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New proposal to revise the classification for squamous cell carcinoma of the external auditory canal and middle ear

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Abstract

Background. The prognosis of patients with advanced squamous cell carcinoma of the external auditory canal and middle ear has been improved by advances in skull base surgery and multidrug chemoradiotherapy during the last two decades.

Methods. Ninety-five patients with squamous cell carcinoma of the external auditory canal and middle ear who were treated between 1998 and 2017 were enrolled. The number of patients with tumour stages T_1, T_2, T_3 and T_4 was 15, 22, 24 and 34, respectively. Oncological outcomes and prognostic factors were retrospectively investigated.

Results. Among patients with T_4 disease, invasion of the brain ($p = 0.024$), carotid artery ($p = 0.049$) and/or jugular vein ($p = 0.040$) were significant predictors of poor prognosis. The five-year overall survival rate of patients with at least one of these factors (T_{4b}) was significantly lower than that of patients without these factors (T_{4a}) (25.5 *vs* 65.5 per cent, $p = 0.049$).

Conclusion. It is proposed that stage T_4 be subclassified into T_{4a} and T_{4b} according to the prognostic factors.

Main Article

Dr H Shinomiya takes responsibility for the integrity of the content of the paper

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Introduction

Squamous cell carcinoma (SCC) of the external auditory canal and middle ear is an extremely rare entity, with an annual incidence estimated at between one and six cases per million of the population.[1] While early stage SCC of the external auditory canal has been successfully treated by sleeve resection or lateral temporal bone resection, more advanced cancer requires subtotal temporal resection, resulting in facial palsy, hearing impairment and balance disorder, with severe post-operative complications such as cerebral infarction and meningitis.

The modified Pittsburgh classification proposed by Moody *et al.*[2] in 2000 has been most commonly used for SCC of the external auditory canal and middle ear. In Moody's classification, tumours limited to the temporal bone are defined as T_1 or T_2 disease. Tumours extending to the middle ear or apparently eroding the temporal bone are defined as T_3 disease. Tumours with invasion into the cochlea, petrous apex, middle-ear medial wall, carotid canal, jugular foramen or dura, or with extensive soft tissue involvement, such as the temporomandibular joint (TMJ) or styloid process, or evidence of facial paresis, are defined as T_4 disease. Thus, T_4 disease covers a fairly wide range of invasion, from a small extent (to the middle-ear wall) to a large extent (to the brain).

According to this classification, in the late twentieth century, while the reported oncological outcomes of patients with T_1, T_2 and T_3 disease were favourable, the survival rates of patients with T_4 disease were extremely poor.[3–7] However, during the last two decades, advances in surgical techniques for skull base surgery and multidrug concomitant chemoradiotherapy with docetaxel, cisplatin and 5-fluorouracil have improved oncological results for patients with advanced SCC of the external auditory canal and middle ear, especially when oncological resection is feasible.[8–10] Nevertheless, the prognosis of patients with unresectable T_4 disease remains poor.

Considering this background, this study investigated the prognostic factors for patients with advanced SCC of the external auditory canal and middle ear, to update the staging system and ensure ongoing relevance to advances in surgical and non-surgical treatments.

Materials and methods

Patients

Between 1998 and 2017, 102 consecutive patients with SCC of the external auditory canal and middle ear were treated at Kobe University Hospital, Japan. Among the 102 patients, we retrospectively reviewed 95 patients who were pathologically diagnosed with SCC of

Table 1. Treatment strategies of our institute

Tumour (T) stage	Recommended treatment	Treatment option	Parotidectomy	Prophylactic neck dissection
T_1	Sleeve resection or LTBR	RT alone	None	None
T_2	LTBR	RT alone	Superficial parotidectomy	None
T_3	STBR (LTBR)	Before 2006: CDDP-CRT	Total parotidectomy	Levels II–III
		2007 onwards: TPF-CRT		Levels II–III
T_4 operable	STBR	Before 2006: CDDP-CRT	Total parotidectomy	Levels II–III
		2007 onwards: TPF-CRT		
T_4 inoperable	Before 2006: CDDP-CRT	–	–	–
	2007 onwards: TPF-CRT	–		

