



# Tracheal Stenosis After Intubation and Tracheostomy in Patients Admitted to Intensive Care Units: A Case-Control Study

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## Abstract

**Background:** One of the most dangerous complications after endotracheal intubation or tracheostomy is tracheal stenosis.

**Objectives:** This study aimed to determine the personal and clinical characteristics of tracheal stenosis following intubation or tracheostomy in intensive care unit patients.

**Methods:** This is a nested case-control study. Thirty-five patients who suffered from tracheal stenosis from March 2016 to March 2021 and had been intubated and tracheostomized in intensive care units (ICU) were selected for the case group. The control group included 105 patients intubated and tracheostomized in ICU during the same period without tracheal stenosis. A demographic and clinical characteristics questionnaire was used to collect data from the patients' medical records.

**Results:** The mean length of intubation ( $P < 0.001$ ), endotracheal and tracheostomy tube cuff pressure ( $P < 0.001$ ), chronic obstructive pulmonary disease (COPD) ( $P = 0.043$ ), intubation history ( $P = 0.045$ ), and airway management ( $P < 0.001$ ) showed significant differences between the case and control groups. The logistic regression model revealed that COPD (OR = 8.519,  $P = 0.037$ ), intubation history (OR = 3.939,  $P = 0.013$ ), length of intubation (OR = 1.118,  $P = 0.003$ ), age (OR = 0.960,  $P = 0.030$ ), and endotracheal and tracheostomy tube cuff pressure (OR = 1.988,  $P < 0.001$ ) were associated with tracheal stenosis. The time interval between intubation/tracheostomy ranged from approximately 28 to 938 days.

**Conclusions:** Given the impact of certain care practices during hospitalization on the occurrence of tracheal stenosis, such as the mean length of intubation, endotracheal and tracheostomy tube cuff pressure, and airway management, it is recommended that standardized training on these interventions be prioritized for staff in intensive care departments. Additionally, attention must be given to specific patient characteristics, such as age, COPD, and history of intubation.

**Keywords:** Intensive Care Unit, Intubation, Pressure, Tracheal Stenosis, Tracheostomy

## 1. Background

Patients admitted to intensive care units (ICU) often experience low levels of consciousness, acute respiratory failure, or cardiopulmonary arrest, and endotracheal intubation is a commonly performed procedure in critically ill patients (1). In these situations, it usually takes several days before the patient is extubated; therefore, with prolonged hospitalization, a tracheostomy is performed (2). Tracheostomy is a common procedure, performed in 2 - 11% of patients requiring mechanical ventilation in the ICU, and it is one of the most commonly performed procedures in

critically ill patients. Several advantages have been reported for performing tracheostomy following endotracheal intubation, including improving patient comfort, reducing airway resistance, ensuring safer and easier tracheal suction, improving patient communication, and enhancing oral feeding (3, 4). The tracheostomy tube is the preferred method of maintaining the airway in patients who require long-term intubation. The rate of intubation in the United States is 13 - 20 million per year (5). Although endotracheal intubation and mechanical ventilation are therapeutic approaches for managing critically ill patients, they are associated with serious complications.

A possible complication that can occur after endotracheal intubation is tracheal stenosis (6). Although iatrogenic tracheal injuries are very rare, they are considered life-threatening. Therefore, intubation is the most common cause of iatrogenic injuries (7, 8). The incidence of tracheal stenosis following laryngeal-tracheal intubation and tracheostomy has been estimated to be in the range of 6 - 21% and 0.6 - 21%, respectively (2, 9-11). The incidence of tracheal stenosis after intubation in Iran is relatively high, and most tracheal surgeries are performed to treat this type of stenosis (12). With the introduction of endotracheal tubes with high-volume low-pressure cuffs in the 1970s, the risk of tracheal stenosis after intubation has decreased, but its occurrence remains in the range of 6% to 21% and remains a problem (13). The cost of treating laryngeal-tracheal stenosis is significant, and patients with intubation-related stenosis have significantly higher annual costs than those with idiopathic stenosis. Therefore, laryngeal-tracheal stenosis is a costly consequence of tracheal intubation and generates high overall costs to the US healthcare system (14).

