



Original Article

The Clinical Characteristics and Surgical Outcomes of Carcinoma of the External Auditory Canal: A Multicenter Study

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OBJECTIVE: To analyze the clinical characteristics and evaluate the surgical outcomes of carcinoma of the external auditory canal (CEAC).

MATERIALS and METHODS: Overall, 31 patients from four multicenter hospitals, who were diagnosed and surgically treated for CEAC in 2009–2014, were enrolled for this retrospective study. Medical records were reviewed to determine cancer stage according to the Pittsburgh classification. Clinical data of age, sex, site, initial symptoms, surgery extent, postoperative complications including recurrence, follow-up period, and current patient status were collected for analysis. Five-year cumulative survival rate was obtained using Kaplan–Meier method.

RESULTS: At initial diagnosis, 22 patients were in the early stages (stage I: 15; stage II: 7) and 9 patients were in the advanced stages (stage III: 1; stage IV: 8). Lymph node metastasis was present in 5 patients and distant metastasis in 2. Of the 31 patients, 4 patients died (stage II: 1, stage IV: 3) during the follow-up period. Early-stage patients showed 100% 5-year estimated cumulative survival rate, whereas the advanced-stage patients showed 5-year estimated survival rate of 53.6% ($p=.006$). The overall survival rate of all enrolled patients was 90.3%. Although 5-year estimated disease-free survival rate of stage I was 100.0%, that for stage II was low at 30.0% because of considerable recurrences.

CONCLUSION: The results of this multicenter study suggest that more aggressive treatment modality, including adjuvant therapy, is necessary for patients with CEAC with Pittsburgh stage II or more.

KEYWORDS: Ear canal, carcinoma, survival rate, multicenter

INTRODUCTION

Cancers of the external auditory canal (EAC) are rare, with an estimated incidence of less than 0.2% of all head and neck cancers^[1]. Representative symptoms are otorrhea, otalgia, hearing impairment, and external visible mass. It is frequently misdiagnosed owing to its similar clinical features to benign conditions, such as granulation tissue formation in the EAC, EAC cholesteatoma, and chronic otitis externa. The most common histological type of EAC malignancy is squamous cell carcinoma, followed by adenoid cystic carcinoma, basal cell carcinoma, malignant melanoma, Merkel cell carcinoma, angiosarcoma, adnexal carcinoma, ceruminous adenocarcinoma, and lymphoma^[1-3].

Since 1970s, the survival rates of carcinoma of the EAC (CEAC) have improved owing to the development of microsurgery and advanced diagnostic imaging systems, such as computed tomography (CT) and magnetic resonance imaging (MRI). Various previ-

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ous studies have reported the survival rates of CEAC to be from 15% (advanced stage) to 100% (early stage), depending on the extent of the disease [1, 2, 4-6]. The prognosis seems to be influenced by the histological type of cancer, local or distant recurrence, and lymph node invasion [4, 7, 8].

To date, there is no consensus on the guideline for the treatment of EAC malignant tumors, and the optimal management of patients is still a debatable topic. In the present study, the authors collected data of patients with CEAC from four tertiary hospitals and analyzed the surgical outcomes related to the stage, adjuvant therapy, and simultaneous surgeries to suggest treatment options for patients with CEAC.

MATERIALS AND METHODS

Study Population

Data of 33 patients who were diagnosed with and surgically treated for CEAC in 2009–2016 were collected from four tertiary multicenter hospitals for retrospective analysis. Data closing date of the study was December 31, 2017. Medical records and radiological findings from CT and/or MRI were reviewed to determine cancer stage according to the Pittsburgh classification (Figure 1, Table 1). Of the 33 patients, 2 were excluded because of premature follow-up loss, i.e., follow-up of less than 1 month; therefore, 31 patients were enrolled in this study. All patients underwent surgical treatments, such as lo-

