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Timing of Oral Feeding in Patients Who have Undergone Free Flap Reconstruction for Oral Cancer

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Objective: Determine the safety and effectiveness of a nasogastric tube removal plan designed to shorten nasogastric tube indwelling time after oral cancer surgery plus free flap reconstruction.

Materials and Methods: A parallel randomized clinical trial was conducted from May 2021 to December 2021 at Peking University School of Stomatology. Volunteers ($n = 128$) were separated into four groups: non-tracheostomy control and intervention groups and tracheostomy control and intervention groups. Control patients received the conventional nasogastric tube removal plan. Non-tracheotomy intervention patients were asked to swallow 5 ml of water on the first postoperative day. If there was no coughing, they were allowed progressively increasing amounts of water for the following 2 days. The nasogastric tube was removed only after ensuring level I/II performance on the Watian water swallowing test, no "wet voice" after drinking water, no marked decrease in blood oxygen saturation after drinking, and satisfactory daily oral nutritional intake. Tracheotomy intervention patients received the same protocol plus an additional Watian water swallowing test after tracheal tube removal.

Results: Nasogastric tube removal time was earlier in the intervention subgroups than in control subgroups: 5.0 ± 2.3 days versus 7.8 ± 3.9 days ($p = 0.001$) in non-tracheostomy patients and 9.8 ± 1.1 days versus 16.2 ± 13.0 days ($p = 0.049$) in tracheostomy patients. Incidence of wound complications and daily food intake were comparable between the groups. The incidence of pneumonia was lower in the tracheostomy intervention group than in the tracheostomy control group (12.5% vs. 3.1%, $p = 0.162$). Pharyngeal pain score was lower in tracheotomy intervention patients than in tracheotomy control patients ($p = 0.029$). Postoperative hospital stay was shorter in tracheotomy intervention patients than in tracheotomy control patients ($p = 0.005$).

Conclusions: On the basis of ensuring safety and effectiveness, patients undergone free flap reconstruction for oral cancer could be offered oral intake early after surgery, which will not increase the incidence of wound complications and pneumonia or adversely affecting the oral intake of the patients; it can also help minimize pharyngeal pain and shorten postoperative hospital stay of patients with a tracheotomy.

Key Words: nasogastric tube remove plan, oral cancer, free tissue flap, early oral intake, swallowing function.

Level of Evidence: 2

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INTRODUCTION

According to the International Agency for Research on Cancer, 377,713 new cases of oral cancer were diagnosed in 2020 and there were 177,757 related deaths.[1] Following tumor resection, free tissue flap surgery is widely used for the restoration of shape and function. The surgery causes major trauma and often results in damage to oral organs, muscles, and nerves, with postoperative wound infection and dysphagia being common complications. According to some studies, early swallowing action may lead to wound dehiscence or fistula formation.[2,3] Malnutrition may also occur because wound pain causes patients to limit oral intake in the early postoperative period.

To maintain gastrointestinal mucosal integrity and ensure adequate nutritional intake, nasogastric tube feeding is commonly used postoperatively.[4] The duration of nasogastric tube placement depends on the individual surgeon's experience, with the decision mostly being based on satisfactory oral wound healing and the patient's ability to swallow. In previous studies, the nasogastric tube indwelling time has ranged from 5 to 63 days (mean, 13 days),[5] the wide variation reflecting the lack of a standard, scientifically sound plan for nasogastric tube removal. Prolonged indwelling time may cause complications such as nasal pressure ulcers and eustachian tube dysfunction. It can also lead to aggravated dysphagia and increase the risk of malnutrition.[6,7] The indwelling nasogastric tube causes discomfort, and up to 23.26% of patients complain of pharyngeal pain[8]; some patients even extubate themselves because of the discomfort.