Due to the physical consequences and high costs, early diagnosis and consideration of risk factors are essential. However, despite the importance of the issue and the potential harm to patients, few studies have been conducted in this field. A study by Stuckey et al. reported the occurrence of laryngeal-tracheal stenosis between 32 days and three months after extubation (15). Increased cuff pressure in the endotracheal tube is considered the most important factor in tracheal stenosis after intubation (16). The Thoracic and Infectious Diseases Society of America recommended a cuff pressure level of 25 cmH<sub>2</sub>O (17). Several other predisposing factors for the development of tracheal stenosis after intubation and tracheostomy have been suggested; these include a high tracheostomy site, a history of intubation or tracheostomy in the past, high blood pressure at the time of intubation, excessive use of corticosteroids, old age, female gender and the effect of estrogen, severe respiratory failure, severe gastroesophageal reflux disease, obstructive sleep apnea, and radiotherapy for the treatment of laryngeal and oropharyngeal cancer (6, 18-22). Additionally, the recurrence of tracheal stenosis after surgery was observed in 24.2% of cases (23). It seems that the incidence of tracheal stenosis after intubation in developing countries will be significant in the coming years. Therefore, identifying the risk factors of this

complication and its treatment and prevention methods should be a priority for the health system (8). Among the most important points related to tracheal stenosis after intubation and tracheostomy are preventing the occurrence of this complication, implementing the correct treatment, and avoiding additional problems during the treatment, which leads to a reduction in hospital stays and ultimately a reduction in the cost of treatment. Therefore, accurately identifying each of these factors can play an important role in preventing tracheal stenosis caused by intubation and tracheostomy. Despite the importance of this issue, there are few reports in this field, and no study was found that investigated the demographic factors of patients in a cohort.

## 2. Objectives

Therefore, this study was conducted to determine the personal and clinical characteristics of confirmed cases of tracheal stenosis after intubation and tracheostomy in patients admitted to ICU.

## 3. Methods

### 3.1. Study Design

This is a case-control study nested in a cohort of patients who were admitted to the ICUs of Namazee and Shahid Faghihi hospitals in Shiraz, Iran, and underwent tracheal intubation from March 2016 to March 2021.

### 3.2. Participant and Sampling

After obtaining the ethics code and coordinating with the hospitals, we attended the archive section to perform the sampling. Two groups of patients were selected as cases and controls. The samples for both groups were patients whose records were available in the hospitals and were selected based on the inclusion criteria. The inclusion criteria were age over 18 years, ICU admission from March 2016 to March 2021, and residency in Shiraz. In addition, in both the case and control groups, patients underwent endotracheal intubation or tracheostomy. In the case group, a specialist confirmed the diagnosis of tracheal stenosis after intubation or tracheostomy, and the patient was readmitted to the same departments of the same hospitals where they had previously undergone intubation or tracheostomy. The control group did not

have tracheal stenosis at the time when the case group patients had tracheal stenosis. The exclusion criteria included patients who had previously received a diagnostic code associated with tracheal stenosis from a specialist physician but whose tracheal stenosis was not confirmed after intubation and tracheostomy, including pre-existing tracheal stenosis without a history of intubation and tracheostomy, total laryngectomy, obstruction of the intrathoracic airway due to cancer, out-of-hospital tracheostomy, and tracheal stenosis due to trauma to the neck.

The sample size in this research is based on the variable of the proportion of people with cuff pressure greater than 0.3 in the case and control groups ( $P_1 = 0.54$ ,  $P_2 = 0.25$ ) (24),  $k = 3$ ,  $\alpha = 0.05$ , and study power = 0.86. Thus, 35 people in the case group and 105 people in the control group were calculated by G\*power 3.1.9.4 software.

$$n_1 = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \times (P_1(1 - P_1) + P_2(1 - P_2))}{k(P_1 - P_2)^2}, n_2 = kn_1$$

After assessing 927 patient files from 2015 - 2016, we identified 35 patients with a definite diagnosis of tracheal stenosis after intubation or tracheotomy, who were selected as the case group. For each patient in the case group, three patients without tracheal stenosis were randomly selected as the control group. After sample selection, personal and clinical information for both groups was extracted from existing hospital records.

