



# Scoring system for selective tracheostomy in head and neck surgery with free flap reconstruction

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## Abstract

**Background:** Selective tracheostomy is an effective but invasive airway management method for patients undergoing head and neck free flap reconstruction. Studies have shown that not all patients need tracheostomy. Several systems evaluating the need for tracheostomy have been proposed, but none is used clinically.

**Methods:** A total of 533 cases underwent head and neck free flap reconstruction at Peking University School of Stomatology were reviewed for system development. Another 131 cases undergone the same surgery were included for system verification. Patients' demographic and surgical-related information were analyzed.

**Result:** A total of 321 cases in the development cohort and 68 cases in the system cohort underwent tracheostomy. The score was estimated:  $\text{score} = \Sigma(\log_2 \text{OR})$ . Patients scoring  $>3$  required tracheostomy, those scoring  $<2$  should avoid tracheostomy, and those scoring 2 or 3 need further evaluation.

**Conclusion:** This scoring system can help determine the need for selective tracheostomy in patients undergoing head and neck free flap reconstruction.

## KEYWORDS

airway management, free flap reconstruction, head and neck, scoring system, tracheostomy

## 1 | INTRODUCTION

Patients who undergo head and neck surgeries with free flap reconstructions usually have a higher risk of airway obstruction, which makes selective tracheostomy a popular and effective method in such cases.<sup>1,2</sup> During an investigation in 2009 in approximately 30% institutions in the UK, Marsh et al<sup>3</sup> found that selective tracheostomy was performed in every case of head and neck surgery with free flap reconstruction. However, recent studies have shown that surgery can be safely performed in such patients without the need for selective tracheostomy,<sup>4,5</sup>

which can help to avoid tracheostomy-related complications<sup>6,7</sup> and delayed recovery.<sup>8,9</sup> Several scoring systems<sup>10-14</sup> have been established to evaluate the need for selective tracheostomy in these patients, although none of these have been widely used in the clinical setting. Therefore, decisions for tracheostomy are usually dependent on surgeons' experiences and preferences.<sup>15</sup>

Airway obstruction for these patients is a serious complication that may lead to acute asphyxia, brain damage, and even death, thus the management of postoperative airway is utmost important. However, tracheostomy is not without risks and hazards. In the present study, we

aimed to develop a clinically feasible evaluation system for performing selective tracheostomy in patients undergoing head and neck surgeries with free flap reconstruction to avoid unnecessary tracheostomy while maintaining a patent airway.

## 2 | PATIENTS AND METHODS

Cases of head and neck surgery with free flap reconstruction, performed at the Peking University School of Stomatology from January 2015 to December 2016 were included. Cases involving reconstruction with more than one flap, as well as those requiring emergency surgery or preoperative tracheostomy, were excluded. All the patients were examined using the standard methods and were determined to be appropriate for undergoing surgery. All surgeries were conducted by the same anesthetic, surgical, and nursing team, and all tracheostomies were performed transcutaneous in the standard way. All the patients without tracheostomy were extubated within 24 hours after surgery and were kept in the post-anesthesia care unit for 8-20 hours.

Patient demographic information, etiology factors (especially malignant tumor), surgical defects, the need for neck dissection, type of flaps, general conditions, and complications were recorded based on the result in previous studies. All related factors were included as potential factors; univariate and multivariate analyses were performed to identify the risk factors. Logistic regression was performed to determine the odds ratio (OR) for each risk factor, and the score of each case was calculated using the formula:  $t = \Sigma(\log_2 OR)$ .<sup>11</sup> The median value was determined in both the tracheostomy and non-tracheostomy group. The Mann-Whitney rank sum test was used for assessments between the two groups.

The values between the median values of the two groups were considered as potential thresholds, and the accuracy, positive predicative value (PPV), and negative predicative value (NPV) were calculated. Thresholds with high accuracy (>75%) and acceptable PPV and NPV (>0.7) were adopted, and the cases were accordingly categorized into three groups: cases requiring selective tracheostomy, cases not requiring selective tracheostomy, and cases requiring further evaluation during surgery. Receiver operating characteristic (ROC) curves were established, and the area under curve (AUC) was calculated to evaluate the efficacy of the system.

