A Clinical Study of Pharyngolaryngectomy with Total Esophagectomy: Postoperative Complications, Countermeasures, and Prognoses

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Abstract

Objective. Patients with advanced hypopharyngeal or cervical esophageal cancer have a comparatively high risk of also developing thoracic esophageal cancer. Pharyngolaryngectomy with total esophagectomy is highly invasive, and few reports about it exist. We examined the postoperative complications and respective countermeasures and prognoses of patients who underwent pharyngolaryngectomy with total esophagectomy.

Study Design. Case series with chart review.

Setting. Department of Head and Neck Oncology, Cancer Institute Hospital of Japanese Foundation for Cancer Research, Japan.

Subjects and Methods. We examined the postoperative complications and respective countermeasures and prognoses of 40 patients who underwent pharyngolaryngectomy with total esophagectomy in our hospital.

Results. Postoperative complications were observed in 23 patients (57.5%) and consisted of 8 groups: tracheal region necrosis in 5 patients; neck abscess formation/wound infection in 5; fistula in 4; tracheostomy suture leakage in 2; ileus in 2; lymphorrhea in 2; pulmonary complications in 2; and other complications, including hemotherax, tracheoinnominate artery fistula, temporary cardiac arrest due to intraoperative mediastinum operation, methicillin-resistant Staphylococcus aureus enteritis, and sepsis, in 1 patient each. A lethal complication—brachiocephalic vein hemorrhage due to tracheostomy suture leakage and hemorrhagic shock due to tracheoinnominate artery fistula—occurred in 2 (5%) patients. The crude 5-year survival rate was 48.6%.

Conclusions. Serious postoperative complications were related to tracheostomaplasty. Although pharyngolaryngectomy with total esophagectomy is highly invasive, we believe that our outlined treatment method is the most appropriate for cases of advanced hypopharyngeal or cervical esophageal cancer that also requires concurrent surgery for esophageal cancer.

Keywords
hypopharyngeal cancer, esophagectomy, complications, mortality

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Hypopharyngeal and cervical esophageal cancers are often discovered in the advanced stages; they are characterized by poor prognoses, with 5-year survival rates of 24% to 47%.1-5 This occurs because the cancer is locally advanced and lymph node metastasis tends to occur in the early stages. Concurrent occurrence of other carcinomas is common.1,6 Multiple neoplastic changes in the upper gastrointestinal tract are believed to arise from “field cancerization,” a phenomenon usually associated with repeated exposure to carcinogens such as alcohol and cigarette smoke. Genetic polymorphisms, such as alcohol dehydrogenase and aldehyde dehydrogenase, have also been implicated.7,8 Multiple cancers of the upper gastrointestinal tract have been observed in several Japanese patients because of a genetic background of aldehyde dehydrogenase, as well as better diagnoses due to recent improvements in endoscopic technology.

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Although advanced hypopharyngeal or cervical esophageal squamous cell carcinoma often spreads to lymph nodes and is prone to metastasize, the range of lymph node metastasis is relatively limited, thereby making many of the nodes operable. The radical operation frequently requires a laryngectomy. Owing to recent advances in chemoradiotherapy, quite a few patients do not choose surgery but opt for chemoradiotherapy. However, the risks of salvage operations after chemoradiotherapy are actually high.

Cases of advanced hypopharyngeal or cervical esophageal cancer sometimes overlap thoracic esophageal cancer because of genetic polymorphisms. The number of pharyngeal and esophageal cancers has been gradually increasing in Japan. Therefore, cases for which concurrent total pharyngolaryngectomy and total esophagectomy (PLTE) are indicated have also been increasing. Both procedures are highly invasive, and few reports on PLTE exist because an otolaryngologic surgeon and a gastrointestinal surgeon are necessary to perform the surgeries and the number of patients is limited. Thus, we focused on patients at our hospital who underwent PLTE, and we documented the frequency and treatment of postoperative complications, countermeasures, and respective prognoses.

Materials and Methods

This study and its methods were approved by the ethics committee for clinical studies of the Cancer Institute Hospital. Treatment strategy for each patient was based on discussion among the cancer board members, consisting of surgeons, gastroenterologists, and medical and radiation oncologists. In this study, surgery and chemoradiotherapy were explained to each patient, and each was able to choose the treatment method himself or herself.