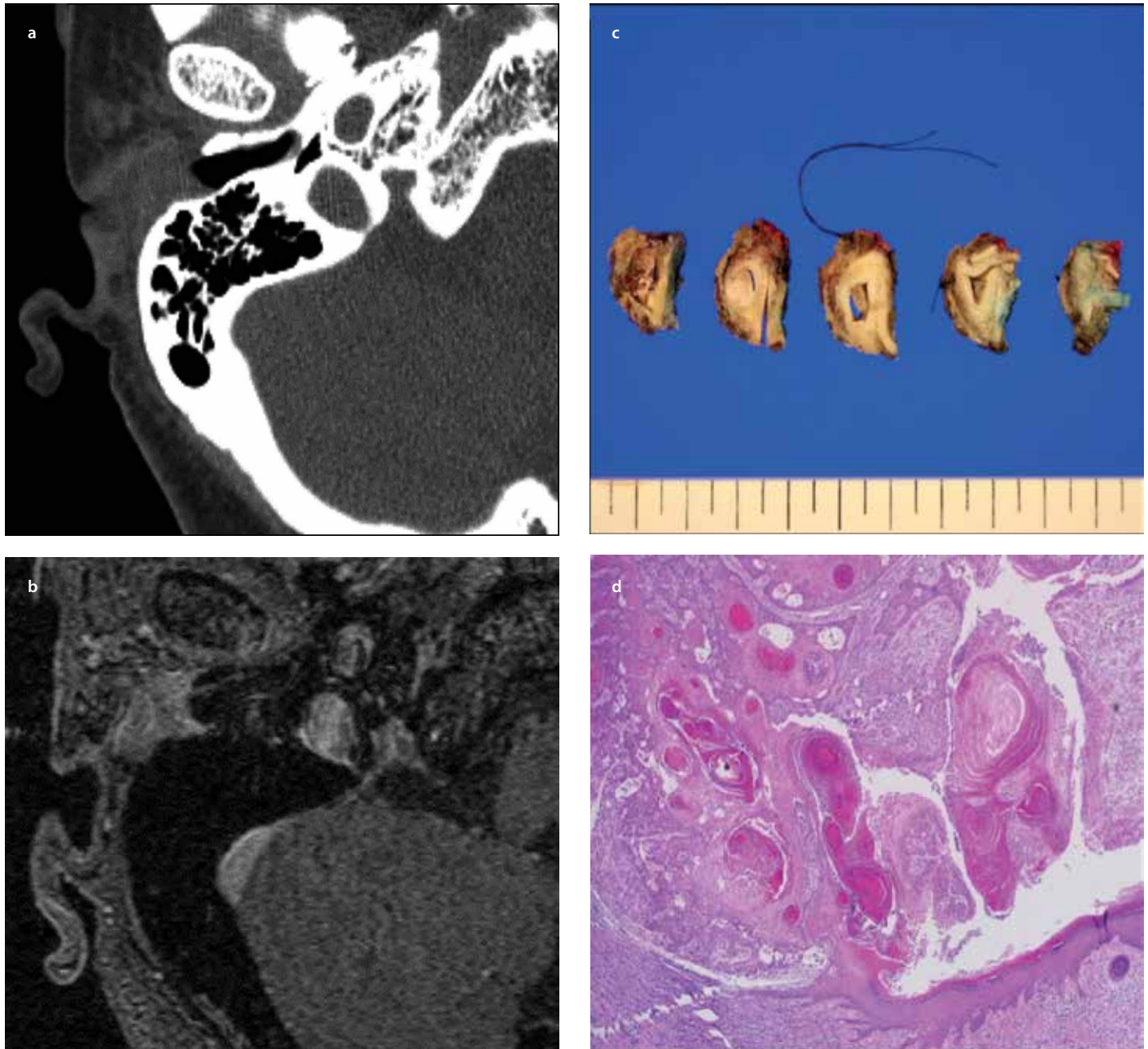


Figure 1. a-d. Representative case of cancer of the external auditory canal. (a) Axial non-enhanced CT scan. Soft tissue obliterates in right external auditory canal. (b) Axial T1-weighted MRI image. The main tumor shows a heterogeneous intermediate signal intensity. (c) Specimen (size, 1.8×1.5 cm). (d) Histological section (H&E). Histological section of the specimen shows a well-differentiated squamous cell carcinoma characterized by hyperchromatic nuclei and keratin pearl formation.