To evaluate the clinical applicability of the system, we included cases that underwent head and neck surgery with free flap reconstruction by the same surgical and nursing team from January to July 2017, after certain inclusion and exclusion criteria were met. The

patients were assigned to the tracheostomy and non-tracheostomy groups, and the demographic information, surgical defects, the need for neck dissections, types of flaps, general condition, and complications were recorded for each patient. The total score was estimated for each patient and was compared using the Mann-Whitney test between the groups. The scores were compared with those associated with the actual condition, and the accuracy, false-positive rate, and false-negative rate were determined. An accuracy of >80% was considered to be acceptable.

All the measured data were analyzed using IBM SPSS Statistics, version 20.0 (IBM, Armonk, New York). *P* value of <.05 was considered statistically significant.

## 3 | RESULTS

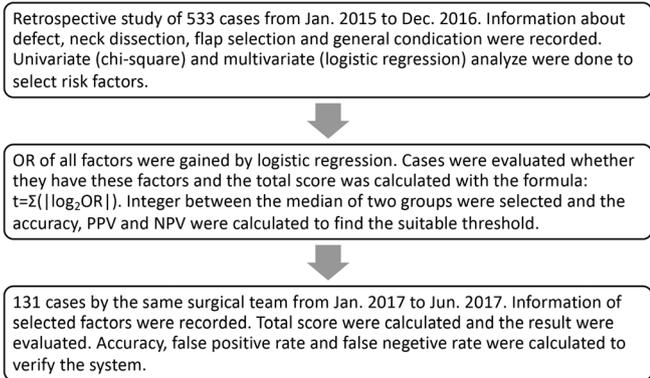
A total of 533 cases that met the criteria were included in the system development cohort. Of these cases, 321 (60.2%) underwent selective tracheostomy and 1 underwent emergency tracheostomy within 12 hours postoperatively. The male to female ratio was higher in the tracheostomy group. Malignant tumor was the most common etiology in the tracheostomy group, whereas benign and malignant tumor exhibited a similar ratio in the non-tracheostomy group (Table 1). The study workflow is shown in Figure 1.

### 3.1 | Risk factor selection

Based on the literature, we selected and categorized potential risk factors into four groups: defect-related factors, neck dissection-related factors, flap-related factors, and general condition-related factors (Table 2). Our data showed that defects of the bilateral mandible, tongue, floor of mouth, or oropharynx; unilateral or bilateral neck dissection; thick soft tissue flap reconstruction;

**TABLE 1** Patient demographic and etiology data in the system development cohort

	Tracheostomy	Non-tracheostomy
Mean age	54.54 ± 14.9	45.48 ± 18.13
Male to female ratio	220:101	109:103
Etiology		
Benign tumor	28	99
Malignant tumor	270	99
Inflammation	17	7
Tissue defect	6	12



**FIGURE 1** Workflow of the study

history of radiotherapy; and smoking habits were the risk factors for selective tracheostomy.

### 3.2 | Development of the evaluation system

The abovementioned risk factors were included into a logistic regression model, and ORs were estimated for each risk factor (Table 3). All risk factors showed significant difference between the tracheostomy and non-tracheostomy group, with an OR of  $>2$  and a score ranging from 1 to 4.

The total score in each case was determined, and the absolute frequency of total score in both the groups and the distribution is shown in Figure 2. Most patients with zero or one point were handled without selective tracheostomy, whereas those with four or more than four points were more likely to receive tracheostomy.

The median score of tracheostomy group was 7, whereas non-tracheostomy group got 1, and the Mann-Whitney rank sum test showed significant differences in the total score between the two groups ( $P < .001$ ).