LTBR = lateral temporal bone resection; RT = radiotherapy; STBR = subtotal temporal bone resection; CDDP-CRT = cisplatin-based chemoradiotherapy; TPF-CRT = chemoradiotherapy with docetaxel, 5-fluorouracil and cisplatin

the external auditory canal and middle ear and treated with curative intent. The remaining seven patients were excluded from this study. Two patients aged 90 years or older refused definitive therapy and were treated with palliative radiotherapy (RT) for pain relief. Three patients had other advanced cancer simultaneously and underwent palliative RT as best supportive care. Another two patients with severe dementia were not suitable for treatment with curative intent. Patients who had unresectable tumours and had undergone non-surgical treatment were considered to have undergone radical treatment and were included in this study.

Diagnosis and treatment

At the initial diagnosis, the extent of disease was assessed with the aid of contrast-enhanced computed tomography, magnetic resonance imaging and 18-fluoro-2-deoxyglucose positron emission tomography. Disease was staged according to the most recent version of the modified Pittsburgh classification (2000).[2] Sites of invasion were determined by pre-operative imaging study.

For patients with T_1 and T_2 disease, we principally recommended surgical treatment. Radiotherapy was employed for patients who refused surgery. Sleeve resection or lateral temporal bone resection was performed for T_1 and T_2 disease. For patients with T_3 disease, we recommended subtotal temporal bone resection or lateral temporal bone resection, depending on the extent of the disease. When patients refused surgery, concurrent chemoradiotherapy with cisplatin, or the combination of docetaxel, cisplatin and 5-fluorouracil,[8] was recommended. For patients with resectable T_4 disease, we recommended subtotal temporal resection. Invasion of the carotid artery and extensive dural invasion were considered as contraindications, while minor dural and/or brain invasion was considered as resectable. For patients with unresectable T_4 disease and patients who refused subtotal temporal resection, chemoradiotherapy with cisplatin, or the combination of docetaxel, cisplatin and 5-fluorouracil,[8] was performed. Particle beam therapy (carbon or proton) was employed in patients who strongly requested this therapy. Post-operative RT was given to surgically treated patients with positive or close surgical margins.

Surgical procedures

In lateral temporal bone resection, principally, the bony external auditory canal, tympanic membrane, malleus and incus were resected with extended mastoidectomy in an en bloc manner. The superficial lobe of the parotid gland was resected in 3 out of 11 patients with T_1 disease and in 12 out of 20 with T_2 disease. If parotid gland invasion or parotid lymph node involvement was identified, total parotidectomy was performed. The facial nerve was preserved in all cases. Neck dissection was not performed in any case of lateral temporal bone resection.

In subtotal temporal resection, after total parotidectomy and prophylactic neck dissection (levels II–III), the temporal bone was resected in an en bloc manner with temporosuboccipital craniotomy. Resection lines were anteriorly along the internal carotid artery and posteriorly at the sigmoid sinus. The medial resection line was along the internal auditory canal. The mandibular condyle was removed to obtain the surgical field, and the facial nerve was sacrificed. Principally, the jugular bulb, sigmoid sinus and dura were preserved, but were resected according to the extent of disease. The defect was reconstructed using a rectus abdominis musculocutaneous free flap.

Tumours with extension to the carotid artery, extensive dura and/or brain were considered as contraindications to subtotal temporal resection. While tumours with limited infiltration to the jugular vein could be successfully resected by sacrificing the jugular vein in selected cases, it was difficult to ensure negative surgical margins in most cases. Thus, we consider tumours with invasion of the jugular vein as relatively inoperable. Limited dural invasion, TMJ invasion and facial nerve invasion were considered resectable. Our treatment strategies are summarised in Table 1.