The expert consensus on the perioperative management of patients with free tissue flap reconstruction for head and neck cancer (issued by the Society for Enhanced

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Recovery after Surgery in 2017[9]) recommends early resumption of oral feeding after surgery. The benefits of early nasogastric tube removal have been confirmed in patients undergoing surgery for laryngeal cancer and esophageal cancer,[10,11] but there have been few studies in patients with oral cancer. In our study, we designed a nasogastric tube removal plan for two types of patients (those with and without tracheostomy) according to the patients' swallowing function and oral intake, and performed this parallel randomized clinical trial to determine the safety of the methods and their effectiveness in facilitating the early resumption of oral feeding.

MATERIALS AND METHODS

This prospective, randomized controlled trial was approved by the Ethics Committee of Peking University School of Stomatology (No. PKUSSIRB-202164064). Written informed consent was obtained from all patients.

Patients

Patients with oral cancer admitted to Peking University School of Stomatology from May 2021 to December 2021 were invited to participate in this clinical trial. Participation was purely voluntary. The inclusion criteria were (1) pathological diagnosis of oral cancer; (2) treatment by extended resection of oral and maxillofacial lesions + free tissue flap repair (forearm/fibula/anterolateral femur/iliac/); (3) normal body mass index (18.5–23.9 kg/m^2), serum albumin (40.0–55.0 g/L), and hemoglobin (115–150 g/L); and (4) no participation in other clinical trials within the previous 3 months. The exclusion criteria were (1) history of oral and maxillofacial radiotherapy; (2) high tension at the suture of the intraoral wound (determined by the surgeon after the operation); (3) history of dysphagia due to other causes (e.g., stroke); or (4) inability to follow the investigators' instructions due to any reason.

METHODS

Normally, a patient suffering aspiration during oral feeding can cough out the aspirated food. However, in a patient with a tracheostomy, the indwelling tracheal cannula will hinder the closure of the pharynx and glottis; the subglottic air pressure and pharyngeal pressure are significantly reduced, and the glottic reflex is weakened; thus, the aspirated food will not be removed and may enter the lung. Therefore, in this study, patients were grouped according to whether or not they had undergone tracheostomy. After the surgery plan was determined, a random number table was used to assign the selected patients into one of four groups: a non-tracheotomy control group ($n = 32$), a non-tracheostomy intervention group ($n = 32$), a tracheotomy control group ($n = 32$), and a tracheostomy intervention group ($n = 32$). The researcher responsible for patient enrollment and randomization was not involved in the collection of data on outcome indicators; this information was recorded by clinicians and nurses not involved in the study. The disposable nasogastric tube used in this study (registration No. 20152141018; Beijing Lingze Pharmaceutical Technology Development Co., Ltd., Beijing, China) was made of medical polyurethane, and had a length of 1.2 m and outer and inner diameters of 4.0 and 2.8 mm, respectively).

Control Groups

Non-tracheostomy control patients received the conventional nasogastric tube removal plan, that is, according to the surgeon's assessment of the wound healing and swallowing ability. For tracheotomy control patients, after the tracheal tube was removed, the timing of nasogastric tube removal depended on the wound and swallowing conditions.

Intervention Groups

The nasogastric tube removal plan was devised to ensure safety and effectiveness, with each patient's swallowing function being assessed by nurses specializing in dysphagia.

Non-tracheotomy patients. On day 1 after surgery, patients who were able to swallow saliva were allowed a sip of 5 ml of water. If no cough was induced, a nurse instructed the patient to have 5 ml of water orally every time thirst was experienced. The amount of water was increased to 15 ml per drink on the second day and to 30 ml on the third day. If there was no cough or other discomfort, the nasogastric tube was removed after checking that four conditions were met: (1) the Watian water swallow test (WWST) was rated as level I or level II. The WWST was proposed by the Japanese scholar Toshio Kubota in 1982, which was considered a reliable screening tool for swallowing disorders.[12] The patient is asked to drink 30 ml of warm water, and according to the time taken to drink this volume and the presence or absence of coughing, the results are divided into 5 grades, with grade I and grade II indicating that the patient has no coughing when drinking water. The test is simple to apply and has a sensitivity of 64%–79% and specificity of 61%–81% for the diagnosis of aspiration, (2) no "wet voice" after drinking water, (3) blood oxygen saturation decreased by less than 3% within 5 min after oral water intake, and (4) daily oral intake more than 2000 ml. If these conditions were not met, the fluid intake plan of the previous day was continued until such time as all four conditions were met. Fig. 1 summarizes the protocol followed.

