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Reconstructive

Efficacy of Tensed and Straight Free Jejunum Transfer for the Reduction of Postoperative Dysphagia

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Background: Free jejunal transfer (FJT) is a standard method of reconstruction after total pharyngo-laryngo-cervical esophagectomy (TPLE) in patients with advanced head and neck cancer. However, it is related to various degrees of postoperative swallowing dysfunction. This study aimed to assess whether the tensed and straight FJT method results in a reduced rate of postoperative dysphagia compared with historical controls.

Methods: Patients who were undergoing FJT after TPLE for squamous cell carcinoma of the hypopharynx or cervical esophagus were enrolled. The primary endpoint was the rate of not developing dysphagia within 6 months of the surgery, and we compared this value with that obtained from historical data of patients who underwent FJT. The secondary endpoint was the rate of developing surgical complications.

Results: Although 128 patients were registered between August 2012 and July 2015, 7 were excluded based on the exclusion criteria. Of the remaining 121 patients, FJT with the craniocaudally tensed and straight method was performed in all patients. The rate of not developing dysphagia and its 95% confidence interval (CI) were 66.1% and 57.0–74.5%, respectively. The lower limit of the CI was higher than the prespecified threshold value of 50.0%. The rate of developing complications of total necrosis of the jejunum was 3.3%, cervical infection was 9.9%, and major anastomotic leakage was 4.1%.

Conclusions: Our findings revealed that the proportion of postoperative dysphagia decreased in patients who underwent tensed and straight FJT. This method may become the standard surgical method in reconstruction of defects after TPLE.

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BACKGROUND

Free jejunal transfer (FJT) is the favored method of reconstruction after total pharyngo-laryngo-cervical esophagectomy (TPLE)[1–3] because of its rich vascularization, self-lubricating character. Although Yu et al.[4] reported the superiority of the anterolateral thigh flap compared with the jejunal flap, we still believe that FJT is safer than classical skin flap roll reconstruction.[5] However, FJT after TPLE

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is associated with postoperative dysphagia at various rates and degrees.[1,6,7] A previous study found dysphagia after FJT in 49.8% of patients among 764 retrospectively accumulated subjects, which is the largest multi-institutional study conducted in the Japanese population.[6] Possible causes of dysphagia include anastomotic stricture, cancer recurrence, perioperative irradiation, and intestinal peristalsis.

The method used for suturing during FJT may also be an important factor influencing the risk of developing dysphagia. Previously, it was reported that FJT with the tensed and straight method helped reduce the proportion of developing dysphagia.[8] However, that report was an expert opinion based on no data.

In this study, we examined whether the tensed and straight FJT method results in a lower proportion of patients developing dysphagia than in historical controls.

MATERIALS AND METHODS

Study Design and Patient Selection

Our multi-institutional, nonrandomized, prospective study was conducted in August 2012 to confirm the superiority of the tensed and straight FJT method versus the method used in a historical study in terms of rate of dysphagia. All patients undergoing FJT after TPLE for squamous cell carcinoma of the hypopharynx or cervical esophagus were enrolled. The Institutional Review Board of the National Cancer Center Hospital approved our study protocol in August 2012, and approval from each institutional review board was obtained before starting registration of the subjects. This study was registered in the UMIN Clinical Trials Registry as UMIN 000018965 (http://www.umin.ac.jp/ctr/).

Patients who met the following eligibility criteria were registered: provided written informed consent, at least 20 years of age, Eastern Cooperative Oncology Group performance status of 0 or 1, cancer status with R0 resection expected, and no distant metastasis. Patients with a history of radical surgery for esophageal or gastric cancer were excluded from the study. Synchronous or metachronous malignancies within 5 years, except for carcinoma in situ or mucosal tumors treated with local therapy, were also excluded from this study. Other exclusion criteria were as follows: cancer resection beyond the upper pole of the tonsil, resection below the cervical esophagus, and cancer resection with larynx preservation. Patients with poorly controlled hypertension of diabetes mellitus or severe pulmonary fibrosis or emphysema were also excluded.