Statistical analysis

Medical records were retrospectively reviewed to obtain information concerning characteristics of the patients, extent of disease, treatment, surgical procedures, surgical margins, post-operative RT, treatment period and oncological results. The treatment period was divided into two time periods: 1998–2005 and 2006–2017. This is because we started to apply chemoradiotherapy with docetaxel, cisplatin and 5-fluorouracil to patients with SCC of the external auditory canal and middle ear from 2006 when applicable.

Kaplan–Meier plots were used to summarise time to event, measured from the end of the first treatment. The log-rank test was used for univariate analysis of survival rates, and the Cox proportional hazards regression analysis was used for multivariate analysis of survival rates. A p-value of 0.05 or less

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Table 2. Patients' characteristics

Characteristic	Value
Age (median (range); years)	64 (38–94)
Sex (*n* (%))	
– Male	35 (39)
– Female	60 (61)
Tumour (T) classification (*n* (%))	
– T_1	15 (16)
– T_2	22 (23)
– T_3	24 (25)
– T_4	34 (36)
Lymph node metastasis (*n* (%))	
– Negative	89 (93)
– Positive	6 (7)
Side (*n* (%))	
– Right	44 (46)
– Left	51 (54)
Treatment (*n* (%))	
– Surgery only	32 (33)
– Surgery + RT	14 (15)
– Surgery + CRT	5 (5)
– RT only	15 (16)
– Proton beam therapy	3 (3)
– CRT only	26 (27)
Neck dissection? (*n*)	
– Yes	15
– No	36
Clinical lymph node metastasis? (*n*)	
– Yes	6
– No	89

RT = radiotherapy; CRT = chemoradiotherapy

was defined as a significant difference. R software (version 3.0.2. 2013; R foundation for Statistical Computing, Vienna, Austria) was used for the statistical analysis.

This study was approved by Kobe University Hospital Internal Review Board.

Results

The characteristics of the patients are summarised in Tables 2 and 3. The patients' ages ranged from 38 to 94 years, with a median age of 64 years. Follow-up periods ranged from 7 to 144 months (median of 50 months, mean of 49.7 months). The numbers of the patients with T_1, T_2, T_3 and T_4 disease were 15, 22, 24 and 34, respectively. Only six patients had metastatic lymph nodes.

The most common treatment was surgery, which was selected mainly for early stage disease. Among T_1 and T_2 patients, 11 out of 15 patients with T_1 disease and 20 out of 22 patients with T_2 disease underwent surgical resection, while 5 patients underwent RT alone, and only 1 patient underwent proton beam therapy. Among T_3 patients, 11 had surgical resection, 6 underwent chemoradiotherapy, 6 received RT alone and 1 patient underwent proton beam therapy. Among T_4 patients, 9 had surgical resection, 20 underwent chemoradiotherapy (12 with cisplatin, and 8 with docetaxel, cisplatin and 5-fluorouracil), 4 patients received RT alone and 1 patient underwent proton beam therapy.

The data for patients treated with (chemo)radiotherapy are summarised in Table 4. Fifteen patients were treated with RT alone. Eighteen patients were treated with cisplatin-based chemoradiotherapy, and eight patients were treated with chemoradiotherapy with docetaxel, cisplatin and 5-fluorouracil. Three patients had proton beam therapy. Nineteen patients received post-operative RT.

The details for univariate analysis of survival rates are summarised in Table 5. Significant differences were found in terms of: original tumour site ($p = 0.011$), T classification ($p < 0.001$), surgical margin status ($p = 0.001$), post-operative RT ($p = 0.004$) and treatment period ($p = 0.013$). Surgical margin status was obtained from medical records in 46 out of 51 surgically treated patients. The results of multivariate analysis for the 46 surgically treated patients for whom information on surgical margins was available are shown in Table 6, and the results of all 95 patients are shown in Table 7. Regardless of treatment modality, T classification (T_4) was found to be a significant independent prognostic factor, as was treatment period.