Table 1. Pittsburgh staging system for carcinoma of the external auditory canal**T status**

T1 Tumor limited to the external auditory canal without bony erosion or evidence of soft tissue involvement

T2 Tumor with limited external auditory canal bony erosion (not full thickness) or limited (<0.5 cm) soft tissue involvement

T3 Tumor eroding the osseous external auditory canal (full thickness) with limited (<0.5 cm) soft tissue involvement or tumor involving middle ear and/or mastoid

T4 Tumor eroding the cochlea, petrous apex, medial wall of middle ear, carotid canal, jugular foramen or dura, with extensive (≥0.5 cm) soft tissue involvement, such as involvement of temporomandibular joint or styloid process, or evidence of facial paresis

N status

Lymph node involvement is a poor prognostic sign; any node involvement should automatically be considered as advanced stage (i.e., T1N1=stage III and T2, 3, 4 N1=stage IV)

M status

Distant metastases indicate a very poor prognosis and should be considered as stage IV

In the absence of metastatic lymph nodes or distant metastases, T status of the tumor defines the clinical stage

Table 2. Initial symptoms of patients with cancer of the external auditory canal

Initial symptoms	Number of patients (percentage)
Otalgia	15 (48.4%)
Otorrhea	13 (41.9%)
Ear fullness	5 (16.1%)
Visible mass	5 (16.1%)
Hearing impairment	2 (6.5%)
Facial palsy	2 (6.5%)

cal resection, temporal bone resection, and subtotal petrosectomy. Local resection, indicated to patients with early CEAC, is defined as the complete removal of primary malignant tumor. Tumor-free surgical margin was defined as a pathologically free field of at least 0.5-cm margin of the primary tumor. In advanced-stage patients, surgeons retained free surgical margins by removing adjacent invaded soft tissues in en-bloc or drilling out invaded osseous structures until fresh bony surface was reached. Selective or modified radical neck dissection and/or superficial parotidectomy were definitely indicated when a clinically positive node or a direct invasion to the parotid was found during the preoperative evaluation; otherwise, it depended on the surgeon's discretion to conduct a simultaneous surgical procedure. Some patients received adjuvant treatment of radiation therapy (RT) or chemoradiation therapy (CRT) if the additional treatment was proposed by the multidisciplinary consultation group of the relevant hospital. Although specific RT processes varied in each hospital, the overall treatment protocols were similar; radiation was administered once a day at 1.8–2.25 Gy per fraction to the primary tumor bed, up to 60 Gy in total, as needed. When concurrent chemotherapy was advised, a combination therapy of paclitaxel and cisplatin was administered to the selected patients. Clinical data of age, sex, site, initial symptoms, surgery extent, postoperative complications including recurrence, follow-up period, and current patient status were collected for analysis.

Statistical Analysis

Data were analyzed using Statistical Packages for the Social Sciences (SPSS) software version 22.0 (IBM Corp., Armonk, NY, USA). Survival

rate among two groups (early stages vs advanced stages) were compared using Kaplan–Meier method. A two-tailed $p < 0.05$ was considered statistically significant.

Ethics Considerations

The study protocol and procedures were reviewed and approved by the Institutional Review Board of our institution (IRB No. XC16RIMI0043), which did not request informed consent for this retrospective study.

RESULTS

The mean age of the enrolled patients was 67 years (range, 44–84 years), with gender distribution of 13 males (41.9%) and 18 females (58.1%). The right-sided tumors were 16 cases (51.6%) and the left sided tumors were 15 cases (48.4%). The most common representative symptom was otorrhea ($n=16$), defined as any discharge from EAC, followed by ear fullness ($n=11$), hearing impairment ($n=5$), and visible mass ($n=3$) (Table 2). According to the Pittsburgh TNM stage, at initial diagnosis, 22 patients were in the early stages (stage I: 15; stage II: 7) and 9 were in the advanced stages (stage III: 1; stage IV: 8). The most common histological type was squamous cell carcinoma ($n=20$). The detailed demographic data of study subjects are shown in Table 3.