Patient Population

This study retrospectively examined 40 patients (36 men, 90.0%; 4 women, 10.0%) receiving PLTE as first-line treatment in our hospital from March 2005 to April 2012. Patients who had previously undergone chemoradiotherapy or had been treated at another hospital were excluded. The mean age at the initial visit was 62.6 years (45-77 years), and the mean follow-up period was 37.6 months (2-93 months). All patients were classified according to the TNM staging system.

Treatment

Total pharyngolaryngectomy, total esophagectomy, bilateral neck dissection, paratracheal dissection, and thyroidectomy were performed in all 40 patients as the first-line treatment. We investigated postoperative treatments, esophageal surgery approaches, reconstruction methods, and whether partial thoracic excision (partial excision of sternoclavicular joint or ribs) was performed. Resection and reconstruction procedures were performed cooperatively by otolaryngologic and gastroenterologic surgical teams.

Postoperative Complications

We examined the miscellany of nonlethal and lethal complications and their recurrence rate. We also analyzed the relationship with countermeasures for complications and reconstructive methods for tracheostomaplasty in particular.

Total Survival

We calculated actuarial data and disease-specific survival rates for all patients for 5 years postsurgery.

Statistical Analysis

Survival rate was estimated through the Kaplan-Meier survival curve. The correlation between the partial thoracic excision and the length of remaining trachea was determined by the Mann-Whitney U test, and the statistical significance of tracheostomy complications was determined by the Fisher exact probability test. For all parameters, P < .05 was considered significant.

Results

Patient Population

PLTE was performed on 40 patients, with primary sites as follows: hypopharyngeal and thoracic esophageal cancer was detected in 19 patients (47.5%; including 1 patient who had hypopharyngeal, thoracic esophageal, and gastric cancer), cervical esophageal cancer in 13 (32.5%), cervical esophageal and thoracic esophageal cancer in 5 (12.5%), hypopharyngeal and cervical esophageal cancer in 1 (5.0%), and laryngeal and thoracic esophageal cancer in 1 (2.5%). The tissue type was squamous cell carcinoma in all cases. One patient with gastric cancer also had adenocarcinoma (gastric cancer). The second tumors were detected through esophagogastroduodenoscopy and computed tomography scans.

The staging systems for hypopharyngeal, cervical esophageal, and thoracic esophageal cancer are shown in Tables 1-3. Patients who mainly had advanced hypopharyngeal and cervical esophageal cancer (which required total pharyngolaryngectomy) and esophageal cancer (which required total esophagectomy) were selected for PLTE. In total, 21 patients had hypopharyngeal cancer. Of these, 18 (85%) had T3 or T4a cancer. Twenty patients had cervical esophageal cancer. Of these, 17 (85%) had T3 or T4a cancer (Tables 1 and 2). These included 2 patients who had hypopharyngeal and cervical esophageal cancer and 1 patient who had laryngeal cancer (supraglottic, T3 N1). The 21 patients with hypopharyngeal cancer were divided into 3 subsets as follows: piriform sinus in 17 patients, posterior pharyngeal wall in 3, and postcricoid region in 1.

In total, 24 patients had thoracic esophageal cancer (Table 3). Of the 28 lesions observed (including multiple carcinomas) by the gastroenterologists at our hospital, 23 (82%) were T1. Most T1 lesions were multiple and circumferential; thus, these cases were assessed by the gastroenterologists as not being suitable for endoscopic resections.
Treatment

PLTE, bilateral neck dissection, paratracheal dissection, and thyroidectomy were performed on all 40 patients. Twelve patients underwent radiation therapy, and 5 received postoperative adjuvant chemotherapy.

Right thoracotomy was performed in 10 patients (25%), whereas 30 patients (75%) did not require this procedure. For those patients who received thoracotomy, mediastinal and abdominal dissection was also performed.

Partial thoracic excision (partial excision of the sternoclavicular joint or ribs) was performed in 10 patients (25%); no such excision was performed in 30 (75%) patients. A significant statistical difference was observed in the distance between the tracheostomy and the carina. The mean distance between these structures in patients in whom a partial thoracic excision was performed was 52.5 mm (30-70 mm) and in patients who did not undergo this procedure, 68.5 mm (45-115 mm, P = .036, Mann-Whitney U test).