Based on the median value of both groups, we selected 2-6 points as potential thresholds. The accuracy, PPV, and NPV of each threshold were obtained. We found that the evaluation system had a high accuracy and acceptable PPV and NPV at a threshold of 2 or 3, whereas the accuracy and NPV decreased at a threshold of  $>3$  (Table 4). This finding suggests that patients scoring  $<2$  should avoid selective tracheostomy, those scoring  $>3$  should undergo selective tracheostomy, and those scoring 2 or 3 should be evaluated further based on our data. ROC curves were established, and the AUC was found to be  $0.892 \pm 0.013$  ( $P < .001$ ), which suggests an acceptable efficacy for the system (Figure 3).

### 3.3 | Clinical verification of the evaluation system

An additional 131 cases that met the inclusion criteria were assessed for system verification. Among these patients, 68 (51.9%) underwent selective tracheostomy. There were a greater number of male patients than female patients in both groups. However, the distribution of etiology was similar to that in the system development cohort (Table 5).

The total score for each patient was calculated retrospectively using the scoring system, and the score distribution was similar to that in the system development cohort (Figure 4). The Mann-Whitney rank sum test also showed significant differences in the total score between the two groups ( $P < .001$ ). The ROC curve and AUC also showed satisfied result with AUC of  $0.913 \pm 0.023$  ( $P < .001$ ; Figure 5).

The threshold in the verification cohort also showed high accuracy, false-positive rate, and acceptable false-negative rate. After excluding cases that required further evaluation (those who got two or three points) (Table 6), we found that the accuracy was 88.89%, false-positive rate was 4.26%, and false-negative rate was 17.31%, thus achieving the study goal (accuracy  $>85\%$ ). The AUC of this part was  $0.913 \pm 0.023$  ( $P < .001$ ), also showed a satisfied efficacy.

### 3.4 | Complications and subsequent consequences

One case (0.47%) without selective tracheostomy developed airway obstruction within 12 hours postoperatively. This was a case of a 68-year-old man with sarcoma of right mandible, with defect of hemimandible, tongue and floor of mouth, unilateral neck dissection, and smoking habit, had a total score of 6 according to our scoring system. The patient received emergency tracheostomy, and the airway was secured but showed symptoms of pneumonia on the second day after tracheostomy. Another 11 patients experienced slight discomfort while breathing postoperatively, but no tracheostomy was needed. Among patients with tracheostomy, 27 (8.39%) developed tracheostomy-related complications (one scored one point, two scored three points, and others scored more than four points) and all were diagnosed and treated accordingly. Pneumonia (14 cases, 4.35%) occurred most commonly in patients who received tracheostomy, followed by hemorrhage (12 cases, 3.73%), subcutaneous emphysema (4 cases, 1.24%), and accidental dislodgement of the tracheostomy tube (2 cases, 0.62%). However, only one patient (0.47%) without tracheostomy developed

