/M	1	OP→RT	PTR	66.6	−	6.9	NED
21	T2N0	46/M	1	OP→RT	PTR	60	−	8.5	NED
22	T2N0	50/M	1	OP→RT	PTR	66	−	6.2	DOD
23	T2N0	55/M	1	OP→RT	PTR	60	−	1.0	NED
24	T2N1	58/M	1	OP→RT	PTR	61.2	−	4.6	NED
25	T2N0	71/F	2	OP→RT	PTR	55.8	−	7.6	RR
26	T2N0	63/M	0	OP→RT	PTR	64.8	−	6.0	RR
27	T2N0	69/F	2	OP→RT	STR#	59.4	−	4.7	LR
28	T3N0	60/M	1	OP→RT	WE	61.2	−	5.9	NED
29	T3N0	49/M	1	OP→RT	STR	64.8	−	1.1	LR
30	T3N0	35/F	2	OP→RT	STR	54	−	0.6	DOD
31	T3N0	46/M	1	OP→RT	STR	61.2	−	1.2	DOD
32	T3N1	55/M	1	OP→RT	STR	66.6	−	5.3	NED
33	T3N0	61/M	2	OP→RT	STR	64.8	−	0.2	DOD
34	T3N0	55/M	1	OP→RT	STR	63	−	4.9	NED
35	T3N0	38/M	2	OP→RT→CT§	STR	60	FP #2	7.6	NED

*Eastern Cooperative Oncology Group performance status, †operation, ‡radiotherapy, §chemotherapy, ‖artial temporal bone resection, ¶wide excision, #subtotal temporal bone resection, **fluorouracil+cisplatin; ††cisplatin, ‡‡Docetaxel+fluorouracil+cisplatin, §§no evidence of disease, ‖‖ocal recurrence, ¶¶dead of disease, ##dead of intercurrent disease, ***regional recurrence

was used for multivariate analysis. In subgroup analysis for RT versus RT with surgery, student T-test and Fisher's exact test were performed to the mean values and incidences between the two groups. Differences were considered statistically significant for $p < 0.05$.

Results

1. Survival and failure pattern

The CSS rate at 3-years after treatment was 80%. Seven patients died of cancer and one patient died of treatment related complication. Twenty-three patients (66%) remained without evidence of disease recurrence at the time of the last follow-up. The LRFS rate at 3-years was 63%. Seven patients (20%) developed local disease relapse and neck recurrences developed in four patients (11%). Four patients underwent neck dissection at the time of initial surgery and none of the patients experienced regional recurrence. Distant metastases developed in one patient located at mediastinal and supraclavicular lymph nodes. Patient characteristics and treatment outcomes are summarized in Table 2. Two patients (patient number 16 and 17) died after chemotherapy followed by RT less than 40 Gy. Their diseases had progressed during treatment and the aim of RT was palliative.

2. Prognostic factor

Based on univariate analysis, ECOG performance status and response after treatment were predictive for CSS (Table 3). Patients with good performance status had better CSS compared with those with poor performance (3 year rate, 90% vs. 53%, p=0.032); patients with complete response had better 3 year CSS rate (94% vs. 58%, p=0.027). With respect to LRFS, ECOG performance status and histologic differentiation were predictive for LRFS based on log-rank analysis. Patients with good performance status (72% vs. 22%, p=0.004) and well differentiated tumors had better 3 year LRFS (72% vs. 46%, p=0.014).

3. Toxicity

Treatment related complications are summarized in Table 4.

Table 3. Univariate and Multivariate Analysis of Various Potential Prognostic Factors for Cause Specific Survival and Local Relapse-Free Survival in Patients with Squamous Cell Carcinoma of the External Auditory Canal and Middle Ear

Variable	No. of patients	Cause specific survival		Local relapse-free survival	
		3-yr rate (%)	p-value*	3-yr rate (%)	p-value*
Sex			0.807		0.608
Male	23	79		62	
Female	12	66		64	
Age (yr)			0.287		0.183
≤60	22	84		69	
>60	13	74		54	
ECOG†			0.032		0.004
0, 1	26	90		78	
2	9	53		22	
Location			0.649		0.362
EAC‡	27	83		69	
ME§	8	70		35	
Stell/McCormack stage			0.056		0.053
T1, T2	21	93		78	
T3	14	61		41	
Type of operation			0.559		0.059
Radical resection	22	85		71	
Biopsy alone	13	70		50	
Differentiation			0.099		0.014
Well differentiated	22	88		72	
Others or unknown	13	67		46	
Treatment response			0.027		–
No residual disease	21	94		–	
Others	14	58		–	

*p-value for univariate analysis, †Eastern Cooperative Oncology Group performance status, ‡external auditory canal, §middle ear

Severe complications related to RT such as osteonecrosis, cataracts and brain injury were not observed. However, nausea or vomiting was observed in six patients and we could found that some extent of brain tissue was irradiated in a review of the RT field of the patients. Most of patients suffered mild to moderated treatment related toxicities except one who had developed grade 3 vomiting during RT.