Reconstructive Surgical Methods

Several methods used for pharyngeal and esophageal reconstruction were as follows: posterior mediastinal gastric pull-up was performed in 28 patients (70%), gastric pull-up and free jejunal transfer in 10 patients (25%), and pedicled colon segment pull-up in 2 (5%, both after gastrectomy). Of the 40 patients who underwent PLTE, 35 (87.5%) required microsurgical vascular anastomosis.

Postoperative Complications

Postoperative complications were observed in 23 (57.5%) of 40 patients; details are listed in Table 4.

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### Table 1. Staging of Patients with Hypopharyngeal Cancer (n = 21): TNM Classification.*

<table>
<thead>
<tr>
<th></th>
<th>N0 (pN0)</th>
<th>N1 (pN1)</th>
<th>N2a (pN2a)</th>
<th>N2b (pN2b)</th>
<th>N2c (pN2c)</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>T2</td>
<td>1 (1)</td>
<td>2 (2)</td>
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<td>0 (0)</td>
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<td>T3</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>5 (5)</td>
<td>3 (3)</td>
<td>10</td>
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<tr>
<td>T4a</td>
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<td>3 (4)</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>4 (3)</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>2 (2)</td>
<td>6 (7)</td>
<td>0 (0)</td>
<td>6 (6)</td>
<td>7 (6)</td>
<td>21</td>
</tr>
</tbody>
</table>

*Patients who had hypopharyngeal and cervical esophageal cancer, n = 2.

### Table 2. Staging of Patients with Cervical Esophageal Cancer (n = 20): TNM Classification.*

<table>
<thead>
<tr>
<th></th>
<th>N0 (p0)</th>
<th>N1 (pN1)</th>
<th>N2 (pN2)</th>
<th>N3 (pN3)</th>
<th>Total</th>
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<td>2 (1)</td>
<td>0 (1)</td>
<td>0 (0)</td>
<td>2</td>
</tr>
<tr>
<td>T3</td>
<td>2 (1)</td>
<td>4 (3)</td>
<td>2 (2)</td>
<td>0 (2)</td>
<td>8</td>
</tr>
<tr>
<td>T4</td>
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<td>6 (4)</td>
<td>2 (4)</td>
<td>1 (0)</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>3 (3)</td>
<td>12 (8)</td>
<td>4 (7)</td>
<td>1 (2)</td>
<td>20</td>
</tr>
</tbody>
</table>

*Patients who had hypopharyngeal and cervical esophageal cancer, n = 2.

### Table 3. Thoracic Esophageal Cancer (n = 24): T Staging of Cancers by Type.*

<table>
<thead>
<tr>
<th></th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ut</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Mt</td>
<td>13</td>
<td>1</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>Lt</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>3</td>
<td>2</td>
<td>28</td>
</tr>
</tbody>
</table>

Abbreviations: Lt, lower thoracic esophagus; Mt, middle thoracic esophagus; Ut, upper thoracic esophagus.

*Overlapping due to multiple cancers possible. N1 patients, n = 8; N2 patients, n = 1.

### Table 4. Postoperative Complications (n = 23 of 40).

<table>
<thead>
<tr>
<th>Complications</th>
<th>Patients, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial tracheal necrosis</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>Neck abscess or wound infection</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>Anastomotic leak</td>
<td>4 (10.0)</td>
</tr>
<tr>
<td>Tracheostomy suture leakage</td>
<td>2 (5.0)</td>
</tr>
<tr>
<td>Ileus</td>
<td>2 (5.0)</td>
</tr>
<tr>
<td>Lymphorrhea</td>
<td>2 (5.0)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>2 (5.0)</td>
</tr>
<tr>
<td>Hemothorax (postoperative hemorrhage)</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Tracheoinnominate artery fistula (hemorrhagic shock)</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Cardiac arrest of unknown etiology during surgery</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Methicillin-resistant <em>Staphylococcus aureus</em> enteritis</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Total</td>
<td>27*</td>
</tr>
</tbody>
</table>

*Includes overlapping.
Partial tracheal necrosis developed in 5 patients (12.5%). Of these, 2 required a second operation, in which tracheostomaplasties with a deltopectoral (DP) or radial forearm flap were performed. The other 3 patients successfully recovered with only local treatment.