All patients received surgical treatments: local resection ($n=15$; 48.4%), temporal bone resection ($n=13$; 41.9%), and subtotal petrosectomy ($n=3$; 9.7%). Pathological evaluations of the resected tissues showed negative surgical margins in all patients, and 1 patient (Case No. 30) with the closest tumor margin of 2 mm underwent a secondary resection. Simultaneous parotidectomy was performed in all patients except for patients with local resection ($n=15$) and subtotal petrosectomy ($n=1$). Simultaneous neck dissection was performed in 11 patients. One patient (Case No. 22), who was clinically N0 before the surgery, showed a level II metastatic lymph node during the postoperative pathological evaluation and was transferred to the oncology department for adjuvant RT. Two patients showing pathologically direct invasion to the parotid glands were also clinically diagnosed before the surgery. No patient showed an occult metastasis in the intraparotid lymph node. An analysis of simultaneous surgical resection of simultaneous neck dissection showed a trend toward a better

Table 3. Baseline characteristics of 31 patients operated for cancer of the external auditory canal

No.	Age	Sex	Side	Stage	Pittsburgh TNM	Histopathology	Surgical Type	Adjuvant therapy	Recurrence	F/U (mo)	Patient status
1	59	M	L	II	T2N0M0	SCC	LTBR,P, SND	-	-	41	A
2	77	F	R	I	T1N0M0	SCC	LTBR, P	RT	-	5	A
3	78	M	L	II	T2N0M0	VC	LCR	-	-	4	A
4	78	M	R	I	T1N0M0	SCC	LCR	-	-	7	A
5	61	F	L	I	T1N0M0	BCC	LCR	-	-	80	A
6	82	F	R	I	T1N0M0	SCC	LCR	-	-	12	A
7	59	F	L	I	T1N0M0	SCC	LCR	-	-	64	A
8	78	F	L	I	T1N0M0	BCC	LCR	-	-	4	A
9	69	F	R	I	T1N0M0	SCC	LCR	-	-	74	A
10	78	M	R	I	T1N0M0	SCC	LCR	-	-	16	A
11	57	M	L	IV	T3N1M0	SCC	LTBR, P, SND	RT	Local/reOP	14	A
12	56	M	L	IV	T4N0M0	SCC	STBR, P, MRND	CRT	-	6	A
13	72	M	R	IV	T4N0M0	SCC	STBR, P, SND	RT	-	17	A
14	57	F	R	III	T3N0M0	SCC	LTBR, P, SND	RT	-	79	A
15	48	F	L	II	T2N0M0	SCC	LTBR, P	-	-	51	A
16	67	M	R	I	T1N0M0	SCC	LTBR, P	-	-	19	A
17	77	F	R	I	T1N0M0	SCC	LTBR, P	RT	-	8	A
18	70	M	L	II	T2N0M0	SCC	SP	RT	Local/reOP	30	A
19	68	F	L	IV	T3N2M1	AC	SP, P, MRND	CRT	-	13	D
20	47	F	R	IV	T3N1M0	SCC	SP, P, SND	RT	Distant	8	D
21	62	F	L	II	T2N0M0	ACC	LTBR, P, SND	RT	Distant	81	D
22	44	F	L	IV	T2N1M0	SCC	LTBR, P, SND	RT	-	95	A
23	67	F	R	IV	T1N0M1	BCC	STBR, P, SND	CRT	-	41	A
24	84	F	R	I	T1N0M0	BCC	LCR	-	-	5	A
25	73	F	R	I	T1N0M0	BCC	LCR	-	-	8	A
26	61	M	L	I	T1N0M0	BCC	LCR	-	-	22	A
27	51	M	R	I	T1N0M0	BCC	LCR	-	-	9	A
28	67	M	R	IV	T2N1M0	SCC	LTBR, P,SND	RT	-	16	D
29	83	F	R	II	T2N0M0	SCC	LCR	-	-	8	A
30	72	M	L	II	T2N0M0	SCC	LCR	RT	Distant	47	A
31	70	F	L	I	T1N0M0	BCC	LCR	-	-	8	A

SCC: squamous cell carcinoma; BCC: basal cell carcinoma; ACC: adenoid cystic carcinoma; VC: verrucous carcinoma; AC: adenocarcinoma; LCR: local canal resection; LTBR: lateral temporal bone resection; STBR: subtotal temporal bone resection; SP: subtotal petrosectomy; P: parotidectomy; SND: selective neck dissection; MRND: modified radical neck dissection; RT: radiation therapy; CRT: chemoradiation therapy; A: alive; D: died.

Table 4. Postoperative complication rate of patients with cancer of the external auditory canal

Complication type	Number of patients (percentage)
Facial palsy	4 (12.9%)
Surgical wound dehiscence	3 (9.7%)
Wound infection	2 (6.5%)
Dizziness	1 (3.2%)
Total	10 (32.3%)

survival rate ($p=.053$, Log Rank). However, simultaneous parotidectomy did not seem to influence the survival ($p=.127$, Log Rank).