4. Subgroup analysis (RT alone ver. surgery and RT)

To investigate the role of RT, we analyzed patients treated with RT alone or surgery with RT; four patients treated with partial temporal bone resection without adjuvant treatment were excluded in the analysis. As shown in Table 5, the distribution of variables predicting local control and survival including age, performance, tumor differentiation, RT dose and RT plan was not different between patients treated either with RT alone or with surgery and RT. More residual disease after planned treatment was observed in patients treated with RT alone than in patients treated with RT and surgery. However, no significant difference was observed in the CSS curves (Fig. 1A) although more local failure for patients treated with RT alone was seen as an early drop in the LRFS curve (Fig. 1B). We performed further analysis for patients with T2 or T3 disease as T1 tumor is considered resectable and not in need

Table 4. Radiothearpy Related Toxicity (N=35)

	No. of patients
Nausea/vomiting	6
Anorexia	4
Peripheral neuropathy	1
Dysphagia	1

Table 5. Distribution of Variables in Patients Treated with Surgery and RT and Patient Treated with RT Alone

	Treatment group		p-value‡
	S*+RT† (N=18)	RT (N=13)	
	Mean value		
Age (yr)	54.5	60.6	0.154
2 Gy-BED§ (Gy)	60.6	62.3	0.618
	Total no. of patients		
Stell/McCormack stage			0.925
T1, T2	10	7	
T3	8	6	
ECOG			1.000
0, 1	13	9	
2	5	4	
Differentiation			0.141
Well differentiated	5	7	
Others	13	6	
RT plan			1.000
3D	12	9	
Conventional	6	4	
Treatment response			0.022
Residual disease	5	9	
Others	13	4	

*surgery, †radiotherapy, ‡p-value for comparison of means (student's t-test) and categorical variables (Pearson chi-squared or Fisher's exact test), §2 Gy/fraction biologically effective dose

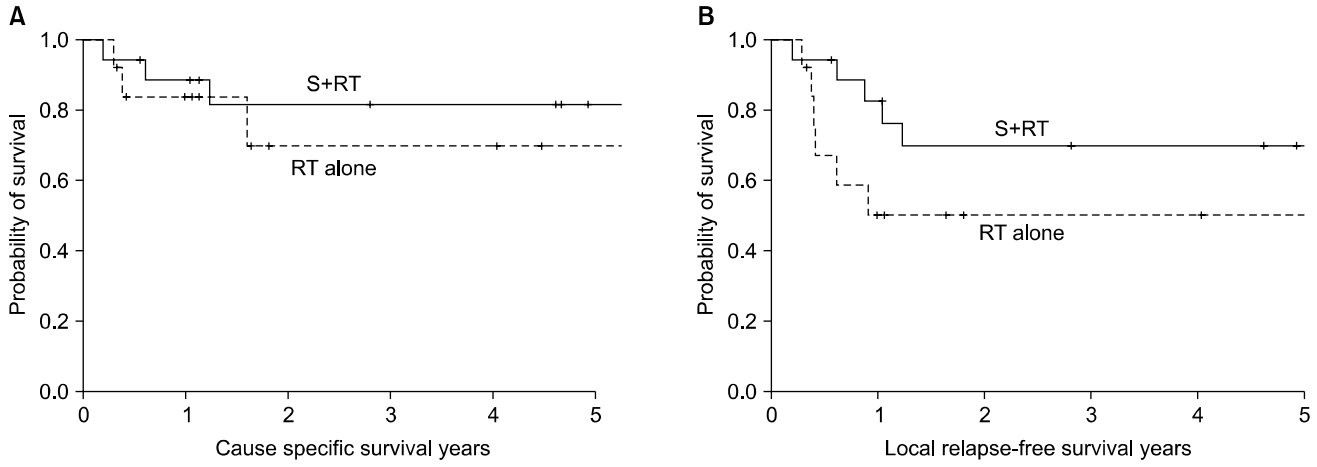

Fig. 1. Survival outcomes for patients treated with surgery (S) and radiotherapy (RT) (n=18) ver. patients treated only RT alone (n=13) are shown. The solid line represents patients treated with surgery and RT and the dotted line represents patients treated with RT alone (A: cause specific survival, p=0.641; B: local relapse-free survival, p=0.085).