Neck abscesses and wound infections developed in 5 (12.5%) patients. All patients successfully recovered with local treatment. Fistulas developed in 4 (10.0%) patients. The fistula was closed in 1, whereas the other 3 patients successfully recovered after conservative treatment. Tracheostomy suture leakage developed in 2 (5.0%) patients. Brachiocephalic vein hemorrhage occurred in 1, on whom surgery was performed, but he died during the procedure because of difficulty with hemostasis.

The other patient successfully recovered with local treatment. Ileus was noted in 2 (5.0%) patients. Operative treatment for ileus was performed in 1, and the other patient successfully recovered after conservative treatment. Lymphorrhea developed in 2 (5.0%) patients. All patients successfully recovered with local treatment. Pneumonia and respiratory failure developed in 2 (5.0%) patients, but both successfully recovered after temporary ventilatory management.

Serious postoperative complications occurred in several cases. These included hemothorax (postoperative hemorrhage), temporary cardiac arrest (of idiopathic etiology) during mediastinal surgery, methicillin-resistant *Staphylococcus aureus* enteritis, and sepsis occurred. All patients recovered after operative or pharmacologic treatment. Lethal complications occurred in 2 patients (5%) who had brachiocephalic vein hemorrhage because of tracheostomy suture leakage and hemorrhagic shock due to tracheoinnominate artery fistula. The average recovery time to oral intake after severe postoperative complications was 51 days (30-98 days). All patients, except 2 with lethal complications, recovered with good oral intake and were discharged from hospital.

**Quality of Life for the Survivors**

The ability to swallow in 38 cases (except 2 with lethal complications) was assessed by the Functional Oral Intake Scale. 14 Thirty-two cases were level 7 (total oral diet with no restrictions); 5 were level 5 (total oral diet with multiple consistencies but requiring special preparation or compensations); and 1 was level 3 (tube dependency with consistent oral intake of food or liquid). Anastomotic stricture was observed in 3 of 38 cases, and all of them were treated with repeated endoscopic balloon dilation and cured.

Performance status in 37 patients was grade 1, and 1 was grade 2. Two patients were able to return to work. They could manage their tracheostomas without assistance, and 11 patients could manage the silicon tube by themselves; thus, it prevented stenosis of the tracheostoma.

Loss of vocal function occurred by all means in this operation, but 3 patients had undergone secondary insertions of voice prosthesis and recovered good vocal function.

**Tracheostomaplasty and Tracheostomy-Related Complications**

The mean distance from permanent tracheostomy to carina in 40 patients was 64 mm (30-115 mm). Nine (22.5%) patients with the brachiocephalic trunk displaced to the left of the trachea required mediastinal tracheostomy. The mean length of the remaining trachea was 50.6 mm (30-70 mm).

A significant difference was noticed in tracheostomy complications between patients who received a mediastinal tracheostomy and those who received a standard tracheostomy. Of the 9 patients who received a mediastinal tracheostomy, 4 (44.4%) had tracheostomy-related complications; however, of the 31 patients with a standard tracheostomy, complications developed in 4 (12.9%, *P* = .037, Fisher exact probability test).

The techniques used for tracheostomaplasty are listed in **Table 5**. The length of the remaining trachea refers to the distance between the permanent tracheostomy and carina. Tracheostomaplasty using the DP flap was performed in 17 (42.5%) patients—by attaching the thyroid lobe to the trachea in 9 (22.5%), anterior chest skin flap in 8 (20.0%), neck skin flap in 5 (12.5%), and radial forearm flap in 1 (2.5%).

No significant correlation was observed between mediastinal dissection and tracheostomy complications. Complications occurred in 2 of 10 patients (20%) in whom right thoracotomy (mediastinal or abdominal dissection) was performed and 6 of 30 patients (20%) in whom thoracotomy was not performed.