Surgical Technique and Free Jejunum Tension

The elevation of free jejunum was performed according to the preference of each institution, and no data were provided on the harvested segment of the small intestine. FJT was performed immediately after TPLE via the craniocaudally tensed and straight method in all patients. Neither end-to-side anastomosis nor a mechanical anastomosing device was used for jejunal anastomosis. Although the order of the free jejunum suturing method was decided according to the preference of each institution, the most common order was as follows: (1) pharyngojejunal anastomosis, (2) jejunoesophageal anastomosis, and (3) microvascular anastomosis. The length of the pharyngeal defect was measured at the posterior wall midline before starting free jejunum anastomosis. After completion of pharyngojejunal anastomosis or jejunoesophageal anastomosis, another stump of the intestine was pulled toward the caudal or cranial side, and the length of the jejunal transfer was decided. The length was measured under ischemic conditions, and the percentage was calculated (Fig. 1). Historically, the length of the free jejunum that was transferred was of the same length as the hypopharyngeal defect. In such cases, there were many cases in which the jejunum was transferred without craniocaudal tension. Furthermore, many patients showed a poor postoperative swallowing function after such type of reconstructive procedure. On the other hand, it is difficult to anastomose the jejunum conduit, when a jejunum of less length than half the length of hypopharyngeal defect is transferred. Thus, we use a jejunum length that was between half and the full length of the hypopharyngeal defect. The degree of free jejunum tension was divided into 3 groups according to the ratio of the transferred jejunum length to the defect length. Free jejunum tension was defined as high when the ratio was smaller than 66.7%, medium when the ratio was between 66.6% and 80%, and low when the ratio was larger than 80%. Finally, microvascular anastomosis of the jejunal artery and vein to cervical vessels was performed, and skin closure with permanent tracheostomy was performed.

Endpoints

The primary endpoint was the proportion of dysphagia-free patients at 6 months after surgery. The secondary endpoint was the proportion developing surgical complications during the postoperative hospital stay. Dysphagia-free patients had to have met all of the following criteria at 6 months after surgery: (1) never experienced swallowing dysfunction greater than grade 2 in the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 (Table 1), (2) never experienced clinically evident dysphagia, (3) never required balloon dilatation for dysphagia, (4) survived, and (5) never lost to follow-up.

Data Collection

Data were collected via a case report form (CRF). The treating surgeons in each institution sent CRFs to the study secretariat at the National Cancer Center Hospital East at patient registration, during the perioperative period and at 3 and 6 months after surgery. As preoperative data, the patients' age, sex, primary site, cancer status, preexisting comorbidities, and history of irradiation to the neck were recorded. As surgical factors, the operation time, amount of blood loss, neck dissection, type of the pharyngeal defect, and free jejunum tension were recorded. As postoperative data, the development and symptom of dysphagia and any requirement of balloon dilatation were also recorded. The postoperative complications evaluated were vascular thrombosis, free jejunum necrosis, anastomotic leakage, cervical infection, hematoma, and lymphorrhea. Furthermore, the development of postoperative ileus was also recorded.