**TABLE 2** Analysis of potential risk factors

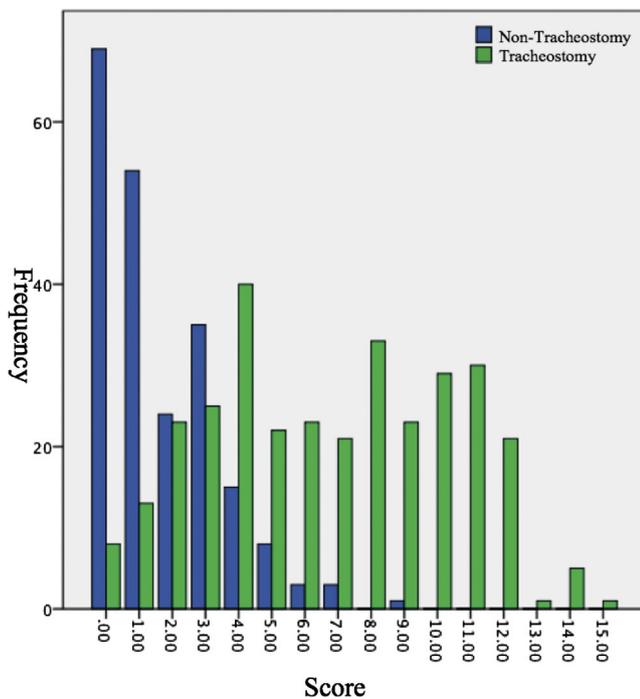
	Tracheostomy	Non-tracheostomy	P	Odds ratio	P
Malignant tumor	270	99	<.001	2.178	.07
Maxilla					
Unilateral	7	33	<.001	0.942	.92
Bilateral	8	11	.10		
Mandible					
Unilateral	38	98	<.001	1.122	.32
Bilateral	37	9	.003	31.651	<.001
Cutaneous, lip, and buccal	15	2	<.001	0.763	.77
Tongue	55	2	<.001	9.293	.002
Mouth floor <sup>a</sup>	48	17	.02	4.533	.01
Oropharynx <sup>a</sup>	126	27	<.001	6.590	<.001
Unilateral neck dissection	143	77	<.001	2.241	.01
Bilateral neck dissection	97	6	<.001	9.617	<.001
Thin soft tissue flap	49	38	.42		
Thick soft tissue flap	99	35	<.001	2.356 <sup>b</sup>	.03
Osseous tissue flap	175	138	.02	0.457 <sup>b</sup>	.22
History of surgery	112	83	.36		
History of radiotherapy	41	15	.03	4.107	.002
History of chemotherapy	18	5	.07		
Respiratory diseases	24	4	.004	3.733	.11
High blood pressure	76	34	.03	1.006	.99
Diabetes	30	12	.11		
Cardiovascular and cerebrovascular diseases	34	18	.40		
Hepatopathy	8	4	.63		
Nephropathy	1	0	.41		
Hemopathy	6	3	.94		
Smoking	133	43	<.001	2.603	.004
Alcohol abuse	101	25	<.001	1.178	.43

<sup>a</sup>Along with its combined defects.

<sup>b</sup>Compared with cases undergoing thin soft tissue flap reconstruction.

	OR	95% CI		P	Score
		Lower	Upper		
Bilateral mandible defect	24.442	10.177	58.603	<.001	4
Bilateral neck dissection	6.267	2.035	19.298	.001	3
Radiotherapy	3.395	1.526	7.556	.003	2
Oropharynx defect	3.311	1.855	5.910	<.001	2
Tongue defect	3.185	1.183	8.579	.02	2
Mouth floor defect	3.102	1.476	6.521	.003	2
Unilateral neck dissection	2.842	1.624	4.974	<.001	1
Smoking	2.356	1.380	4.204	.002	1
Bulky flap reconstruction	2.149	1.177	3.925	.01	1

**TABLE 3** Logistic regression of risk factors for selective tracheostomy



**FIGURE 2** Distribution of scores in the system development cohort [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

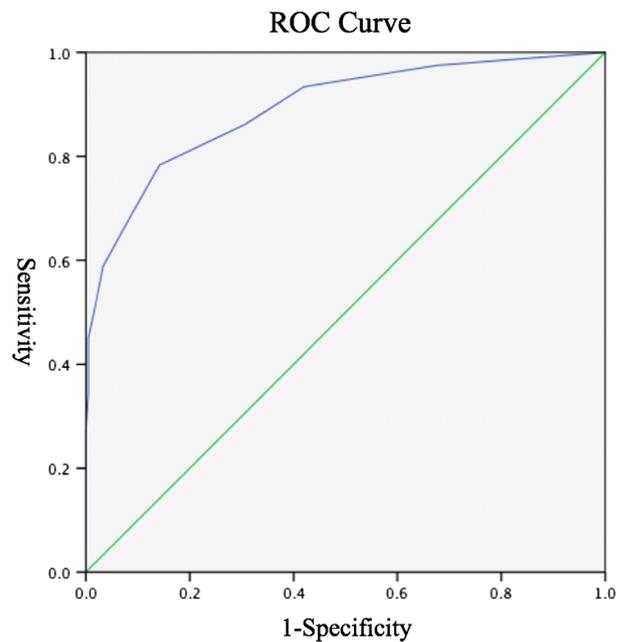
**TABLE 4** Selection of threshold scores

Threshold	Accuracy	PPV	NPV
2	79.43	0.808	0.770
3	81.32	0.892	0.725
4	76.98	0.933	0.644
5	73.96	0.964	0.610
6	70.19	0.976	0.575

Abbreviations: NPV, negative predicted value; PPV, positive predicted value.

pneumonia postoperatively while five patients (1.55%) acquired more than one tracheostomy-related complications, but no serious comorbidities or death directly related to tracheostomy was recorded.