Tracheotomy patients. The postoperative water intake plan and nasogastric tube removal conditions were the same as in non-tracheotomy patients. However, to ensure safety, these patients also underwent the WWST after the removal of the tracheal tube.

All patients were followed up by the nurses at 2 weeks and 1 month after the operation, with special attention paid to the oral wound healing, swallowing function, and dietary intake. Personalized guidance was provided to each patient.

Outcome Measures

Patient characteristics (age, sex, surgical site, type of free tissue flap, preoperative WWST level); time to removal of nasogastric tube (recorded by the nurse).

Wound complications included surgical site infection (wound dehiscence or wound pus) and fistula formation.[13] Wound dehiscence was defined as the separation of the closed skin incision edge; wound pus was defined as the presence of redness and purulent secretions at the incision; fistula formation was defined as the formation of a pathological channel between the skin and the deep tissue at the wound. Physicians evaluated patients on the 6th postoperative day, at the time of discharge, and at 1 month after the operation.

Pneumonia was suspected if the patient had excessive sputum production after the operation. Chest radiographs were obtained if fever was present. Pneumonia was diagnosed if the chest radiograph was positive (i.e., new or progressive infiltrating shadows, consolidation shadow, or ground glass shadow) and there were two or more of the following three clinical symptoms: (1) fever, with temperature >38°C; (2) purulent airway secretion; and (3) peripheral blood cell count >10 × 10^9/L or <4 × 10^9/L.[14] Patients were evaluated by the doctor during hospital stay and followed up by the nurse after discharge. All patients complaining of fever, cough and excessive sputum underwent detailed examination and were evaluated as having or not having pneumonia (Yes/No).

The outcome of the flap was evaluated by the doctor at 1 month after the operation, and classified as "survived" or "necrosed."

Daily food intake of patients from 1 day before nasogastric tube removal to 3 days after nasogastric tube removal was recorded by a nurse, both during hospital stay and during follow-up visits.

Pharyngeal pain (before nasogastric tube removal and at 24 h after its removal) was evaluated by a nurse using a visual analog scale (VAS); the pain was graded on a scale of 0 to 10, where "0" represented no discomfort and "10" represented the maximum discomfort.

Postoperative hospital stay was recorded, and hospitalization costs were calculated.

Statistical Analysis

The sample size calculation was based on the findings of a pilot study conducted initially to verify the safety and feasibility of the proposed procedures and the feasibility of the trial design. The pilot study was performed on 17 patients (9 non-tracheostomy patients and 8 tracheostomy patients), with time to nasogastric tube removal as the outcome index. Sample size estimation was performed using the two independent sample mean estimation formulae, in which, α was set as 0.05, β was set as 0.2, and a two-sided test was conducted; by table lookups $t\alpha/2 = 1.96$, and $t\beta = 1.28$. According to the pilot study test, $\sigma^2 = 24.11$ and $\delta^2 = 19.8$, $N1 = N2 = 2*[(t\alpha/2 + t\beta)\sigma/\delta]^2 \approx 26$. Assuming a drop-out rate of 20%, we estimated that at least 32 patients per group would be required (a total, of 128 patients).