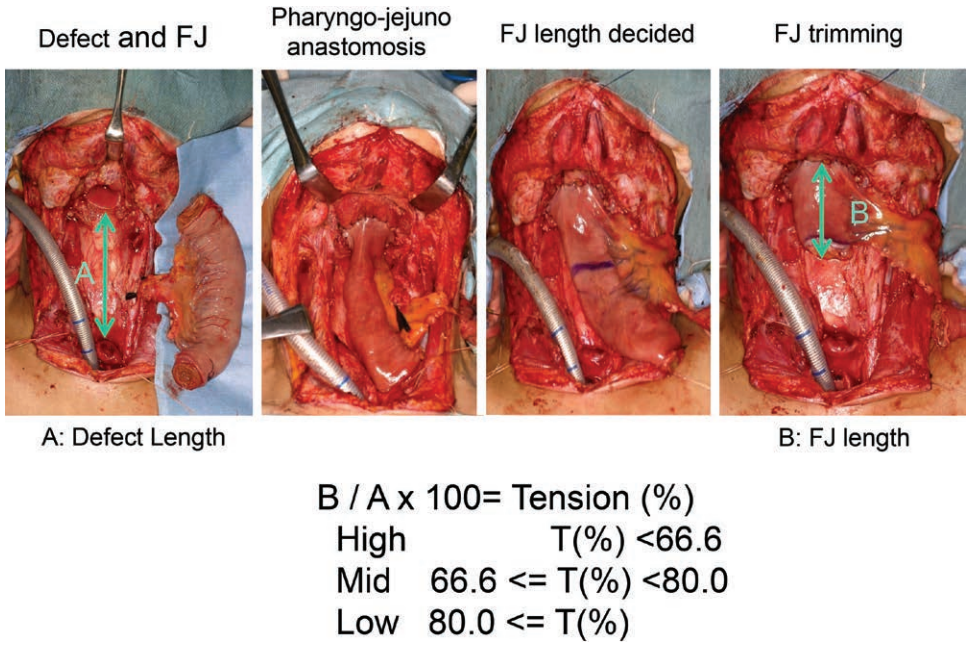

Fig. 1. Definition of free jejunum tension.

Table 1. Definition of Dysphagia Grade in CTCAE version 4.0

Grade 1. Symptomatic, able to eat regular diet
Grade 2. Symptomatic and altered easting/swallowing
Grade 3. Severely altered eating/swallowing; tube feeding or TPN or hospitalization indicated
Grade 4. Life-threatening consequences; urgent intervention indicated
Grade 5. Death

TPN, total parenteral nutrition.

Statistical Considerations

The primary endpoint was decided to have been met if the lower limit of the 95% confidence interval (CI; calculated by the Clopper and Pearson method) exceeded its threshold value of 50%. The threshold value was determined based on a historical survey reporting that dysphagia occurred at a proportion of 49.2% when 715 patients were treated with standard FJT after TPLE. Of note, the eligibility criteria of the historical control survey were almost the same as this study. The expected value of the primary endpoint was 65%. Our primary aim was to evaluate the efficacy of the tensed and straight FJT method in reducing the rate of dysphagia. Patients who were diagnosed with laryngeal cancer, who underwent larynx-preserving surgery, or who underwent resection beyond the upper pole of the tonsil or beyond the cervical esophagus were planned to be excluded in the primary analysis. The primary analysis was planned to be performed approximately 6 months after enrolling 121 patients, giving a 1-sided alpha of 2.5% and power of 90%.

Except for in the primary analysis, we evaluated the efficacy of the method in question in both all registered patients and the primary analysis set. The proportion of patients who were dysphagia-free at 6 months and the proportion of patients who developed postoperative complications were presented with their 95% CIs. Fisher's exact test was used to evaluate the difference in these proportions among subgroups constructed based on the risk factors listed in Tables 4 and 6. Univariate and multivariate logistic regression analyses were performed to estimate the odds ratios and associated 95% CIs. Stepwise variable selection was performed in the multivariate regression model, which included all of the possible risk factors listed in Tables 4 and 6.

All P values were calculated as 2-sided, and $P < 0.05$ was considered to indicate statistical significance. The IBM SAS Statistics software program, version 9.4 (SAS Institute Inc., Cary, N.C.), was used.

RESULTS

Baseline Data

Between August 2012 and July 2015, 128 patients from 10 institutions were registered in this study, and 7 were excluded based on the exclusion criteria. The exclusions were due to a different diagnosis in 2 patients, larynx-preserving surgery in 2 patients, advanced resection in 2 patients, and withdrawal of agreement in 1 patient. As a result, 121 patients were ultimately evaluated. The present and historical patient demographic data are shown in Table 2. Most of the patients had primary hypopharyngeal cancer, and 25% had recurrent cancer after radiation therapy. Preexisting diabetes mellitus was observed in 19 patients (15.7%) in the study group, whereas the rate was 7.6% in the historical controls.