Decannulation was done following occlusion of uncuffed tracheostomy tube for 24 hours. On an average, most patients in the tracheostomy group were decannulated  $7.87 \pm 1.78$  days after surgery, and the average length of postoperative hospital stay was  $9.11 \pm 1.98$  days, except for one patient (a 56-year-old man with left buccal squamous cell carcinoma) who suffered from necrosis of the first anterolateral thigh flap along with wound infection and who was decannulated on the 22nd day after the first surgery and discharged on the 33rd day after surgery. No delayed extubation or airway related re-intubation was needed in the non-tracheostomy group. There were also no significant differences between the two groups on other local and general complications.



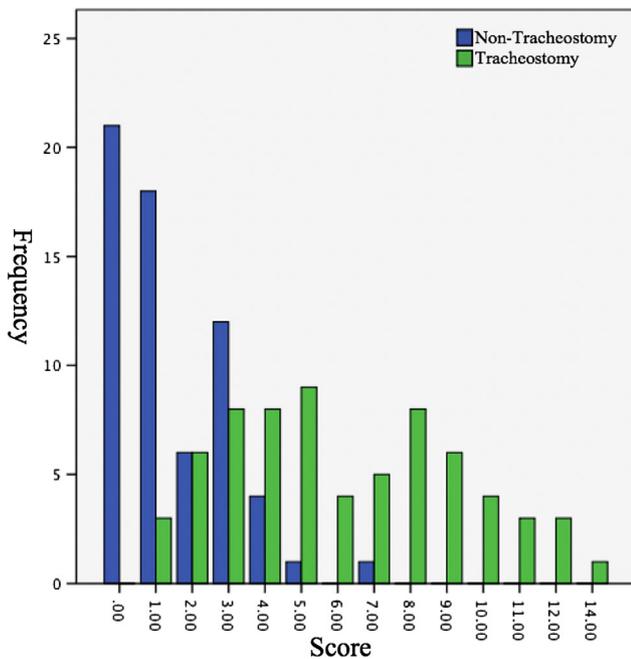
**FIGURE 3** Receiver operating characteristic (ROC) curves of the evaluation system [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

**TABLE 5** Patient demographic and etiology data in the system verification cohort

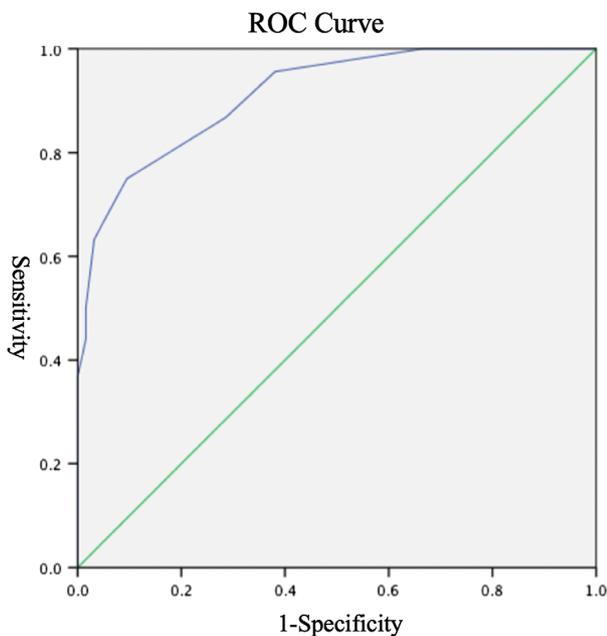
	Tracheostomy	Non-tracheostomy
Mean age	$54.58 \pm 12.51$	$44.15 \pm 15.70$
Male to female ratio	46:22	44:19
Etiology		
Benign tumor	3	22
Malignant tumor	61	35
Inflammation	0	2
Tissue defect	4	4