### 3.3. Tools and Instruments

The data collection method involved reviewing hospital records of the samples and then registering the information in the demographic and clinical characteristics questionnaire. The demographic and clinical characteristics questionnaire was a researcher-designed tool, adjusted based on Li's study (24) and Songu and Ozkul's research (11). The questions included the presence or absence of tracheal stenosis, diagnosis of disease, age, gender, weight, height, body mass index, smoking habit, alcohol consumption, asthma, chronic obstructive pulmonary disease (COPD), diabetes, hypertension, gastroesophageal reflux disease, intubation history, length of intubation, endotracheal tube size, tracheostomy technique (open vs.

percutaneous), airway management (intubation/intubation and tracheostomy), the mean time interval between intubation and the occurrence of tracheal stenosis, the mean time interval between tracheostomy and the occurrence of tracheal stenosis, endotracheal and tracheostomy tube cuff pressure (the cuff pressure was randomly selected on three days, including morning, evening, and night shifts from the beginning, middle, and end days of intubation), and mean endotracheal and tracheostomy tube cuff pressure (cmH<sub>2</sub>O).

The questionnaire consisted of 29 questions in 4 sections: Presence or absence of tracheal stenosis and diagnosis of disease (2 items), patient-related risk factors (14 items), treatment-related risk factors (8 items), and treatment procedure-related risk factors and cuff location (5 items). The content validity of the questionnaire was reviewed and approved by six nursing faculty members and two anesthesiology and critical care specialists. Since the above questionnaire was used to collect objective factors, only the content validity of the questionnaire was examined.

### 3.4. Data Analysis

After data collection, the data were entered into SPSS v26 software. The normal distribution of quantitative data was examined using the Kolmogorov-Smirnov test. Due to the non-normality of the data, the Mann-Whitney test was used to determine the relationship between independent quantitative variables and tracheal stenosis. The chi-square test was used to determine the association between independent qualitative variables and tracheal stenosis. Data from 140 cases were analyzed using backward stepwise logistic regression to determine the predictor variables of tracheal stenosis. The independent variables were the quantitative and qualitative variables from the questionnaire. The outcome variable was the presence or absence of tracheal stenosis. The level of statistical significance was set at less than 0.05.

## 4. Results

This case-control study included 140 patients, of which 35 were in the case group (with tracheal stenosis) and 105 were in the control group (without tracheal stenosis). Among the samples, 46.4% were women and 53.6% were men, with ages ranging from 19 to 88 years (mean age = 47.6). Table 1 compares the demographic

**Table 2 . Variables Associated with Tracheal Stenosis Based on Backward Stepwise Logistic <sup>a</sup>**

Variables	P-Value	Odd Ratio	95% CI for OR	
			Lower	Upper
Smoking (yes/no)	0.033	0.216	0.053	0.884
COPD (yes/no)	0.037	8.519	1.133	64.076
Hypertension (yes/no)	0.066	3.091	0.927	10.307
Intubation history (yes/no)	0.013	3.939	1.331	11.653
Length of intubation (day)	0.003	1.118	1.038	1.205
Endotracheal tube size (mm)	0.060	2.996	0.956	9.392
Mean ETT and tracheostomy tube cuff pressure (cmH <sub>2</sub> O)	0.001	1.988	1.338	2.952
Age (y)	0.030	0.960	0.924	0.996

<sup>a</sup>Variables entered on step1: Body Mass Index category, gender, smoking, alcohol consumption, asthma, COPD, diabetes, hypertension, intubation history, length of intubation, endotracheal tube size, mean (ETT) and tracheostomy tube cuff pressure, age.

and clinical characteristics of the case and control groups. Based on the statistical analysis, among the quantitative variables, the mean length of intubation ( $P < 0.001$ ) and the mean cuff pressure of the endotracheal and tracheostomy tube ( $P < 0.001$ ) showed significant differences between the case and control groups (Table 1). Among the qualitative variables, COPD ( $P = 0.043$ ), intubation history ( $P = 0.045$ ), airway management ( $P < 0.001$ ), and cuff pressure greater than 30 cmH<sub>2</sub>O ( $P < 0.001$ ) also showed significant differences between the case and control groups (Table 1).