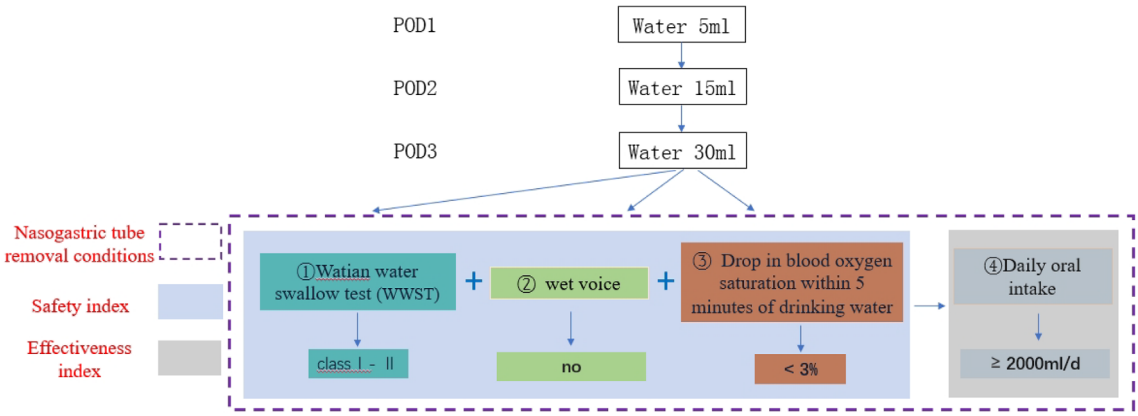

Fig. 1. Nasogastric tube removal plan. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

TABLE I.
Patient and surgery characteristics.

		Non-tracheostomy patients				Tracheostomy patients			
		Control group ($n = 32$)	Intervention group ($n = 32$)	Z/χ^2	p	Control group ($n = 32$)	Intervention group ($n = 32$)	Z/χ^2	p
Age, years (mean ± SD)		49.2 ± 12.8	47.3 ± 17.9	−0.188	0.851*	53.0 ± 12.4	56.5 ± 11.8	−1.176	0.240*
Sex (n, %)	Male	17 (53.1)	16 (50.0)	0.063	0.802†	21 (65.6)	22 (68.8)	0.071	0.790†
	Female	15 (46.9)	16 (50.0)			11 (34.4)	10 (31.2)		
Surgical site (n, %)	Buccal	7 (21.9)	10 (31.3)	4.952	0.550†	0 (0.0)	0 (0.0)	4.546	0.603†
	Maxilla	4 (12.5)	8 (25.0)			3 (9.4)	4 (12.5)		
	Mandible	11 (34.4)	7 (21.9)			9 (28.1)	13 (40.6)		
	Tongue	2 (6.3)	3 (9.4)			5 (15.6)	7 (21.9)		
	Mouth Floor	1 (3.1)	1 (3.1)			6 (18.8)	4 (12.5)		
	Palate	6 (18.8)	2 (6.3)			4 (12.5)	1 (3.1)		
	Root of tongue	1 (3.1)	1 (3.1)			4 (12.5)	3 (9.4)		
	Lip	0 (0.0)	0 (0.0)			1 (3.1)	0 (0.0)		
Type of free flap (n, %)	RFFF	6 (18.8)	12 (37.5)	2.891	0.409†	4 (12.5)	4 (12.5)	6.517	0.089†
	Fibula flap	6 (18.8)	5 (15.6)			14 (43.8)	15 (46.9)		
	ALTF	9 (28.1)	6 (18.8)			12 (37.5)	5 (15.6)		
	Iliac crest	11 (34.4)	9 (28.1)			2 (6.3)	8 (25.0)		
Preoperative WWST level (n, %)	I–II	31 (96.9)	32 (100.0)	1.016	0.313†	32 (100.0)	31 (96.9)	1.016	0.313†
	III–V	1 (3.1)	0 (0.0)			0 (0.0)	1 (3.1)		

*Wilcoxon rank sum test.
†Chi-squared test.

Two investigators analyzed the outcome measures. Continuous data were summarized as means ± SD or medians (with range), depending on the normality of the distribution, and compared between groups using the independent samples *t*-test or the Wilcoxon rank sum test, as appropriate. Count data were summarized as percentages and compared using the chi-squared test. Statistical analysis was performed with SPSS 17.0 (SPSS Inc., Chicago, IL). $p < 0.05$ indicated statistical significance.