**Survival**

The crude 5-year survival rate for all patients was 48.6%, and the disease-specific 5-year survival rate was 50.2% (Figure 1).
The crude 5-year survival rate of hypopharyngeal cancer was 53.3% (n = 21), whereas that of cervical esophageal cancer was 48.5% (n = 20, \( P = .71 \), log rank test; Figure 2). Two patients had hypopharyngeal and cervical esophageal cancer.

The crude 5-year survival rate of hypopharyngeal cancer was 53.3% (n = 21), whereas that of cervical esophageal cancer was 48.5% (n = 20).

The crude 5-year survival rate of hypopharyngeal cancer was 50.0% (n = 4) for stage III and 51.3% (n = 16) for stage IV (\( P = .70 \); Figure 3). Stage II was excluded because of only 1 case.

The crude 5-year survival rates according to stage of cervical esophageal cancer were as follows: 33.3% (n = 4) for stage II and 48.8% (n = 15) for stage III (\( P = .88 \); Figure 4). One case of stage I was excluded because stage IV hypopharyngeal cancer overlapped.

The crude 5-year survival rate of thoracotomy was 51.4% (n = 10), whereas that of blunt dissection was 47.3% (n = 30, \( P = .53 \); Figure 5). Right thoracotomy was performed in 10 patients, whereas 30 patients did not require this procedure.

**Discussion**

Smoking and alcohol intake have been implicated in the high occurrence of multiple cancers of the upper gastrointestinal tract and respiratory system. The concurrent or metachronous development of hypopharyngeal or esophageal cancer ranges from 25% to 33%.\(^{15,16}\) The correlation between (1) genetic polymorphisms for alcohol dehydrogenase and aldehyde dehydrogenase and (2) alcohol carcinogenicity in the upper gastrointestinal tract is well established. Many Japanese people have these genetic polymorphisms and thus may be at high risk for esophageal squamous cell carcinomas.

Based on this genetic background, thoracic esophageal cancer is frequently observed in patients of Japanese origin with hypopharyngeal or cervical esophageal cancer, and multiple carcinomas make selection of treatment even more difficult. The most important factor to consider for surgery is the necessity of surgical treatment for concurrent advanced hypopharyngeal or cervical esophageal cancer and thoracic esophageal cancer. In addition, PLTE is required in cases when hypopharyngeal or cervical esophageal lesions are continuous to the site of the thoracic esophageal lesions, making complete excision of the inferior portion of the neoplasm through the neck difficult. Because total pharyngolaryngectomy and total esophagectomy are both highly invasive treatments, patients must be carefully screened for concurrent surgery. Optimal surgical resection and reconstruction procedures increase local control rate and survival rate, decrease postoperative
complications, and lead to an early resumption of oral ingestion and rehabilitation.

Although various techniques for PLTE reconstruction exist, gastric pull-up reconstruction may be most effective because head and neck and gastroenterologic surgical teams can concurrently work in different surgical fields, good blood flow can be obtained, few anastomoses are required, and stenosis or fistula development is rare. In our study, blood flow can be obtained, few anastomoses are required, and we can concurrently work in different surgical fields. Good head and neck and gastroenterologic surgical teams exist, gastric pull-up reconstruction may be most effective.

In this study, the rate of PLTE-related operative mortality was 5% (2 patients). Deaths were due to bronchioesophageal vein hemorrhage from tracheostomy suture leakage and hemorrhagic shock from tracheoinnominate artery fistula. Because postoperative mortality rates range from 5% to 15%, our results can be described as favorable. Patients who experienced operative mortality in this study had short remaining tracheas; therefore, surgeons were forced to displace the bronchioesophageal trunk to the left of the trachea to perform mediastinal tracheostomy. Although it appears that improvements in surgical techniques, perioperative care, and nutritional management are most required to lower postoperative mortality, the biggest factors that lead to an increased risk of death are advanced stage of cancer and a short remaining trachea.