The backward stepwise logistic regression model showed that COPD (OR = 8.519,  $P = 0.037$ ), intubation history (OR = 3.939,  $P = 0.013$ ), length of intubation (OR = 1.118,  $P = 0.003$ ), age (OR = 0.960,  $P = 0.030$ ), and mean endotracheal and tracheostomy tube cuff pressure (OR = 1.988,  $P < 0.001$ ) were associated with tracheal stenosis (Table 2).

The mean time interval between intubation and the occurrence of tracheal stenosis was 186.60 days (median = 125, minimum = 28, maximum = 942). The mean time interval between tracheostomy and the occurrence of tracheal stenosis was 191.22 days (median = 103, minimum = 28, maximum = 898) (Table 3).

## 5. Discussion

Among the quantitative variables, the mean length of intubation and the mean endotracheal and tracheostomy tube cuff pressure showed a significant difference between the case and control groups. These findings are consistent with those of previous studies that have shown that prolonged intubation and high

cuff pressure are major risk factors for tracheal stenosis after intubation or tracheostomy (24-28).

The length of intubation is related to the degree of mucosal ischemia and inflammation caused by the endotracheal tube, which can lead to fibrosis and scar formation (27). It is a well-known risk factor for tracheal stenosis, as prolonged intubation increases the exposure of the trachea to mechanical trauma and infection (26, 28). A study by Barreiro showed that the incidence of laryngotracheal stenosis in patients intubated for more than 11 days was 12%, for 6 - 10 days it was 5%, and for less than 6 days it was 2% (19). While the optimal length of intubation is not clearly defined, some studies suggest that intubation for more than 7 to 10 days increases the risk of tracheal stenosis (26, 28). Therefore, early extubation or elective tracheostomy should be considered for patients requiring prolonged mechanical ventilation (29). The onset of stenosis usually ranges from 28 to 168 days following extubation (30), but in our study, the time interval between intubation and the occurrence of tracheal stenosis was 28 to 942 days. Additionally, the time interval between tracheostomy and the occurrence of tracheal stenosis was 28 to 898 days.

Endotracheal tube cuff pressure is another important risk factor for tracheal stenosis; higher cuff pressure leads to more compression and ischemia of the tracheal mucosa (21, 24). Excessive cuff pressure can result in direct compression and necrosis of the tracheal wall, particularly at the cuff site or at the level of the cricoid cartilage (25, 27). Therefore, it is recommended to limit the length of intubation as much as possible and to monitor and adjust cuff pressure regularly to

**Table 3.** Comparison of the Time Interval Between Intubation/Tracheostomy and the Occurrence of Tracheal Stenosis

The Time Interval (day)	Mean	Median	Minimum	Maximum
Between intubation and tracheal stenosis	186.60	125	28	942
Between tracheostomy and tracheal stenosis	191.22	103	28	898

prevent excessive pressure on the trachea. An optimal cuff pressure of about 20 - 30 cmH<sub>2</sub>O has been determined to avoid aspiration pneumonia due to low cuff pressure and tracheal stenosis due to high cuff pressure (24, 31). However, many studies have reported that cuff pressures are often not monitored or maintained within the recommended ranges in clinical practice (32). Thus, regular measurement and adjustment of cuff pressure using a manometer or minimal occlusive volume technique should be performed to prevent tracheal injury (5). It is important to measure cuff pressure levels at intervals of 6 to 12 hours and use appropriate methods to correct them (33). A study by Dokoohaki et al. showed that while nurses' performance in measuring cuff pressure was appropriate, their knowledge about the normal range of cuff pressure and complications resulting from an abnormal range was low (34).