## 4 | DISCUSSION

Selective tracheostomy is the preferred method for avoiding airway obstruction in patients undergoing head and neck surgery with free flap reconstruction. However, certain studies indicated that some of these patients do not require selective tracheostomy, given its associated complications, and thus surgeons should consider carefully before making the decisions for selective tracheostomy.<sup>6</sup> Although selective ventilation is not necessary in most patients with head and neck free flap reconstruction, longer postoperative recovery time and occasionally longer length of stay (LOS) in ICU were observed in patients with elective tracheostomy, which directly increased the total medical costs. In a study conducted by Coyle et al,<sup>15</sup> the average LOS in ICU for patients with tracheostomy was



**FIGURE 4** Distribution of scores in the system verification cohort [Color figure can be viewed at wileyonlinelibrary.com]



**FIGURE 5** Receiver operating characteristic (ROC) curves of the verification part [Color figure can be viewed at wileyonlinelibrary.com]

2.6 times longer than those without tracheostomy or subjected for delayed extubation. The total LOS was noted to be 1.4 times longer, which added approximately 4808£ to the medical costs for patients with tracheostomy. Other studies,<sup>1,3,10,16</sup> however, concluded that it was the nature of the surgery, instead of tracheostomy that caused

**TABLE 6** Comparison between the scoring recommendations and actual practice

	Need tracheostomy <sup>a</sup>	Do not need tracheostomy <sup>a</sup>
Tracheostomy	43	9
Non-tracheostomy	2	45

<sup>a</sup>According to the result from the scoring system.

significant increase in the total medical cost and the LOS in ICU. However, to our knowledge, no standard evaluation methods are available yet for selective tracheostomy in these patients, and the decision regarding tracheostomy is relied on the experience of the surgeon.

In 2005, Kruse-Lösler et al<sup>10</sup> established the first scoring system for patients undergoing major head and neck tumor surgery. Based on 152 cases of oral cancer, the scoring system evaluated the need for selective tracheostomy according to tumor location, tumor size (T stage), chest radiography findings, multimorbidity, and alcohol consumption. A score of 6 was determined as the threshold. This is the first evaluation system in this field and received a satisfied result in their patients. However, the flap-related factors were not considered as not all the cases in the study had undergone free flap reconstruction; in fact, only 59 cases had received radial forearm flap reconstruction, and no other types of flap reconstruction procedures were noted. There was also no related study that acknowledges the feasibility of the system to date.

Cameron et al<sup>11</sup> proposed another scoring system for guiding airway management following major head and neck surgery in 2009. After evaluating 148 cases of head and neck surgery, the researchers assessed the need for selective tracheostomy according to the tumor site (cutaneous, mouth, and oropharynx), mandibulectomy, and bilateral neck dissection and reconstruction (none, radial forearm free flap, or other free flaps), with 5 considered as the “trigger score.” Compared to the previous study, this study included free flap reconstruction as a risk factor but ignored previous treatments, comorbidities, and personal habits such as smoking and alcoholism abuse, which were listed as indications of selective tracheostomy in some other studies. Some other institutions conducted studies to verify the applicability of this system; in particular, Lee et al<sup>17</sup> observed that this scoring system was not consistent with the actual airway management in their patients in 2015.

Gupta et al<sup>12</sup> proposed another version for determining the criteria for tracheostomy in cases with head and neck malignancies in 2016. Out of the 386 cases with malignant tumor of the head and neck, 175 had

undergone free flap reconstruction, which makes this the largest sample in the literature. The scoring system included six major criteria (history of radiotherapy, multi-site resection, bilateral neck dissection, extended hemi or central arch mandibulectomy, bulky flap reconstruction, and flap with a compressing element; two points were assigned for each criterion) and four minor criteria (age > 65 years, previous operation at the same site, trismus, and pathological chest computed tomography findings; one point was assigned for each criterion). Patients with a total score of  $\geq 7$  were recommended to undergo tracheostomy. This system also yielded a satisfied result in their own patients. Though covered most risk factors while clinically friendly, the methodology of this system remained untested, have yet to be verified clinically.