RESULTS

Patient and Surgery Characteristics

There were no significant differences in age, sex, surgical site, free tissue flap type, and WWST results between the tracheostomy and non-tracheostomy patients ($p > 0.05$; Table I).

Tube Removal Time, Pharyngeal Pain, Wound Complications, Pneumonia, Flap Outcome, Postoperative Hospital Stay, and Hospitalization Costs

Nasogastric tube removal was significantly earlier in the two intervention groups than in the two control groups (Table II). Among tracheotomy patients, the mean pharyngeal pain score was significantly lower in the intervention group than in the control group. There were no significant differences between the other groups. Postoperative hospital stay was significantly shorter in the tracheostomy intervention group than in the control group ($p = 0.005$); there were no significant differences between the groups in the incidence of wound complications and pneumonia or in hospitalization costs.

Daily Food Intake

Mean daily food intake in the four groups fluctuated between 2204 ml on the day of nasogastric tube removal and 2272 ml at 3 days after nasogastric tube removal. The differences between the groups were not statistically significant. Fig. 2 is a contour map of the daily food intake in the four groups before and after nasogastric tube removal, calculated by one-way repeated measures ANOVA. The lines show that all patients had reduced food intake on the day of nasogastric tube removal and on day 1 after nasogastric tube removal; however, the amount exceeded 2000 ml and increased progressively. By day 3, the volume ingested was the same as that before nasogastric tube removal.

DISCUSSION

The postoperative indwelling nasogastric tube is commonly used to ensure adequate nutritional intake in

TABLE II.
Tube removal time, pharyngeal pain, wound complications, pneumonia, flap outcome, postoperative hospital stay, and hospitalization costs.

		Non-tracheostomy patients				Tracheostomy patients			
		Control group ($n = 32$)	Intervention group ($n = 32$)	Z	*p*	Control group ($n = 32$)	Intervention group ($n = 32$)	Z	*p*
Tube removal time (mean ± SD)	Nasogastric tube	7.8 ± 3.9	5.0 ± 2.3	−3.843	0.001*	16.2 ± 13.0	9.8 ± 5.3	−1.969	0.049*
	Tracheal tube					6.1 ± 2.3	5.8 ± 1.1	−0.375	0.707*
Pharyngeal pain (mean ± SD)	Before NGT removal	2.9 ± 2.3	2.4 ± 1.9	−0.511	0.609*	4.3 ± 2.5	2.9 ± 1.9	−2.187	0.029*
	Day 1 after NGT removal	0.8 ± 1.3	0.6 ± 1.0	−0.525	0.600*	1.4 ± 1.7	0.8 ± 1.1	−1.600	0.110*
Wound dehiscence (*n*, %)		0	0	−0.192	0.849†	1 (3.1)	1 (3.1)	−0.699	0.487†
Wound pus (*n*, %)		2 (6.3)	3 (9.4)			3 (9.4)	1 (3.1)		
Fistula (*n*, %)		1 (3.1)	0			1 (3.1)	1 (3.1)		
Pneumonia (*n*, %)	No	32 (100)	32 (100)	0	1.000†	28 (87.5)	31 (96.9)	−1.397	0.167†
	Yes	0	0			4 (12.5)	1 (3.1)		
Flap outcome (*n*, %)	Survived	31 (96.9)	32 (100.0)	1.016	0.313†	31 (96.9)	30 (93.8)	0.350	0.554†
	Necrosed	1 (3.1)	0 (0.0)			1 (3.1)	2 (6.3)		
Length of postoperative hospital stay, days (mean ± SD)		8.6 ± 3.3	7.5 ± 1.2	4.745	0.065‡	10.4 ± 3.2	8.6 ± 1.7	6.867	0.005‡
Hospitalization costs, USD (mean ± SD)		11.2 ± 3.2	10.2 ± 2.6	−1.386	0.339*	13.4 ± 3.4	13.5 ± 2.7	0.208	0.782*

Note: The annual average exchange rate in 2021 (6.45:1) was used to convert RMB to US dollars.
NGT = nasogastric tube; SD = standard deviation.
*Wilcoxon rank sum test.
†Chi-squared test.
‡Independent sample *t*-test.