The five-year overall survival rates of the patients with T_1, T_2, T_3 and T_4 disease were 93.3, 95.2, 84.7 and 42.9 per cent, respectively. The five-year disease-specific survival rates of the patients with T_1, T_2, T_3 and T_4 disease were 100, 100, 84.7 and 48.3 per cent, respectively. Kaplan–Meier plots of overall survival according to T classification are shown in Figure 1. According to the survival curve, the survival rate of patients with T_4 disease was markedly worse than the survival rates of patients with T_1, T_2 and T_3 disease. Thus, next, we further analysed the prognostic factors for patients with T_4 disease in detail.

The results of univariate analysis according to the invasion sites of 34 patients with T_4 disease are shown in Table 8. Brain invasion ($p = 0.024$), internal carotid artery invasion ($p = 0.049$) and internal jugular vein invasion ($p = 0.040$) were found to be significant predictors of poor prognosis. From these results, we subclassified T_4 disease invading the brain, carotid artery or jugular vein as T_{4b}, and T_4 disease without these features as T_{4a}. Characteristics of T_{4a} and T_{4b} patients are shown in Table 9.

Chemoradiotherapy or RT tended to be applied in patients with T_{4b} disease, as most T_{4b} diseases were unresectable. The Kaplan–Meier curves of patients with T_{4a} and T_{4b} disease, as well as those with T_1, T_2 and T_3 disease, are shown in Figure 2. The overall survival rate of T_{4a} patients was significantly higher than that of T_{4b} patients (65.5 per cent *vs* 25.5 per cent, $p = 0.049$). In addition, the overall survival rate of T_{4a} patients undergoing chemoradiotherapy was significantly higher than that of T_{4b} patients undergoing chemoradiotherapy (five-year overall survival rate = 100 per cent *vs* 36.4 per cent, $p = 0.020$).

Discussion

Because of its rarity and aggressive oncological behaviour, no standard treatment for SCC of the external auditory canal and middle ear has yet been established. For most reported cases, the selected treatment comprised surgical resection and post-operative RT.[5–7,11–15] While the cure rates for patients with early stage lesions (T_1 and T_2) treated by en

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Table 3. Treatment method according to tumour stage

Tumour (T) stage	Surgery only	Surgery + RT	Surgery + CRT	RT only	CRT only	Proton beam therapy
T_1	9	2	0	4	0	0
T_2	18	2	0	1	0	1
T_3	3	7	1	6	6	1
T_4	2	3	4	4	20	1

Data represent numbers of patients. RT = radiotherapy; CRT = chemoradiotherapy

Table 4. Summary of patients treated with radiotherapy

Parameter	Definitive RT	Post-operative RT
Concomitant therapy (*n*)	44	19
– RT alone	15	14
– Proton beam alone	3	0
– Cisplatin	18	5
– TPF	8	0
RT fields (*n*)		
– Primary	16	6
– Primary + neck	28	13
RT method (*n*)		
– 3D-RT	33	13
– IMRT	8	6
– Proton beam	3	0
RT dose (Gy)		
– Mean (SD)	66.6 (4.4)	61.4 (7.1)
– Median (range)	66 (45–70)	60 (44–70)

Proton beam therapy was excluded from radiotherapy dose. RT = radiotherapy; TPF = docetaxel, cisplatin and 5-fluorouracil; 3D = three-dimensional; IMRT = intensity-modulated radiotherapy; SD = standard deviation

