Journal of Mechanical Ventilation

Peri-cuff air leakage and computed tomography-derived tracheal dimensions in patients with Amyotrophic Lateral Sclerosis receiving long-term tracheostomy invasive ventilation: A cross-sectional study

Nobuhiko Shibasaki, [1] Tetsuo Miyagawa, [2] Kaoru Konishi [3]

DOI: https://doi.org/10.53097/JMV10157

Cite: Shibasaki N, Miyagawa T, Konishi K. Peri-cuff air leakage and computed tomography-derived tracheal dimensions in patients with amyotrophic lateral sclerosis receiving long-term tracheostomy invasive ventilation: A cross-sectional study. J Mech Vent 2026; 7(3):106-114.

Abstract

Background
In patients with amyotrophic lateral sclerosis (ALS) receiving long-term tracheostomy invasive ventilation (TIV), peri-cuff air leakage may be related not only to insufficient cuff pressure but also to tracheal enlargement and cuff–trachea diameter mismatch. However, to our knowledge, no previous studies have compared computed tomography (CT)-derived tracheal dimensions, tracheostomy tube and cuff characteristics, and ventilator monitoring data between patients with and without peri-cuff air leakage under long-term TIV management in ALS.

Methods
This was a single-center, retrospective, cross-sectional observational study. Patients with ALS who were receiving TIV at the study hospital in October 2020 and had undergone chest CT within the 3 months before patient selection were included. Patients were classified into the leak and non-leak groups according to the presence or absence of peri-cuff air leakage based on medical record entries during the period from 1 month before to 1 month after the index CT examination. Patient characteristics, tracheostomy tube and cuff characteristics, CT-derived tracheal dimensions, and ventilator monitoring data were compared between the groups.

Results
Twenty-six patients were included in the analysis: 10 in the leak group and 16 in the non-leak group. Patient characteristics did not differ significantly between the groups. Compared with the non-leak group, the leak group had higher cuff pressure, larger major and minor tracheal diameters, higher peak inspiratory pressure, a larger difference between major and minor tracheal diameters, lower dynamic compliance, and a smaller difference between cuff diameter and major tracheal diameter. The difference between cuff diameter and major tracheal diameter was −2.3 (−4.1 to −1.6) mm in the leak group and 1.8 (0.7 to 3.0) mm in the non-leak group ($P < 0.001$). The Hodges–Lehmann estimate of the between-group difference was −4.7 mm (95% CI, −7.4 to −3.2 mm). All patients in whom the cuff diameter was smaller than the major tracheal diameter were classified into the leak group.

Conclusions
In patients with ALS receiving long-term TIV, peri-cuff air leakage was associated with larger CT-derived tracheal dimensions and a smaller cuff diameter relative to the major tracheal diameter. These findings suggest that cuff–trachea diameter compatibility, in addition to cuff pressure, may be relevant when evaluating peri-cuff air leakage. However, the small sample size limited statistical precision and precluded multivariable adjustment; therefore, the findings should be interpreted as exploratory.

Keywords: Amyotrophic Lateral Sclerosis; Tracheostomy; Respiration, Artificial; Airway Management; Peri-cuff Air Leakage

Authors:

1. PhD, PT. Department of Rehabilitation, Sayama Neurological Hospital, Sayama, Saitama, Japan
Division of Health Sciences, Graduate School of Medicine, The University of Osaka, Suita, Osaka, Japan
Graduate School of Health, Medicine and Welfare, Saitama Prefectural University, Koshigaya, Saitama, Japan
2. PhD, PT. Division of Physical Therapy, Department of Rehabilitation, Faculty of Rehabilitation, Kochi Professional University of Rehabilitation, Tosa, Kochi, Japan
3. PhD, RN. Division of Health Sciences, Graduate School of Medicine, The University of Osaka, Suita, Osaka, Japan