Postoperative complications including facial palsy ($n=4$), surgical wound dehiscence ($n=3$), wound infection ($n=2$), and dizziness ($n=1$) appeared in 10 of 31 patients (32.3%) (Table 4). All patients with postoperative facial palsy developed their symptom of facial weakness after the surgical treatment that included parotidectomy. Of these 4 patients, 3 patients showed House-Brackmann (H-B) grade II facial

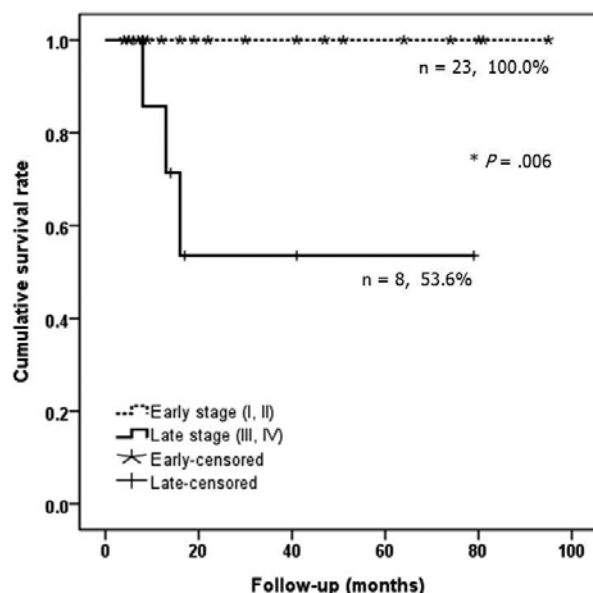


Figure 2. The overall survival rate estimated with the Kaplan–Meier method. The 5-year survival rate of early stage was 100.0% and that for advanced stage was 53.6%. This difference between the two groups was statistically significant ($p=.006$).

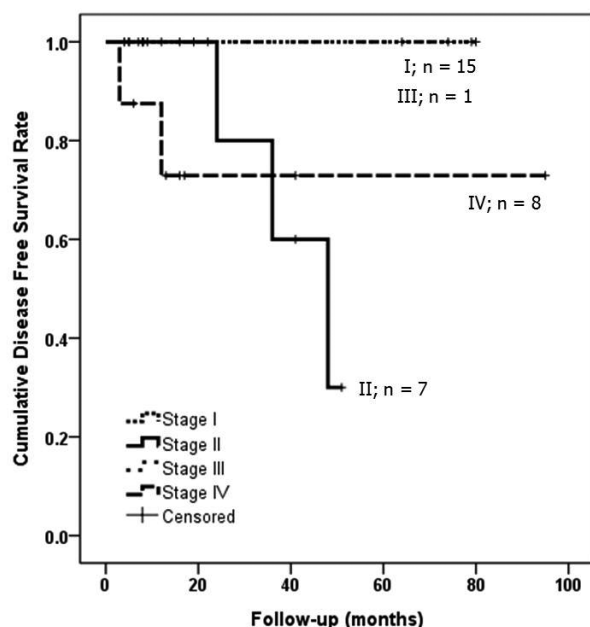


Figure 3. The disease-free survival rate comparing each CEAC stage. The 5-year disease-free survival rate of each stage was as follows: stage I, 100.0%; stage II, 30.0%; stage III, 100.0%; and stage IV, 72.9%. There was no statistically significant difference between the stages (I vs. II, $p=.098$; I vs. IV, $p=.084$; II vs. III, $p=.332$; II vs. IV, $p=.977$; and III vs. IV, $p=.589$).

palsy that eventually improved over the months. One patient with H-B grade V facial palsy underwent facial nerve decompression after 1 month of initial surgery, but the outcome was not successful.