Operative Findings and Surgical Complications

The median length of the hypopharyngeal mucosal defect was 10.0 cm and that of the transferred jejunum was 5.5 cm. FJT was carried out with high tension in 82 cases, me-

Table 2. Patient Characteristics

Variables	Present Study (n = 121), No. Patients	Historical Control (n = 764), No. Patients
Age (y)	68 (median)	63.8 (average)
Sex		
Male	108 (89.3%)	NA
Female	13 (10.7%)	NA
Primary site		
Hypopharynx	109 (90.1%)	NA
Cervical esophagus	12 (9.9%)	NA
Cancer status		
Primary cancer	90 (74.4%)	612 (80.1%)
Recurrent cancer	31 (25.6%)	85 (11.1%)
Unknown	—	67 (8.8%)
Prior irradiation		
Yes	32 (26.4%)	217 (28.4%)
No	89 (73.6%)	523 (68.5%)
Unknown	—	24 (3.1%)
Diabetes mellitus		
Yes	19 (15.7%)	58 (7.6%)
No	102 (84.3%)	676 (88.5%)
Unknown	—	4 (0.5%)

Historical control data extracted from Sugiyama et al.[6]

dium in 34, and low in 5 cases (Fig. 2). Bilateral neck dissection was performed in most patients (72.7%). The types of pharyngeal defect were horizontal in 64 cases and oblique in 37. Bilateral neck dissection was performed in most patients. The median total operating time was 531 minutes, and the average was 534.5 minutes. The median amount of blood loss was 290 ml, and the average was 349.6 ml.

Postoperative Dysphagia

Postoperative dysphagia was observed in 41 patients at least once during the 6-month follow-up period. Of these, dysphagia had been observed in 28 cases by 3-month follow-up and in 34 cases by 6 months. Continuous dysphagia was observed in 21 patients from 3 to 6 months postoperatively. Of 41 patients, 3 patients died (2 because of cancer recurrence and 1 because of respiratory complications), and 10 were lost to follow-up. Five patients required balloon dilation. Ultimately, the proportion not developing postoperative dysphagia within 6 months was 66.1% (95% CI: 57.0–74.5%) among 121 patients. The primary objective of this study was met because the lower limit of the 95% CI was higher than the prespecified threshold value of 50.0%. With regard to radiotherapy, swallowing dysfunction occurred in 50.0% of the patients who received postoperative radiotherapy, 25.0% of those who received preoperative radiotherapy, and 25.5% of the nonirradiated patients.

Postoperative Complications

Surgical complications at the neck were observed in 47 patients (38.8%; 30.1–48.1%). Of these, vascular thrombosis was observed in 5 cases and resulted in total necrosis of the transferred jejunum, requiring immediate second FJT in all cases. Partial necrosis of the transferred jejunum developed in 1 patient. Cervical infection was observed in 12 cases, and anastomotic leakage was observed in 11 cases. Anastomotic leakage resulted in pharyngocutaneous fistula in 5 cases, and additional surgical intervention was required in 3 cases. Other cases of anastomotic leakage were healed with conservative treatment. Among the 40

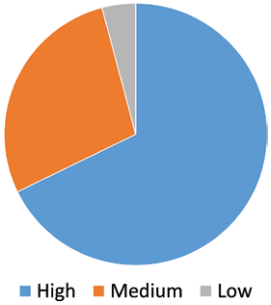

Fig. 2. Distribution of free jejunum tension.

patients with other complications, wound dehiscence was observed in 21 cases, lymphorrhea in 11 cases, postoperative bleeding in 8 cases, and other minor complications in 24 cases. The development of postoperative dysphagia was not related to the degree of free jejunum tension (Table 3). As systemic complications, brain infarction and pulmonary alveolus bleeding were observed in 1 case each. The patient with pulmonary alveolar bleeding could not resume oral feeding and died during his hospital stay. Postoperative ileus was observed in 2 cases during their hospital stay and was treated conservatively.