The number of tracheostomy-related complications was not low in this study (8 of 40). Complications were classified into 3 groups as follows: partial tracheal necrosis in 5 patients (12.5%), tracheostomy suture leakage in 2 (5.0%), and tracheoinnominate artery fistula in 1 (2.5%). Of the 5 patients with partial tracheal necrosis, 3 successfully recovered with only local treatment, but the other 2 required tracheostomaplasty using DP or radial forearm flap. Because tracheostomy-related complications, which can lead to poor patient outcomes, may occur due to insufficient tracheal blood flow, we examined blood flow during the initial tracheostomaplasty. A tracheostomy was created by resecting the trachea until sufficient blood flow in the excised piece of trachea could be confirmed. When the remaining trachea was very short, the bronchioesophageal trunk was displaced to the left of the trachea, and mediastinal tracheostomy was performed. In this study, surgical mediastinal tracheostomy was performed on 9 (22.5%) patients. When standard tracheostomaplasty using a neck skin flap was difficult, local and free flaps from tissue with good blood flow were used to prevent tension. A DP flap was used in 17 patients (42.5%), anterior chest skin in 8 (20.0%), and radial forearm flap in 1 (2.5%). For the 9 patients (22.5%) in whom a long remaining trachea length could be maintained, conservation of the thyroid lobe was attempted by attachment to the trachea to obtain good vascular blood flow. Thus, we examined various surgical procedures for tracheostomaplasty with the goal of reducing postoperative complications, duly noting the significant complications that developed in patients who received mediastinal tracheostomies.

The postoperative complications of PLTE include anastomotic leak, which has been observed in 9% to 14% of patients in the comparatively early postoperative period. In our study, anastomotic leak was observed in 4 patients (10.0%). An external fistula was closed in 1 patient, and 3 successfully recovered after conservative treatment. In this study, there were no significant differences for survival rate for tumors or postoperative complications in the primary location, stage, thoracotomy vs blunt dissection, and comorbidity.

All survivors recovered with good oral intake, and some of them were able to return to their social activities, despite loss of vocal function. Chou et al reported a comparison of quality of life between radical resection and chemoradiotherapy for cervical esophageal cancer. They mentioned that quality of life improved in both groups, and the operative group appeared to be better, although the difference was not significant. They concluded that radical resection is beneficial to patients in terms of better eating function. Drawbacks of radical surgery, such as loss of vocal function or maintenance of the tracheostoma by the patient without assistance, tended to be highlighted. Oral intake is the basis of life support so that the pros and cons of both modes of therapy as well as posttherapy quality of life should be thoroughly explained with discretion to help patients choose the therapy best suited to their wishes.

The 5-year survival rate for patients with hypopharyngeal or cervical esophageal cancer, both associated with poor prognoses, ranges from 24% to 47%. However, in this study, comparatively favorable prognoses were achieved, as the 5-year survival rate for all patients was 48.6%. The 5-year survival rate of 20 cases receiving chemoradiotherapy for cervical esophageal cancer was 30%, and in 102 patients with stage III or IV resectable squamous cell carcinoma of the hypopharynx treated with chemoradiotherapy, the rate was 51.3%. Compared with these published data, our results—which focus on advanced hypopharyngeal or cervical esophageal cancer with thoracic esophageal cancer—were considered satisfactory.
Conclusions

In this study, comparatively favorable prognoses were obtained, as shown by a crude 5-year survival rate of 48.6%. The rate of operative mortality was 5%, with the most serious postoperative complications related to tracheostomyplasty. Although the cases that we investigated involved a highly invasive procedure, we surmised that this was the most appropriate treatment for patients with advanced hypopharyngeal or cervical esophageal cancer who required esophagectomy.

Author Contributions

Ryosuke Kamiyama, data collection, data analysis, drafting and revising, final approval, accountability for all aspects of the work; Hiroki Mitani, conception, study design, revising, final approval, accountability for all aspects of the work; Hiroyuki Yonekawa, data collection, revising, final approval, accountability for all aspects of the work; Hiroyumi Fukushina, data collection, revising, final approval, accountability for all aspects of the work; Toru Sasaki, data collection, revising, final approval, accountability for all aspects of the work; Wataru Shimbashi, data collection, revising, final approval, accountability for all aspects of the work; Akira Seto, data collection, revising, final approval, accountability for all aspects of the work; Yuh Koizumi, data collection, revising, final approval, accountability for all aspects of the work; Aya Ebina, data collection, revising, final approval, accountability for all aspects of the work; Kazuyoshi Kawabata, conception, study design, revising, final approval, accountability for all aspects of the work.

Disclosures

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