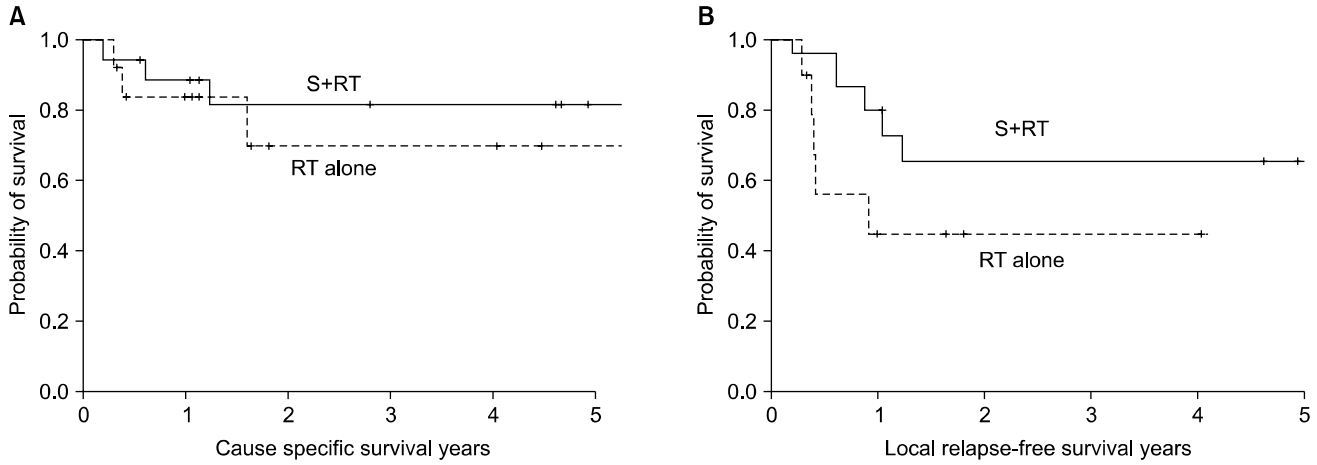

Fig. 2. Survival outcomes in patients with Stell and McCormack stage T2 or T3 disease are presented. The solid line represents patients treated with surgery (S) and radiotherapy (RT) (n=15) and the dotted line represents patients treated with RT alone (n=10) (A: cause specific survival, p=0.811; B: local relapse-free survival, p=0.188).

of adjuvant treatment if radically resected. As shown in Fig. 2A and 2B, survival curves of T2/T3 disease were similar to those of the entire patients.

Discussion and Conclusion

The findings in this report have confirmed the efficacy of definitive or adjuvant RT for the durable local control and survival outcomes for patients with SCC of the EAC and ME. Although a direct comparison could not be made due to variable staging systems used in each study, the reported 5-year overall survival was 80% to 100% for early disease and 30% to 50% for advanced disease.[1,6,13] In our study, 5-year CSS and LRFS for patients with Stell and McCormack[12] stage T1-T2 disease were 86% and 71%, and 5-year CSS and LRFS for patients with T3 disease were 61% and 41%.

Previous reports have identified tumor size, extension to the temporal bone, seventh nerve palsy, tumor type and bone involvement as negative prognostic factors.[14~17] Our findings identified that good performance status and no residual disease after planned treatment were predictive for better CSS, and good performance status and well differentiated grade was associated with a better LRFS. It is noteworthy that tumor differentiation affects LRFS with a statistical significance as other series.[15,17]

There are several staging systems,[12,13,18,19] but no standardized system has been established to evaluate patients with cancer of the EAC and ME. We used the staging system proposed by Stell and McCormick,[12] which stressed radiological and clinical evidence of invasiveness and was advantageous for the present retrospective design. Based on this system, 10 patients (29%) were classified as having stage T1 disease and this rate is higher than reported in other series.[6] Frequent use of MR imaging and improved imaging technologies may probably explain the high portion of T1 patients and consequent favorable outcome.