Univariate/Multivariate Analyses

We conducted subgroup analyses for factors listed in Table 4. Neither preoperative nor intraoperative factors were found to be risk factors for the development of postoperative dysphagia up to 6 months postoperatively. A statistical evaluation revealed that only postoperative radiotherapy was a significant risk factor for the development of dysphagia, both in univariate and multivariate logistic regression analyses, with a P value of 0.014 calculated by Wald's test (Table 5).

Adjuvant Therapy and Cancer Recurrence

Adjuvant radiation therapy or chemoradiation therapy was administered in 30 patients who were at a high risk of cancer recurrence, such as those with extracapsular spread of lymph node metastasis or positive surgical margins. Cancer recurrence was observed in 9 patients, and 2 patients died during the 6-month follow-up period because of cancer recurrence.

Table 3. Overall Results of the Present Study in Comparison with Historical Data

Variables	Present Study (n = 121)	Historical Control (n = 764)
Data collection	2012–2015	1996–2005
Study design	Prospective	Retrospective
No. FJT	121 (100%)	715 (93.6%)
Average operating time (range)	534.5 min (237–822)	573 min (482–878)
Average bleeding (range)	349.6 ml (50–1858)	611 ml (413–955)
Overall complications	47/121 (38.8%)	114/420 (27.1%)
Vascular thrombosis	5/121 (4.1%)	27/674 (4.0%)
Postoperative infection	12/121 (9.9%)	163/581 (28.1%)
Anastomotic leakage (fistulas)	11/121 (9.1%)	105/640 (16.4%)
Postoperative dysphagia*	41/121 (33.9%)	123/250 (49.8%)

*P = 0.0002, statistical significant difference between studies, binominal test.

Table 4. Subgroup Analysis for Proportion of Dysphagia-free till 6 Months (Univariate Analysis)

Variables	*N*	Overall Nondysphagia Proportion (95% CI)	*P* value, Binominal Test	Odds Ratio (95% CI)
Postoperative complications				
Yes	47	61.7% (46.4%-75.5%)	0.4364	0.669 (0.303–1.476)
No	74	68.9% (57.1%-79.2%)		1
Age younger than median				
Yes (<68)	56	64.3% (50.4%-76.6%)	0.7048	1
No (≥68)	65	67.7% (54.9%-78.8%)		1.039 (0.475–2.272)
Gender				
Male	108	65.7% (56.0%-76.6%)	1.0000	1
Female	13	69.2% (38.6%-90.9%)		10.45 (0.300–3.642)
Primary site				
HPC	109	67.9% (58.3%-76.5%)	0.3345	1
CE	12	50.0% (21.1%-78.9%)		0.519 (0.148–1.824)
Cancer status				
Initial cancer	90	63.3% (52.5%-73.2%)	0.3791	1
Recurrent cancer	31	74.2% (55.4%-88.1%)		1.463 (0.583–3.671)
Diabetes mellitus				
Yes	19	57.9% (33.5%-79.7%)	0.4362	0.683 (0.241–1.933)
No	102	67.6% (57.7%-76.6%)		1
Previous irradiation				
Yes	32	75.0% (56.6%-88.5%)	0.2779	1.533 (0.621–3.887)
No	89	62.9% (52.0%-72.9%)		1
Operating time (min) shorter than median				
Yes (<531)	60	71.7% (58.6%-82.5%)	0.2500	1
No (≥531)	61	60.7% (47.3%-72.9%)		0.524 (0.236–1.162)
Amount of bleeding (ml) less than median				
Yes (<290)	58	67.2% (53.7%-79.0%)	0.8491	1
No (≥290)	63	65.1% (52.0%-76.7%)		0.801 (0.366–1.755)
Neck dissection				
No	16	68.8% (41.3%-89.0%)	0.9524*	1
Unilateral	17	70.6% (44.0%-89.7%)		1.091 (0.247–4.817)
Bilateral	88	64.8% (53.9%-74.7%)		0.960 (0.303–3.037)
Pharyngeal defect				
Horizontal	84	67.9% (56.8%-77.6%)	0.5402	1
Oblique	37	62.2% (44.8%-77.5%)		0.663 (0.684–4.305)
Free jejunum tension				
High	82	62.2% (50.8%-72.7%)	0.4657*	1
Medium	34	73.5% (55.6%-87.1%)		1.716 (0.684–4.305)
Low	5	80.0% (28.4%-99.5%)		2.196 (0.234–20.613)
Postoperative RT/CRT				
Yes	30	50.0% (31.3%-68.7%)	0.0215*†	0.339 (0.143-03803)
No	87	74.7% (64.3%-83.4%)		1
NA	4	0.0% (0.0%-60.2%)		NA