Among the qualitative variables, COPD, intubation history, airway management, and endotracheal and tracheostomy tube cuff pressure greater than 30 cmH<sub>2</sub>O showed significant differences between the case and control groups. In this study, COPD was associated with tracheal stenosis. This finding is consistent with previous studies reporting COPD as a risk factor for tracheal stenosis after intubation. Chronic obstructive pulmonary disease can lead to tracheal stenosis by causing chronic inflammation, mucosal damage, and impaired wound healing in the airways (9, 35). The history of intubation was another important variable, as patients who had been previously intubated were more likely to develop tracheal stenosis than those who had not. A study by Songu and Ozkul showed that patients intubated for more than 48 hours were more likely to develop tracheal stenosis than control patients (11). The incidence of tracheal stenosis after tracheostomy is higher than other complications, with rates of 1.1% following percutaneous tracheostomy and 1.9% following open tracheostomy (36). In this study, all patients had only undergone open tracheostomy, so we

could not determine the relationship between tracheal stenosis and the tracheostomy method.

Finally, cuff pressure greater than 30 cmH<sub>2</sub>O was a significant variable in our study, as patients with cuff pressures above this threshold were more likely to develop tracheal stenosis. This is consistent with previous studies suggesting that cuff pressures greater than 30 cmH<sub>2</sub>O can cause irreversible damage to the tracheal wall and compromise mucosal blood flow (24, 32). Attention to this problem is essential. Despite advances in medical science and the use of new technologies, studies have shown that these can be harmful to patients (37).

These results indicate that intubation history, age, COPD, length of intubation, and endotracheal and tracheostomy tube cuff pressure are independent risk factors for tracheal stenosis after intubation or tracheostomy, and that reducing the length of intubation and maintaining endotracheal tube cuff pressure at or below 30 cmH<sub>2</sub>O are protective factors. These findings align with previous studies that have identified similar risk and protective factors for post-intubation tracheal stenosis (20, 24, 25, 27). The use of an endotracheal tube larger than 7.5 mm was identified as a risk factor for developing tracheal stenosis after intubation and tracheostomy (38, 39) but was not significant in our study. However, some studies have reported other risk factors, such as female sex, diabetes mellitus, body mass index, steroid use, infection, and trauma (11, 25), which were not significant in our study. This may be due to differences in sample size, study design, and patient characteristics among different studies.

### 5.1. Limitations

This study has some limitations that should be acknowledged. First, it was conducted in two university hospitals in Shiraz, Iran, which may limit the generalizability of the results to other settings or populations. Second, the study was based on retrospective data from hospital records, which may

introduce selection bias or information bias due to incomplete or inaccurate documentation. Third, in this study, all patients had only undergone open tracheostomy. Therefore, we could not determine the relationship between tracheal stenosis and the tracheostomy method.

## 5.2. Conclusions

This study showed that tracheal stenosis after intubation or tracheostomy is a serious complication. The main risk factors for tracheal stenosis are prolonged intubation, high endotracheal tube (ETT) and tracheostomy tube cuff pressure, COPD, intubation history, and age. The main protective factors include optimal cuff pressure and appropriate endotracheal intubation. Prevention of tracheal stenosis involves minimizing the length of intubation, monitoring and adjusting cuff pressure, selecting the appropriate method of airway management, and avoiding unnecessary trauma to the airway. Additionally, by knowing the time interval between intubation/tracheostomy and the onset of tracheal stenosis, patients can be followed up more effectively for this complication.

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## Footnotes

**Authors' Contribution:** Study concept and design: R. D., M. E., and N. Sh.; acquisition of data: M. E.; analysis and interpretation of data: M. E., N. Sh., and R. D.;

drafting of the manuscript: M. E.; critical revision of the manuscript for important intellectual content: N. Sh., R. D., and M. E.; statistical analysis: N. Sh., and M. E.; administrative, technical, and material support: R. D., M. E., and N. Sh.; study supervision: N. Sh., and R. D.

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**Data Availability:** The datasets of the current study are available from the corresponding author on reasonable request.

**Ethical Approval:** This study is approved under the ethical approval code of [IR.SUMS.REC.1400.174](#).

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**Informed Consent:** The data of this study was collected using the information recorded in the files archived in two hospitals affiliated to Shiraz University of Medical Sciences, and there was no contact with the patients. Also, the information was anonymous.