As there are differing views about the most appropriate staging system to utilize for this unusual disease, there are many opinions about disease management. This controversy arises, as almost no institution will treat more than a few patients a year. In general, surgical resection for early disease is used in many institutions and surgical treatment could provide 100% tumor control as demonstrated in one study.[20] In addition, the use of brachytherapy with a high dose rate of 6×6 Gy with weekly interruptions or with a low dose rate of 5×10 Gy could be used for EAC disease.[21] In advanced disease, EAC and ME specimens are difficult to orient and adequate surgical margins are difficult to achieve. The use of postoperative RT seems justified to keep the risk of local recurrence to a minimum and postoperative RT is considered as an essential part of standard treatment, although some investigators[1,16] have insisted that incomplete resection is the independent cause of recurrence even with the use of adjuvant

RT. In our study, only four of 22 patients were treated with radical resection and the patients did not receive RT. Of the remaining 18 patients, an oncologically safe resection margin could not be obtained and all of the patients received RT.

Disease failure in the neck was uncommon in our study and only occurred in four patients (11%). None of these patients had undergone neck dissection or elective neck irradiation. This failure rate is acceptable given that previous studies have reported similar failure rates.[22] In our series, neck failure occurred in two patients with T1 stage disease and occurred in two patients with T2 stage disease. Three (75%) of these patients had well-differentiated tumors and one patient (25%) had ME disease. These results suggest that the chance of occult disease spread to the regional lymphatics is low even in an advanced stage and elective treatment may not affect prognosis of disease. This process seems more relevant considering that a part of the lymphatic area including the periauricular lymph nodes is involved in the RT field involuntarily and the lymphatics in the ME area are sparse.

We couldn't find an early drop in CSS in patients treated only with RT. But patients treated with radical RT had shorter follow-up duration than patients treated with surgery and RT, thus direct comparison may be impossible between two groups, and more importantly patient selection bias may be exists. In contrast with CSS, local control of RT alone group demonstrated inferior than two modality group. This result suggests that there is room for improvement of treatment in terms of local control, especially for more advanced disease. Patients with advanced disease, particularly patients with large and unresectable tumors, may require treatment that is more aggressive including higher doses of RT; such treatments can be achieved with recent advances in RT techniques. These advances might include intensity modulated ratiation therapy (IMRT) and the use of stereotactic RT where tumoricidal doses can be administered without a serious threat of normal tissue injury.

Approximately two-thirds of patients with SCC of the EAC or ME appear to be cured with aggressive treatment and the appropriate use of RT. Although the number of patients was insufficient to reach definite conclusion, the CSS of patients treated with RT alone was not inferior to the survival of patients with combination therapy. As the risk of early local relapse was high after radical RT, further optimization of RT is needed to improve local control.

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국문초록

외이도 및 중이 편평상피암의 방사선치료

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목 적: 본 연구에서는 외이도 및 중이에 생긴 편평상피암의 치료에 있어서 방사선치료의 역할에 대해 알아보고자 한다.

대상 및 방법: 1981년부터 2007년까지 외이도 및 중이에 생긴 편평상피암으로 치료 받은 총 35명의 기록을 후향적으로 분석하였다. 13명은 방사선치료 단독, 4명은 수술 단독, 18명은 수술 방사선 병용 요법으로 치료하였다. 방사선치료 단독군에서 조사된 중앙 방사선량은 66 Gy (범위, 39～70 Gy)이었고, 수술 방사선 병용 치료군에서는 61.2 Gy (범위, 44～70 Gy)를 조사하였다. 치료 방법에 따른 질병특이생존율 및 무국소진행생존율을 비교하였으며 추적관찰기간은 0.2～14.6년(중앙값 2.8년)이었다.

결 과: 3년 질병특이생존율 및 무국소진행생존율은 각각 80%, 63%이었다. 질병특이생존율에 관한 단변량 분석에서 전신수행상태 및 잔여 종양의 유무가 통계적인 유의성을 보여주었고, 무국소진행생존율에는 전신수행상태 및 조직학적 등급이 유의하였다. 치료 후 잔여 종양은 방사선 단독 치료군(69%)에서 수술 방사선 병용 치료군(28%)에 비해 많이 관찰 되었다. 비록 양군간에 질병특이생존율은 통계학적인 차이를 보이지 않았지만 방사선 단독 치료군에서 병용 치료군에 비해 조기 국소 재발의 빈도가 높았다.

결 론: 외이도 및 중이의 편평상피암 환자에서 방사선 단독 치료는 질병특이생존율에 있어서 수술 방사선 병용 치료와 유사한 결과를 보여주었다. 그러나 낮은 국소 제어율을 높이기 위한 치료 방법의 향상이 있어야 할 것으로 생각된다.

핵심용어: 외이도, 중이, 편평상피암, 방사선치료