*Fisher's multiple comparison test.
†*P* value calculated after excluding patients with missing data.
CE, cervical esophagus; CRT, radiation therapy; HPC, hypopharynx; NA: not accessed; RT, radiation therapy.

Table 5. Multivariate Logistic Regression Analysis for Proportion of Dysphagia-free at 6 Months (4 Patients Were Excluded for Evaluation due to the Lack of Data)

Variables	*N*	Odds Ratio (95% CI)	Wald *P* Value
Postoperative RT/CRT			
No	87	1.00	0.0140
Yes	30	0.339 (0.143–0.803)	

RT, radiation therapy
CRT, chemoradiation therapy

DISCUSSION

This multi-institutional prospective study aimed to assess whether patients who received tensed and straight FJT experienced better subsequent swallowing function than historical controls. Postoperative dysphagia was observed in 41 patients (33.9%), and the proportion of no dysphagia was 66.1% in the study group, versus 50.2% in the historical control study. Therefore, tensed and straight FJT was associated with a significantly better swallowing function than the technique used with the historical controls. To our knowledge, this trial is the first prospective multi-institutional study to evaluate the proportion of postoperative dysphagia based on the method of FJT reconstruction. Furthermore, the subjects were restricted to those who underwent FJT after TPLE for squamous cell carcinoma of the hypopharynx or cervical esophagus.

Carlson et al. reported a lower proportion of functional failure with FJT (20%) than with musculocutaneous reconstruction (40%) or colon reconstruction (42%). Although their report indicated a lower functional failure proportion, the result was based on a small sample, and feeding tube dependence was the only criterion for swallowing dysfunction. Reece et al. retrospectively evaluated the swallowing function of 91 patients who underwent FJT for circumferential defect of the hypopharynx. They also reported that only 20% of patients had some degree of dysphagia and required supplemental tube feeding.

Table 6. Subgroup Analysis of Complications (Univariate Logistic Regression Analysis)

Variables (Baseline)	Evaluation	Odds Ratio (95% CI)	Wald *P* Value
Age (median or older, ≥68)	Age < 68	0.982 (0.301–3.204)	0.9762
Sex (male)	Female	1.139 (0.340–3.824)	0.8326
Primary site (HPC)	CE	1.699 (0.744–3.882)	0.2085
Cancer status (initial Ca)	Recurrent Ca	0.687 (0.241–1.953)	0.4809
Diabetes mellitus (no)	Yes	1.572 (0.693–3.562)	0.2788
Previous irradiation (no)	Yes	1.831 (0.872–3.842)	0.1098
Operating time (<531)	Operating time ≥531	1.642 (0.783–3.442)	0.1890
Bleeding (<290 ml)	Bleeding ≥290	1.875 (0.467–7.526)	0.2447
Neck dissection (no)	Unilateral	0.952 (0.317–2.865)	0.3852
	Bilateral	0.797 (0.357–1.779)	0.5790
Pharyngeal defect (horizontal)	Oblique	1.152 (0.509–2.604)	0.8711
Free jejunum tension (high)	Medium	1.097 (0.173–6.934)	0.9814
	Low	2.196 (0.234–20.613)	0.6510

CE, cervical esophagus; HPC, hypopharynx.