Corresponding author: n_shibasaki@tmg.or.jp

Conflict of interest/Disclosures: None

…

Introduction

In amyotrophic lateral sclerosis (ALS), respiratory muscle strength declines as the disease progresses, and some patients require noninvasive ventilation or tracheostomy invasive ventilation (TIV).[1,2] During TIV management, the cuff of the tracheostomy tube forms a seal within the trachea and plays an important role in maintaining tidal volume and airway pressure by reducing leakage of ventilator-delivered air around the cuff.[3,4] This type of air leakage, referred to here as peri-cuff air leakage, is a clinically important problem in ventilatory management of patients receiving long-term TIV.[4]

Peri-cuff air leakage may be managed by adjusting cuff pressure or adding injected air volume.[4] However, excessive cuff pressure carries the risk of reduced tracheal mucosal blood flow and tracheal wall injury; therefore, relying solely on increasing cuff pressure has limitations.[4–6] A study of adult patients with endotracheal intubation reported that the smaller the difference between cuff area and airway area, the higher the cuff pressure required to achieve adequate airway sealing. This finding indicates that not only cuff pressure but also size compatibility between the cuff and airway is important for airway sealing.[7]

In patients with ALS, case reports have described tracheal enlargement at the cuff level and peri-cuff air leakage during TIV management. [8–10] These reports suggest that, in patients with ALS receiving long-term TIV, peri-cuff air leakage may be related not only to insufficient cuff pressure but also to tracheal enlargement at the cuff level and cuff–trachea diameter mismatch.

However, previous reports have mainly consisted of case reports. To our knowledge, no studies in patients with ALS receiving long-term TIV have compared computed tomography (CT)-derived tracheal dimensions, tracheostomy tube and cuff characteristics, and ventilator monitoring data between those with and without peri-cuff air leakage. Therefore, this study aimed to classify patients with ALS receiving long-term TIV according to the presence or absence of peri-cuff air leakage and to identify the characteristics of the leak group by comparing CT-derived tracheal dimensions, tracheostomy tube and cuff characteristics, and ventilator monitoring data.

Methods

Study design and participants

This was a single-center, retrospective, cross-sectional observational study. The source population comprised patients receiving TIV who were hospitalized at Sayama Neurological Hospital in October 2020. Long-term TIV was defined as ongoing chronic management via tracheostomy rather than temporary invasive ventilation in acute or perioperative care. Among these patients, those with ALS who met the Gold Coast criteria based on a review of medical records, for whom consent for study participation was obtained, and who had undergone chest CT within the 3 months preceding patient selection in October 2020 were included. [11] The corresponding CT examination was defined as the index CT examination for this study. Patients with tracheomalacia or emphysema were excluded because these conditions may affect tracheal dimensions. [12,13] Patients with missing CT imaging data or clinical information required for analysis were also excluded. Patients included in the final analysis were classified into the leak and non-leak groups according to the presence or absence of peri-cuff air leakage during the period from 1 month before to 1 month after the index CT examination.

Assessment of peri-cuff air leakage

The presence or absence of peri-cuff air leakage was retrospectively determined from medical record entries by physicians, nurses, and physical therapists during the air-leak assessment period, defined as the period from 1 month before to 1 month after the index CT examination. At the study hospital, patients receiving TIV were routinely checked for air leakage from around the tracheostomy stoma or from the mouth, as well as leakage sounds on auscultation, as part of routine clinical care. Peri-cuff air leakage was considered to be present if any of these findings were documented in the medical records. For all patients, the physical therapist involved in their care was asked whether clinical findings suggestive of air leakage had been observed during the air-leak assessment period. The consistency between the therapist's report and the medical record entries was then checked. If there was a discrepancy between the therapist's report and the medical record entries, the clinical findings during the air-leak assessment period were re-evaluated by the clinical team, including physicians and nurses, and the final determination was made.