In 2017, Leiser et al<sup>13</sup> described the indications for selective tracheostomy following reconstructive surgery in patients with oral cancer and developed a scoring system. Their study included only 75 patients with oral cancer and did not account for free flap reconstruction. Their scoring system included nine major factors and 50 minor items, and patients scoring  $\geq 8$  were considered as high-risk patients. However, the items exhibited considerable overlap, which increased the difficulty of its use in the clinical setting, while the limited sample also affected the applicability of the system.

In a recent study in 2018, Mohamedbha et al<sup>14</sup> assessed 149 cases with head and neck cancer with primary flap reconstruction and developed a scoring system based on the tumor staging, types of reconstruction, anatomy of the tumor, coexisting medical conditions, history of previous treatment for head and neck cancer, and laterality with bilateral neck dissection; a threshold of 4 offered satisfactory sensitivity and specificity. The system classified the anatomical regions into four categories: lateral (zero point), central (zero point), anterior (two points), and oropharyngeal (two points), according to the classification by Schache et al<sup>18</sup> in 2009. However, as multiregion defects are common in the clinical setting, this system appears to be clinically impractical.

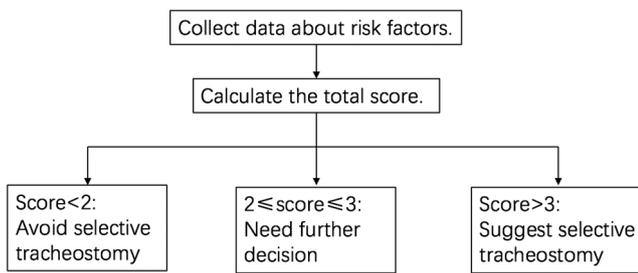
These five scoring systems though can evaluate the risk of airway obstruction and the necessity of selective tracheostomy, none of these evaluation systems have been methodically verified in the clinical setting or have indicated poor validity. Moreover, the studies primarily included patients with head and neck surgeries (usually malignant tumors), without a sufficient number of cases with free flap reconstruction; therefore, the influence of flap reconstruction, particularly with regard to the choice of flap, is occasionally ignored. In addition, most of these studies included small sample populations (the largest included 386 cases with 175 that had undergone free flap reconstruction), and hence, their findings may be limited.

Since these systems have not been adopted clinically in most institutions, there are so far no rules for selective tracheostomy in head and neck free flap reconstruction. Most of these decisions were heavily depending on the clinical experience and inclinations of surgeons and anesthesiologists, adding a potential risk of postoperative airway obstruction as well as unnecessary tracheostomy.

In the present study of 533 patients undergoing head and neck surgery with free flap reconstruction, we found that among all the related factors, surgical defects (bilateral mandible, tongue, floor of mouth, and oropharynx), the need for neck dissection (unilateral and bilateral), bulky soft-tissue flap reconstruction, history of radiotherapy, and smoking habits were potential factors affecting the need for selective tracheostomy. Patients with malignant tumor were more likely to receive selective tracheostomy, possibly due to the different treatment modalities between malignant tumor and benign tumor as well as some nonneoplastic disorders. Patients with malignancy often require larger resection area and the need for neck dissection that may result in increased edema at cervical region and higher risk for airway obstruction postoperatively. Patients with tracheostomy also had an LOS of  $9.1 \pm 2.0$  days compared with  $8.1 \pm 1.9$  days in patients without tracheostomy ( $P < .001$ ). Although tracheostomy is not the main factor affecting the LOS, our data showed that patients with selective tracheostomy appear to occupy more medical source than those without tracheostomy. However, it is still difficult to evaluate only with these risk factors. The evaluating system, firstly, need to guarantee the safety of the patient, then reducing the unnecessary adverse effects from tracheostomy. A scoring system represents an easy approach to address this problem and is commonly employed for clinical decision-making.<sup>19</sup> Therefore, we believed that a clinically friendly scoring system could be established for patients undergoing head and neck surgeries with free flap reconstruction.