Median follow-up period of enrolled patients was 16 months (range, 4–95 months). After the initial surgical treatment, 5 patients (16.1%) showed recurrence; of them, 2 patients with local recurrence were re-operated and 3 patients with distant recurrence were transferred

to the oncology department for further management. Finally, 2 recurrent patients died during the study period. During the follow-up period, 1 stage-II patient and 3 stage IV patients died even after undergoing adjuvant therapy after the surgery. Although early-stage patients showed 100% 5-year cumulative survival rate, the advanced-stage patients showed 5-year survival rate of 53.6%, which is a statistically significant difference ($p=.006$) (Figure 2). The overall survival rate of all enrolled patients was 90.3%. The 5-year disease-free survival rate of each stage was 100.0% for both stages I and III, 30.0% for stage II, and 72.9% for stage IV (Figure 3). Low disease-free survival rate of stage-II patients attributes to 1 local recurrence and 2 distant recurrences of a total of 7 patients.

DISCUSSION

The prevalence of CEAC is estimated to occur in 1-6 people per 1 million population, with a mean age of 61.5 years. Sex ratio is reported to be equal [1-3, 9, 10]. Due to its non-specific clinical symptoms, such as otorrhea, otalgia, and hearing loss, it is often difficult to be detected at early stage. According to a previous report, the misdiagnosed rate of CEAC is up to 69% [2]. Therefore, thorough physical examination, including tympanic endoscopy and full diagnostic imaging, is essential for the early diagnosis of CEAC. CT scans are one of the most reliable methods for the identification of CEAC because it is convenient to find bony erosions of the EAC and determine the extent of the disease. According to Leonetti et al., [11] comprehensive assessment of CT scans strongly correlate with the actual operative findings. However, CT scans cannot accurately detect soft tissue invasion or mucosal thickening without bony erosion and therefore must be supplemented with MRI. Preoperative MRI is particularly important in an advanced CEAC stage because neurovascular invasion and spread into cranial fossae are better detected in a fat-signal suppressed enhanced T1-weighted MRI images than in CT [12]. In addition to CT and MRI scans, positron emission tomography scans may also be considered for detecting invasions to nearby anatomic structures, such as the parotid gland, as well as metastasis to distant organs. As for the staging of CEAC, the University of Pittsburgh Staging System modified by Moody et al. [13] has been demonstrated to be reliable and reproducible in the international literatures since the beginning of the 1990s. Squamous cell carcinoma is the most commonly observed tumor of the EAC and accounts for 80% of the tumors of the temporal bone [10-17]. The survival rate for this type of cancer is poorer than that for adenoid cystic carcinoma and basal cell carcinoma. The result of the present study corresponds well with that of previous studies; squamous cell carcinoma was observed the most (64.5%), followed by basal cell carcinoma (25.8%).

The current problem of CEAC is that there is no consensus on treatment guideline and the optimal management still remains a topic of debate. To our knowledge, no randomized controlled study has been published regarding CEAC owing to its rarity [1]. Consequently, centers that provided data for this study all had different treatment guidelines for CEAC, resulting in different surgical modality and various doses of adjuvant therapy even for the same stage CEAC. In the literature, 5-year overall survival is reported to be 80%–100% for early-stage CEAC and 7%–85% for advanced-stage CEAC [1-5, 8, 18-20]. Because of the relatively low overall survival rate, the standard treatment for CEAC has been lateral temporal bone resection with or without adjuvant RT for the early stage and subtotal temporal bone resection with adju-

vant RT for the advanced stage. Although earlier studies have asserted a necessity for an extensive surgical procedure for CEAC even at an early stage [2, 8, 21], CEAC is no exception to the recent trend of choosing a less aggressive treatment modality for malignant tumors in the head and neck area. Latest studies on CEAC demonstrated that only RT without surgical treatment shows good prognostic results in early-stage patients [22, 23]. Although earlier studies indicated better 5-year survival rate of patients with CEAC who underwent surgical treatment with adjuvant RT compared to those who underwent either surgery or RT, a recent meta-analysis suggested that there is no significant difference in survival between patients who underwent surgery alone and those who underwent adjuvant RT [14, 24]. Therefore, the role of adjuvant RT in survival benefit remains unclear, and to what extent and level of intensity should RT be used is a question that needs to be answered [1, 2, 4, 7-10, 18, 22, 23, 25]. In this study, stage I patients showed 100% survival rate and 0% recurrence rate regardless of surgical type and adjuvant RT. On the other hand, 3 of 7 stage II patients (42.8%) showed recurrence after the initial surgery. Surgical modalities varied in stage-II patients: 3 patients underwent local resection, 3 patients underwent lateral temporal bone resection, and 1 patient underwent subtotal petrosectomy. Surprisingly, all recurred stage-II patients were treated by different surgical methods, and all received adjuvant RT. No correlation was found between other clinical characteristics and recurrence pattern among stage-II patients. Furthermore, even though all advanced-stage patients received adjuvant therapy of either RT or CRT, survival rate was much poorer than that for early stage (53.6% Vs. 100%). From these results, it can be concluded that the good prognosis of stage I CEAC may propose for less aggressive treatment modality and that local canal resection without adjuvant therapy may be enough for the complete eradication of disease. However, more aggressive surgical management with intensive adjuvant RT should be considered for CEAC of stage II or more to avoid recurrence and subsequently lower the mortality rate.