Clinical data and tracheostomy tube measurements

The study variables included age, sex, duration of TIV use, communication impairment stage after TIV in ALS,[14] height, weight, BMI, peri-cuff air-leak status, cuff pressure, tracheostomy tube type, cuff diameter, CT-derived tracheal dimensions, and ventilator monitoring data. Age, sex, duration of TIV use, communication impairment stage after TIV in ALS, height, weight, BMI, cuff pressure, tracheostomy tube type and size, and cuff management method were collected from the medical records. The cuff pressure value recorded or measured under routine management conditions at the time point closest to the index CT examination was used. For patients whose cuff management was based on cuff pressure, the cuff pressure documented in the medical records was used. For patients whose cuff management was based on the volume of injected air, the usual air volume used for routine management was injected using a tracheal tube cuff inflator (Covidien Japan Inc., AG Cuffill, Tokyo, Japan) at the time point closest to the index CT examination. The cuff pressure displayed on the device was then used for analysis. Cuff diameter was not measured in vivo; instead, tracheostomy tube type and size were used to identify the nominal inflated cuff diameter reported by the manufacturer for each tracheostomy tube.

Computed Tomography measurements

CT images were not acquired specifically for this study; instead, chest CT images obtained for clinical indications were used. The CT examinations were performed while the patients were connected to a ventilator, with the arms positioned alongside the body. Given their markedly reduced respiratory muscle strength, no respiratory instructions regarding inspiration or expiration were given. The slice thickness was 5 mm. To evaluate the relationship between cuff diameter and major tracheal diameter, tracheal dimensions were measured on axial CT images at the level of the cuff. When multiple slices included the cuff level, the slice showing the largest major tracheal diameter was selected for analysis. The major tracheal diameter was defined as the longest inner wall-to-inner wall distance on the axial image, and the minor tracheal diameter was measured as the inner wall-to-inner wall distance passing through the midpoint of, and perpendicular to, the major diameter. The difference between the major and minor tracheal diameters and the major-to-minor tracheal diameter ratio were also calculated. The difference between cuff diameter and major tracheal diameter was calculated as cuff diameter minus the major tracheal diameter measured on CT images. A positive value indicated that the cuff diameter was larger than the major tracheal diameter, whereas a negative value indicated that the cuff diameter was smaller than the major tracheal diameter. All CT image measurements were performed by one physical therapist experienced in image measurements.Ventilator monitoring data

Ventilator Monitoring Data

Ventilator monitoring data, including tidal volume (TV), peak inspiratory pressure (PIP), and positive end-expiratory pressure (PEEP), were collected, and dynamic compliance (Cdyn) was calculated. TV was defined as the inspiratory tidal volume displayed on the ventilator monitor. The values used for analysis were those displayed on the ventilator monitor and recorded in the medical records under routine ventilatory management on the day of the index CT examination. When multiple values were available on the same day, the values recorded closest to the time of CT examination were used. Cdyn was calculated as TV/(PIP − PEEP) using TV, PIP, and PEEP values from the same time point. [15]

Statistical Analysis

Continuous variables were presented as medians and interquartile ranges, and categorical variables were presented as counts. Comparisons between the leak and non-leak groups were performed using Fisher's exact test or the Fisher–Freeman–Halton exact test, as appropriate, for nominal categorical variables and the Mann–Whitney U test for continuous and ordinal variables. As an exploratory analysis, comparisons between male and female patients were performed using the same statistical methods to examine the potential influence of sex on computed tomography-derived tracheal dimensions, cuff-related variables, and ventilator monitoring data. For the difference between cuff diameter and major tracheal diameter, the Hodges–Lehmann estimator was used to estimate the between-group difference, defined as the leak group minus the non-leak group. The 95% confidence interval was estimated using the percentile bootstrap method with 10,000 resamples. Statistical analyses were performed using EZR version 1.61 and R version 4.4.2, and a two-sided P value < 0.05 was considered statistically significant.16

Ethics

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Sayama Neurological Hospital (approval number: 2019-3) and the Ethics Committee of Osaka University (approval number: 21112-2). For study participation, the study was explained using written information sheets in accordance with procedures approved by the ethics committees. When the patient's intention to consent could be confirmed, consent was obtained from the patient. When it was difficult to confirm the patient's intention to consent, consent was obtained from a legal representative. Research data were collected and managed at Sayama Neurological Hospital, and anonymized data that did not contain personally identifiable information were used for analysis.