Table 5. Univariate analysis of survival rates

Variable	Patients (*n*)	5-year OS (%)	*P*-value
Age			0.92
– ≥65 years	46	80.3	
– <65 years	49	69.3	
Original tumour site			0.011*
– External auditory canal	85	76.0	
– Middle ear	10	56.0	
Tumour (T) classification			<0.001*
– T_1	15	93.3	
– T_2	22	95.2	
– T_3	24	84.7	
– T_4	34	42.9	
Lymph node metastasis			0.081
– Node-positive	6	54.2	
– Node-negative	89	74.4	
Treatment			0.10
– Surgery only	32	96.8	
– Surgery + post-op RT	19	60.1	
– CRT	26	68.0	
– RT	15	50.0	
– Proton beam therapy	3	50.0	
Surgical margins			0.001*
– Positive	7	53.6	
– Negative	39	94.4	
– No data	5		
Post-op RT?			0.004*
– Yes	19	60.1	
– No	32	96.8	
Treatment period			0.013*
– 1998–2006	31	64.5	
– 2007–2017	64	78.5	

*Indicates statistical significance ($p < 0.05$). OS = overall survival; post-op = post-operative; RT = radiotherapy; CRT = chemoradiotherapy

bloc resection were near to 100 per cent,[11–15] treatment of locally advanced cancers is still challenging.

In previous literature, T classification has been reported to be the most important prognostic factor, as local recurrence is a cause of death in most cases of SCC of the external auditory canal and middle ear. The T classification,[5,15–18] N classification,[15,17] surgical margins,[5,16,17] dural invasion,[18] facial palsy[5,18] and post-operative RT[17] were described as prognostic factors in patients with SCC of the external auditory canal and middle ear, as previously reported. In the present study, T classification by the modified Pittsburgh staging system was also confirmed as a prognostic factor by multivariate analysis of all 95 patients. Of note, the oncological outcome of the patients with T_4 was extremely poor compared with that for patients with T_1, T_2 and T_3 disease. The five-year overall survival rate of T_4 patients was 42.9 per cent, while that of T_1, T_2 and T_3 patients was 93.3, 95.2 and 84.7 per cent, respectively.

Following recent advances in surgical techniques, surgical navigation systems and diagnostic imaging, the oncological outcome of SCC of the external auditory canal and middle ear has gradually improved. In the 1970s, Lewis reported a five-year overall survival rate of 25 per cent in a review of 100 cases.[19] In contrast, in 2006, Yin reported a five-year overall survival rate of 66 per cent.[16] In a meta-analysis, five-year overall survival rates of patients with T_3 and T_4 disease were 57.5 and 22.9 per cent, respectively, for the period covering 1976–2008.[20] These rates increased to 72.5 and 35.8 per cent, respectively, for 2006–2013.[21] In addition, chemoradiotherapy with docetaxel, cisplatin and 5-fluorouracil has provided a promising oncological outcome for advanced SCC of the external auditory canal and middle ear, including unresectable far-advanced cancers.[8–10] These reports and ours demonstrate the necessity for revising the tumour–node–metastasis (TNM) classification.

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Table 6. Multivariate analysis for 51 operated patients

Variable	Comparison	Hazard ratio	95% CI	*P*-value
Tumour (T) classification	$<T_4$ *vs* T_4	12.5	2.2–70.3	0.004*
Surgical margins	Negative *vs* positive	7.82	0.60–95.0	0.11
Post-op RT	No *vs* yes	1.90	0.18–19.7	0.59

Surgical margin status was obtained in only 46 patients. *Indicates statistical significance ($p < 0.05$). CI = confidence interval; post-op = post-operative; RT = radiotherapy

Table 7. Multivariate analysis for all 95 patients

Variable	Comparison	Hazard ratio	95% CI	*P*-value
Tumour (T) classification	$<T_4$ *vs* T_4	5.98	2.58–13.8	<0.001*
Treatment period	1998–2006 *vs* 2007–2017	0.36	0.16–0.80	0.013*