Another complex factor for choosing the optimal extent of surgery for CEAC is whether or not to include parotidectomy and neck dissection in addition to the resection of main tumor. Because lymph node involvement is a known indicator of poor prognosis, it is generally accepted that neck dissection is needed for clinically node-positive cases [4]. Prophylactic neck dissection may be advisable even for node-negative cases because there is a report that the rate of micro-metastasis in clinically negative necks is up to 17% in CEAC [17]. In terms of conducting simultaneous parotidectomy for CEAC, various studies asserted the need for parotidectomy, as the malignant tumor of temporal bone may not only invade parotid directly, but also involve intraparotid lymph nodes via the fissures of Santorini and glenoid fossa of the temporomandibular joint [11, 26]. Similarly, a study that analyzed medical records of 72 patients with temporal bone cancer found that 36% had direct tumor invasion into the parotid and 25% had secondary invasion through metastatic intraparotid lymph nodes [7]. In our study, 15 of 31 patients (48.3%) received simultaneous parotidectomy. An indication of prophylactic parotidectomy in carcinoma of the EAC is not yet established, 5 of 22 early-stage patients (22.7%) underwent simultaneous prophylactic parotidectomy at the surgeon's discretion. However, only 2 patients showed pathologically confirmed direct invasion to the parotid, and no intra-parotid lymph node metastasis was found. As for 7 clinically N0 patients who had prophylactic simultaneous neck dissection, only 1

patient showed micro-metastasis of 1 level II lymph node postoperatively. Overall, simultaneous neck dissection showed a trend toward a better survival rate ($p=.053$), but parotidectomy did not seem to influence the survival ($p=.127$). Of 3 recurred stage-II patients, 2 patients did not receive neck dissection or parotidectomy. Although this study cannot measure the benefits and risks of routine neck dissection and/or parotidectomy as a limitation of retrospective assessment, this result suggests that CEAC of stage II or more requires such prophylactic surgical treatments.

There are some limitations in the present study. First, this retrospective study can only delineate outcomes of already-treated patients and cannot fully assess the suitability of treatment modality that was decided by initial Pittsburgh stage. In addition, each center that provided data for this study had different treatment guidelines that were largely dependent on the surgeons treating the patients with CEAC. On the other hand, this study has concluded that stage I tumors behave differently from stage II tumors, regardless of various treatments; therefore, the fact that patients were treated in different ways rather strengthened this final statement. A standard treatment modality should be set up first in a future prospective study to confirm the validity of this study. Second, due to the rarity of disease, this study did not differentiate patients by their histologic types. The clinical characteristics and responses to the treatment may vary depending on histopathological types of the carcinoma. Nonetheless, it is clear that this study explicitly showed different prognosis for early-stage and advanced-stage CEAC, regardless of its specific histologic types. Third, although this study suggests that stage I CEAC shows different clinical features and should be treated differently compared with stage-II CEAC, the sample size of stage-II CEAC is small and incongruent to compare. To overcome these limitations, a case-control study with large sample is essential.

CONCLUSION

This study evaluated the treatment results of multicenter case series of CEAC. The results of this study suggests that more aggressive treatment modality, including adjuvant therapy, is necessary for patients with CEAC with Pittsburgh stage II or more. On the other hand, CEAC of stage I may warrant a good prognosis and less invasive treatment modality could be considered.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Catholic Medical Center (IRB No. XC16RIMI0043).

Informed Consent: Informed consent is not necessary due to the retrospective nature of this study.

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