However, only 59% of the patients could tolerate a regular diet in their report. In our study, patients who required changes to their food intake were also defined as having dysphagia. Furthermore, we also included dysphagia data from patients who died during the study period or were lost to follow-up. Despite our severe criteria for dysphagia, our results were comparable to those of previous reports.

Sugiyama et al. conducted a retrospective, multiinstitutional study to evaluate the reconstructive results after TPLE in a Japanese population and found the incidence of dysphagia to be 49.2%. Although their report was retrospective, the number of the patients was large enough (764 cases) to perform statistical evaluations. We therefore selected their report as the historical control for comparison. However, although those authors examined patients who had undergone a number of different procedures for free jejunum suturing, such as end-to-side anastomosis, mechanical suture anastomosis, and suturing without craniocaudal tension, only the tensed and straight FJT method was used in our study protocol. We hypothesized that the tensed and straight method would result in a significantly improved swallowing function compared with other methods. Our data showed that the lower limit of the 95% CI exceeded the prespecified threshold value of 50% (1-sided binomial test, $P = 0.0002$), which met the primary endpoint. As a result, the tensed and straight FJT was concluded to be effective in reducing the proportion of swallowing dysfunction. We therefore believe that free jejunum grafts should be transferred using the tensed and straight method. However, the degree of tension was not found to have a statistically significant effect on the swallowing outcomes in the subgroup analysis (Table 4). This is because of the small number of patients in the low-tension group.

Many risk factors affecting the postoperative swallowing function have been reported, such as high age, history of irradiation, radical neck dissection, and postoperative radiation therapy. However, neither the preoperative nor intraoperative factors were defined as risk factors for the development of postoperative dysphagia in this study. A statistical evaluation revealed that only postoperative radiotherapy was a significant risk factor for the development of dysphagia. The negative effects of postoperative radiation therapy on the postoperative swallowing function have been well documented in previous reports.[9,10] This may be due to postoperative mucosal edema of the transferred jejunum or stiffness of the surrounding cervical soft tissue or scar formation caused by irradiation. The effects of irradiation will change according to the time of follow-up; as such, a longer follow-up is required to evaluate the exact effects of radiation therapy.

The rate of developing postoperative complications was the secondary endpoint. Although previous irradiation, diabetes mellitus, recurrent cancer, and wider resection are well-known risk factors for postoperative complications, they were not defined as risk factors in this study. In addition, among these risk factors, the free jejunum tension was not related to the development of complication (Table 6). Furthermore, the proportion of surgical complications in this study tended to be lower than in the historical control study. Theoretically, the tensile strength at the enteric anastomosis can exacerbate the development of wound dehiscence and anastomotic leakage. Although it did not reach statistical significance, the frequency of anastomotic leakage was lower in this study than in the historical study (9.1% vs 16.4%, Table 3). Given these findings, we believe that the tensed and straight FJT method will not increase the risk of postoperative complications.

Several limitations associated with this study warrant mention. First, this was a nonrandomized study, and the results were not obtained from a direct comparison between the tensed method and nontensed methods. Second, the appropriate degree of tension for FJT was not clear in this study. These points should be clarified in a future randomized prospective study. In addition, our definition of the tension of the FJT inset tended to be a subjective evaluation. However, it is impossible to obtain 100% objective data in the evaluation of surgical procedures. We therefore measure the length of defect and the jejunum intraoperatively to evaluate the FJT tension as objectively as possible. Although our data are not perfectly objective, we believe that our evaluation still has some important scientific merit.

CONCLUSIONS

The frequency of postoperative dysphagia was significantly lower in our study group than in the historical

controls. The frequency of complications was not increased with the tensed and straight method of FJT. Given these findings, we believe that free jejunum transfer should be performed with the tensed and straight method.

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