*Indicates statistical significance ($p < 0.05$). CI = confidence interval

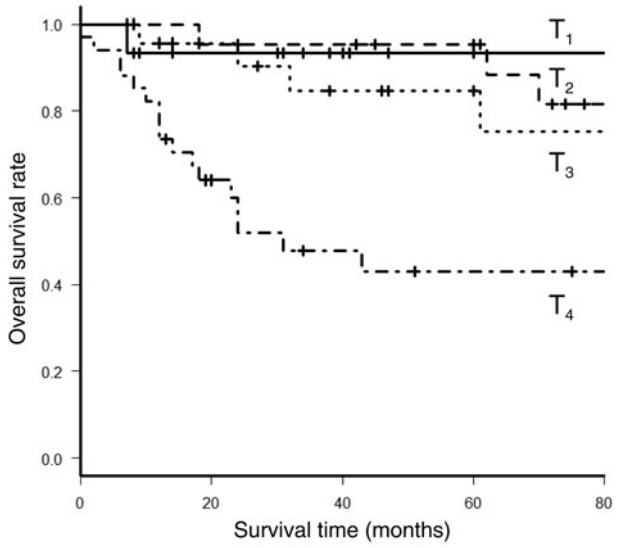

Fig. 1. The Kaplan–Meier curves according to the tumour (T) staging of the modified Pittsburgh classification. The five-year survival rate of T_4 patients was markedly worse than the survival rates of T_1, T_2 and T_3 patients.

- The modified Pittsburgh tumour (T) classification can predict the prognosis of squamous cell carcinoma arising from the auditory canal
- Invasion of the brain, internal carotid artery and internal jugular vein predicted ($p < 0.05$) poor prognosis among T_4 patients
- A new method of categorising T_4 patients regarding the modified Pittsburgh classification into two groups (T_{4a} and T_{4b}) was proposed
- The overall survival rate of T_{4a} patients was significantly higher than that of T_{4b} patients (65.5 *vs* 25.5 per cent, $p = 0.049$)
- The new T_4 tumour classification may be useful for predicting both prognosis and therapeutic effects

Mazzoni *et al.*[22] proposed dividing T_3 of the modified Pittsburgh classification into T_{3a} (tumour extending less than 5 mm from cartilage to peri-auricular soft tissues, or tumour strictly limited to the anterior bone wall and growing less than 5 mm into the parotid space) and T_{3b} (same as for T_{3a}, but extending more than 5 mm). Also, they divided T_4 into T_{4a} (tumour growing into mastoid without facial nerve paresis) and T_{4b} (tumour growing into mastoid with facial paresis, or infratemporal space, or medial wall of tympanum, labyrinth, or petrous bone). Although Mazzoni's classification is useful in the case of surgical resection, there was no consideration of resectable and unresectable tumours treated by intensified chemoradiotherapy such as that with docetaxel, cisplatin and 5-fluorouracil, as shown in the present study and our previous studies.[8–10]

Table 8. Univariate analysis of tumour stage T_4 patients according to invasion site

Invasion site	Patients (*n*)	5-year OS rate (%)	*P*-value
Brain?			
– Yes	6	No patients	0.024*
– No	28	48.4	
Internal carotid artery?			
– Yes	10	20.0	0.049*
– No	24	55.6	
Internal jugular vein?			
– Yes	14	16.3	0.040*
– No	20	70.0	
Dura?			
– Yes	19	39.7	0.37
– No	15	48.9	
Facial nerve?			
– Yes	9	37.0	0.84
– No	25	46.0	
Temporal subcutaneous region?			
– Yes	4	100	0.18
– No	30	38.9	

*Indicates statistical significance ($p < 0.05$). OS = overall survival

To address this limitation, we subclassified T_4 disease into two subclasses according to the prognostic factors of brain invasion, internal carotid artery invasion and internal jugular vein invasion. As shown in Figure 2, patients with T_4 disease were clearly divided into patients without these factors (T_{4a}) and patients with at least one of these factors (T_{4b}). As the majority of T_{4b} diseases were unresectable, patients with T_{4b} disease were mostly treated with RT or chemoradiotherapy. However, the oncological outcomes of patients with T_{4b} disease treated by intensive chemoradiotherapy (with docetaxel, cisplatin and 5-fluorouracil) were still poor. On the other