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**Table 1.** Comparison of Demographic and Clinical Characteristics of Case and Control Groups

Variables	Tracheal Stenosis <sup>a</sup>		P-Value
	No (N = 105)	Yes (N = 35)	
Quantitative demographic and clinical characteristics			
Age (y)	48 (35 - 60)	42 (31 - 59)	0.456 <sup>b</sup>
Weight (kg)	68 (60 - 80)	74 (60 - 80)	0.248 <sup>b</sup>
Height (m)	1.68 (1.60 - 1.74)	1.56 (1.60 - 1.75)	0.785 <sup>b</sup>
Body Mass Index (kg/m <sup>2</sup> )	24.48 (22 - 27)	24.5 (21.25 - 24.5)	0.450 <sup>b</sup>
Length of intubation (day)	8 (5 - 12)	17 (11 - 20)	< 0.001 <sup>b</sup>
Endotracheal tube size (mm)	7.5 (7.5 - 8)	7.5 (7.5 - 8)	0.544 <sup>b</sup>
Tracheostomy tube size (mm)	7.5 (7 - 8)	7.5 (7.5 - 8)	0.937 <sup>b</sup>
Mean endotracheal and tracheostomy tube cuff pressure (cmH <sub>2</sub> O)	27.5 (26.57 - 28)	28.66 (28 - 30.25)	< 0.001 <sup>b</sup>
Individual and qualitative clinical characteristics			
Gender			0.140 <sup>c</sup>
Female	44 (41.9)	19 (54.3)	
Male	61 (58.1)	16 (45.7)	
Body Mass Index category			0.574 <sup>c</sup>
≤ 30	92 (87.6)	31 (88.6)	
> 30	13 (12.4)	4 (11.4)	
Smoking			0.055 <sup>c</sup>
Yes	31 (29.50)	5 (14.3)	
No	74 (70.50)	30 (85.7)	
Alcohol consumption			0.281 <sup>c</sup>
Yes	7 (6.66)	5 (14.28)	
No	98 (93.34)	30 (85.72)	
Asthma			0.581 <sup>c</sup>
Yes	2 (1.90)	1 (2.9)	
No	103 (98.10)	34 (97.1)	
COPD			0.043 <sup>c</sup>
Yes	4 (3.80)	5 (14.3)	
No	101 (96.20)	30 (85.7)	
Diabetes			0.215 <sup>c</sup>
Yes	16 (15.23)	9 (25.71)	
No	89 (84.77)	26 (74.29)	
Hypertension			0.107 <sup>c</sup>
Yes	31 (29.52)	15 (42.85)	
No	74 (70.48)	20 (57.15)	
Gastroesophageal reflux disease			0.561 <sup>c</sup>
Yes	2 (1.90)	1 (2.85)	
No	103 (98.10)	34 (97.15)	
Intubation history			0.045 <sup>c</sup>
Yes	35 (33.33)	18 (51.42)	
No	69 (66.67)	17 (48.58)	
Endotracheal tube size category			0.417 <sup>c</sup>
≤ 7.5	67 (63.80)	21 (60.00)	
> 7.5	38 (36.20)	14 (40.00)	
Tracheostomy technique (open vs. percutaneous)			-
Open	14 (13.3)	23 (65.7)	

Variables	Tracheal Stenosis <sup>a</sup>		P-Value
	No (N = 105)	Yes (N = 35)	
Percutaneous	Non done	Non done	
Airway management			< 0.001 <sup>c</sup>
Intubation	91 (86.7)	12 (34.3)	
Intubation and tracheostomy	14 (13.3)	23 (65.7)	
Endotracheal and tracheostomy tube cuff pressure category			< 0.001 <sup>c</sup>
≤ 30	103 (98.09)	23 (65.71)	
> 30	2 (1.91)	12 (34.29)	

Abbreviation: COPD, chronic obstructive pulmonary disease.

<sup>a</sup> Values are expressed as median (IQR) or No. (%).

<sup>b</sup> Mann-Whitney test.

<sup>c</sup> Chi-square test.