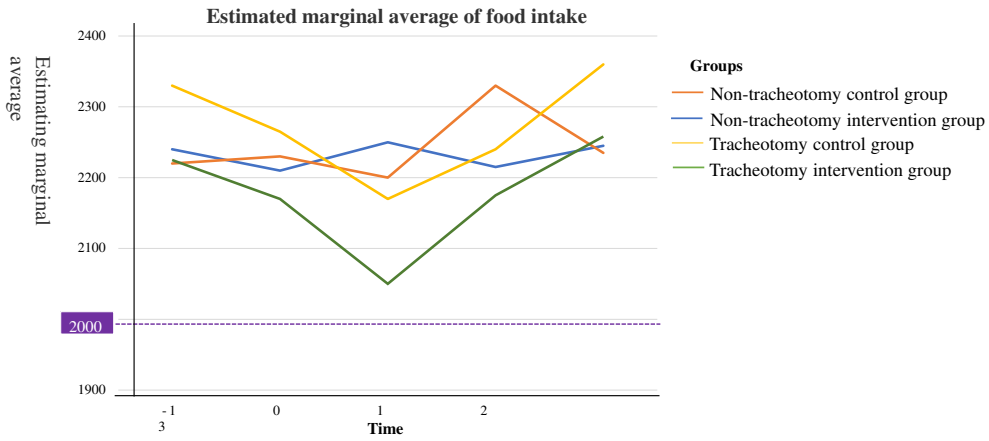

Fig. 2. Contour map of daily food intake before and after nasogastric tube removal in the four groups. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

oral cancer patients treated with free tissue flap. At present, clinical decision-making on the extubation time is based on the treating doctor's experience; therefore, many patients have prolonged indwelling nasogastric tubes.[5] The incidence of postoperative dysphagia in patients with oral cancer-free flaps is as high as 41.3%–88.0%,[15] and the trauma of intraoral surgery is large. Early resumption of oral feeding is associated with a risk of aspiration, pneumonia, and wound complications. In addition, although some patients can eat orally, the swallowing action will aggravate the pain of the wound; this may cause patients to limit their food intake, and malnutrition could result. Therefore, we designed a nasogastric tube removal protocol for such patients for safety and effectiveness, and selected and combined the corresponding indicators that can explain these effects. We hope that this protocol is easy for clinical care to implement, without invasive procedures and without increasing patient burden. Therefore, the selected indicators are all rigorous and recognized clinical evaluation methods.

Safety

Our protocol was designed to avoid patient aspiration, whereas wound complications and pneumonia were observed.

First, according to the judgment standard of aspiration[16]: (1) cough during or after swallowing; (2) wet voice after drinking water; (3) the basal blood oxygen saturation decreases by more than 3% after drinking water, we devised a rigorous clinical evaluation method based on three indicators of aspiration: after the patient passed the WWST (level I or level II), the sound quality was assessed by asking the patient to state his or her name immediately, listening to whether the patient has a "wet voice," and blood oxygen saturation drop by less than 3% within 5 min after oral water intake.

Second, we assessed whether early oral eating increases the risk of wound complications. Previous studies have shown that patients with total laryngectomy can take liquid food orally on the first day after surgery, and that food contact with newly formed mucosa at the wound suture site actually promotes wound healing.[10] Early oral feeding also promotes salivary secretion, which reduces the risk of wound infection.