The tracheostomy rate of 60.2% in the present study was consistent with that in previous studies (range, 36.2%-71.4%) and with only one in the non-tracheostomy group suffered from airway obstruction, most cases in our cases recovered uneventfully postoperatively. We estimated the risk by the total score for each patient using the formula  $t = \Sigma(|\log_2 \text{OR}|)$ , as indicated in a previous study. The scoring system has been described in Figure 6. In both the system development and verification cohorts, the scoring system exhibited a marked difference in the score between the tracheostomy and non-tracheostomy group.

The scoring threshold for the need for tracheostomy should be carefully assessed. An ideal system would have a low false-negative rate, and hence patients who require selective tracheostomy are not neglected. Moreover, a



**FIGURE 6** The work line of the scoring system

low false-positive rate is also preferable, such that patients do not undergo an unnecessary tracheostomy. In the present study, those scoring 0 or 1 were less likely to undergo tracheostomy, and those scoring  $\geq 4$  were more likely to undergo tracheostomy.

Among all the cases in the present study, only one case with a score of 6 (defect of tongue [two points] and floor of mouth [two points], unilateral neck dissection [one point], and smoking habit [one point]), required emergency tracheostomy, and developed postoperative pneumonia, whereas most of the non-tracheostomy patients had uneventful postoperative recovery. In the tracheostomy group, however, there are still chances of related complication, as well as possible dysfunction postoperatively. The postoperative recovery period in the hospital also shows an increase in the tracheostomy group.

Our scoring system represents an optimized version of the systems described in the previous five studies. According to the previous literatures and our knowledge, we combined the various factors assessed into four categories, including surgical defects, the need for neck dissection, flap selection, and comorbidities. Instead of selecting the site and tumor size as a risk factor, they were replaced by the extent of the defect, which could directly influence the risk of airway obstruction. As free flap reconstruction is performed more routinely in the recent years following tumor ablation, particularly in cases with advanced tumors (T3 and T4), we specifically assessed patients with free flap reconstruction rather than all patients with oral and maxillofacial cancer. Furthermore, to our knowledge, this is the largest study of cases with head and neck surgeries with free flap reconstruction (533 in the system development cohort and 131 in the system verification cohort), and therefore, our system may have better applicability than other previous systems.

Given the retrospective nature of the present study, we could only classify the patients into the tracheostomy or non-tracheostomy group based on the decisions made by surgeons in the clinical setting; this might be biased if cases underwent unnecessary selective tracheostomy. There are still 20.08% (107 cases) of the establishment cases and 24.43% (32 cases) of the verification cases that

scored 2 or 3, in which cases this decision still rely on the experience of the surgeons and the system is still unable to provide sound judgment at the moment, and further work is needed to minimize the number of patients within this range. The false-negative rate in the verification group appeared to be higher than anticipated, which could be because of the patients who do not require tracheostomy but received tracheostomy eventually as the final decision for tracheostomy still relies on the clinical experience of the team. There are also patients scored 0 or 1 but finally received tracheostomy, which influenced the result evidently. Moreover, the airway management of these patients also depends on the facilities of medical institution and the setting of the medical team, so a multicenter study is still needed if we were to further validate this scoring system. Although the data were collected from the clinical records with satisfactory quality, the accuracy remains an important issue. Therefore, our system would still need verification from a larger sample and even from different institutions to assess the validity more fully, and surgeons should be fully aware of the bias when using the system. Prospective studies are needed to further evaluate the system to minimize the bias result from experience, especially in those patients with low score but still received emergency tracheostomy in our cases.

## 5 | CONCLUSION

Our scoring system could potentially help to determine whether selective tracheostomy is required in patients undergoing head and neck surgeries with free flap reconstruction, and the verification cohort has exhibited satisfactory outcomes thus far. Nevertheless, further verification is needed, and retrospective, prospective, and clinical trials should be conducted to improve the system.

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## CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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