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Table 9. Characteristics of tumour stage T_{4a} and T_{4b} patients

Characteristics	T_{4a}*	$T_{4b}^{\dagger}$	*P*-value
Nodal (N) stage (*n*)			
– N_+	1	3	0.60
Treatment (*n*)			
– Surgery	7	2	0.11
– CRT	9	11	
– RT	1	3	
– Proton beam therapy	0	1	
Invasion site (*n*)			
– Brain	0	6	0.018‡
– Internal carotid artery	0	10	<0.001‡
– Jugular vein	0	12	<0.001‡
– Dura	8	11	0.49
– Facial nerve	3	6	0.43
– Temporal subcutaneous region	4	0	0.10
Resectability (*n*)			
– Resectable	16	4	<0.001‡
– Unresectable	1	13	
5-year overall survival rate (%)	65.5	25.5	0.049‡

*$n = 17$; †$n = 17$. ‡Indicates statistical significance ($p < 0.05$). CRT = chemoradiotherapy; RT = radiotherapy

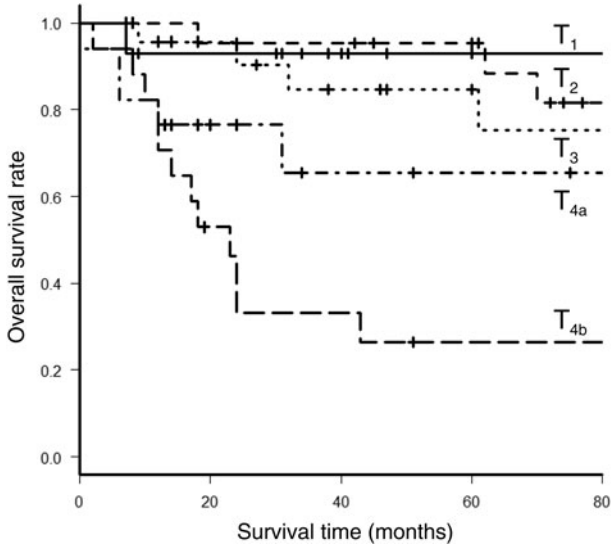

Fig. 2. The Kaplan–Meier curves of the new classification. The five-year survival rate of tumour stage T_{4a} patients was significantly higher than that of T_{4b} patients (65.5 *vs* 25.5 per cent, $p = 0.049$).

hand, almost all T_{4a} disease was oncologically resectable, and the five-year overall survival rate of patients with T_{4a} disease treated by intensified chemoradiotherapy was 100 per cent. Our new classification of T_{4a} and T_{4b} disease may be useful not only for predicting prognosis but also for predicting therapeutic effects.

In the present series, treatment period was also found to be a significant independent prognostic factor on multivariate analysis. The most likely reason for the improved oncological outcome with time is the amendment of our treatment policy for non-surgical treatment, which changed from cisplatin chemoradiotherapy to docetaxel, cisplatin and 5-fluorouracil chemoradiotherapy. Advances in imaging and surgical technique supported by surgical navigation might also have contributed to the improved survival, as shown in the meta-analysis.[21]

One of the limitations of the present study, which has a level of evidence of 4, is its retrospective nature, which may contain several biases in terms of choice of treatment and patient selection. Although the present study is one of the largest series from a single-institute, based on long-term follow up, the number of patients was still small. Currently, we are conducting a multi-institutional retrospective study to draw more definitive conclusions.

Conclusion

We propose a new classification, classifying T_4 of the modified Pittsburgh classification into two groups according to the prognostic factors of invasion of the brain, internal carotid artery and jugular vein.

Competing interests. None declared

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