Known independent risk factors for postoperative wound infection in patients with oral cancer are radiotherapy history, tracheotomy, nutritional status, and the type of surgical incision.[17,18] No study to date has identified early oral feeding as a risk factor for wound infection. Our study found no statistically significant differences between groups in the incidence of wound complications. The overall incidence of wound infection in our cohort was 10.9%, which is consistent with the findings of Yarlagadda et al.[19] Wound dehiscence in the oral cavity was not observed in any patient during the period of hospital stay, but it is possible that some patients with oropharyngeal and tongue base wound dehiscence may have been missed. There were two cases of wound dehiscence: one patient had dehiscence of the neck wound after neck dissection on the 7th day after surgery, and after half a month of dressing changes, the wound healed itself. Another had dehiscence of the leg wound due to the high-tension closure at the fibula donor site, the wound healed after the patient underwent skin grafting on the contralateral limb.

Third, we examined the incidence of postoperative pneumonia. According to the literature, the incidence of pneumonia in patients receiving reconstruction with free flap ranges from 5.4% to 23%,[20,21] with recognized risk factors being advanced age, alcohol abuse, poor oral hygiene, dysphagia, radiotherapy, and postoperative reduction in physical activity.[22,23] Aspiration caused by dysphagia can also lead to pneumonia. None of the non-tracheostomy patients developed pneumonia. Among patients with tracheostomy, the incidence of pneumonia was comparable in the control group and the intervention group. During follow-up (at 2 weeks and 1 month), no patient had symptoms suggestive of pneumonia. Therefore, we infer that early removal of the nasogastric tube does not increase the risk of postoperative wound complications and pneumonia in oral cancer patients treated with a free flap.

Effectiveness

We assessed the effectiveness of the nasogastric tube removal plan by examining whether oral nutritional intake was sufficient to meet daily needs. Most patients with oral cancer are 50–70 years old.[24] According to the 2014 National Physical Fitness Monitoring Bulletin,[25] the average weight of patients in this age-group is 59.2–70.6 kg. According to the Nutritional Support Guidelines for Cancer Patients,[26] normal calorie requirement is 25–30 $kcal \cdot kg^{-1} \cdot d^{-1}$ and protein requirement is 1.0–2.0 $g \cdot kg^{-1} \cdot d^{-1}$. Therefore, a minimum of 1480–1765 kcal, and 59.2–70.6 g of protein is required daily. A 2000-ml liquid diet contains about 1700 kcal of energy and 70 g of protein, which should be sufficient to meet nutritional needs in this age-group. Therefore, intake of at least 2000 mL of liquid food was used as an indicator of effectiveness in this study. We found that the daily food intake in the intervention groups from 1 day before nasogastric tube removal to 3 days after nasogastric tube removal was not lower than in the control groups. In all four groups, food intake on day 3 after nasogastric tube removal was equal to that on the day before nasogastric tube removal, indicating that our plan does not increase the risk of postoperative malnutrition.

Our study showed that nasogastric tube removal was significantly earlier in the two intervention groups than in the respective control groups, indicating that the proposed nasogastric tube removal plan can effectively shorten the indwelling time of the tube. Postoperative hospital stay was significantly shorter for tracheotomy intervention patients than for tracheostomy control patients, indicating that early oral feeding can shorten the postoperative hospital stay of patients, probably via promotion of swallowing and digestive functions; Pharyngeal pain score before extubation in the tracheotomy intervention group was lower than that in the tracheotomy control group ($p < 0.05$), which was mainly related to the longer indwelling time of the nasogastric tube in the tracheotomy patients.

Study Limitations

This study was single-center hospital-based study, with a limited period of hospitalization. Some patients were discharged from the hospital with the indwelling nasogastric tube in place. Post-discharge WWST evaluation, daily oral intake, and so on were self-reported by patients during follow-up visits.

CONCLUSION

This study was a small-sample randomized clinical trial, that aimed to investigate whether patients undergone free flap reconstruction for oral cancer could be offered oral intake early after surgery. The result shows that the limiting aspect of oral intake is not wound healing, but the safety risk caused by aspiration, and the insufficient food intake risk due to wound pain and edema. Therefore, ensuring safety and effectiveness can facilitate the early resumption of oral feeding to these patients.

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