Results

Participant flow

The patient selection process is shown in Figure 1. Among the 145 patients receiving TIV at the study hospital in October 2020, 56 patients with ALS who met the Gold Coast criteria based on medical record information and for whom consent for study participation was obtained were considered eligible. Of these, 30 patients who met the exclusion criteria were excluded, and 26 patients were included in the final analysis. Ten patients had peri-cuff air leakage and were classified into the leak group, whereas 16 patients did not have peri-cuff air leakage and were classified into the non-leak group.

Patient characteristics

Patient characteristics are shown in Table 1. There were no significant differences between the leak and non-leak groups in age, sex, duration of TIV use, communication impairment stage, height, weight, or BMI.

Tracheostomy Tube and Cuff Characteristics

Tracheostomy tube and cuff characteristics are shown in Table 2. There were no significant differences between the leak and non-leak groups in tracheostomy tube type or cuff diameter, whereas cuff pressure was significantly higher in the leak group.

Computed Tomography-derived tracheal dimensions and ventilator monitoring data

CT-derived tracheal dimensions and ventilator monitoring data are shown in Table 3. Compared with the non-leak group, the leak group had significantly larger major and minor tracheal diameters, higher PIP, and a larger difference between major and minor tracheal diameters. Cdyn and the difference between cuff diameter and major tracheal diameter were significantly lower in the leak group. For the difference between cuff diameter and major tracheal diameter, the Hodges–Lehmann estimate of the between-group difference was −4.7 mm (95% CI, −7.4 to −3.2 mm). In contrast, there were no significant differences in tidal volume, PEEP, or the major-to-minor tracheal diameter ratio between the two groups.

Scatter plot findings

Figure 2 shows a scatter plot of major tracheal diameter and the difference between major and minor tracheal diameters. In Figure 2, all patients with a major tracheal diameter ≥30.0 mm and all patients with a difference between major and minor tracheal diameters ≥6.0 mm were in the leak group.

Figure 3 shows a scatter plot with major tracheal diameter on the x-axis and the difference between cuff diameter and major tracheal diameter on the y-axis. All patients with a difference between cuff diameter and major tracheal diameter < 0 mm were in the leak group.

Exploratory analysis by sex

Exploratory comparisons according to sex are presented in Tables 4 and 5. There was no significant association between sex and peri-cuff air-leak status. In contrast, height, weight, cuff pressure, cuff diameter, major tracheal diameter, minor tracheal diameter, and PIP were significantly higher in male patients than in female patients.

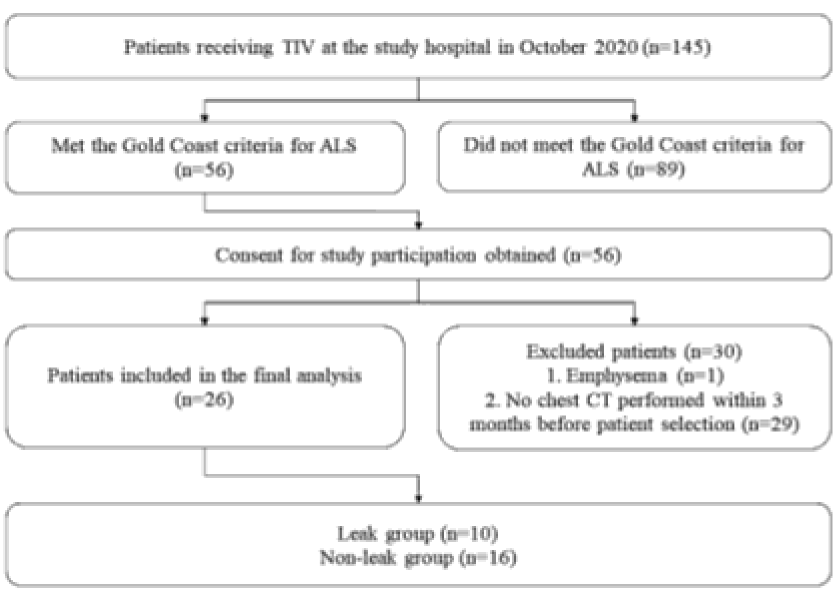

Figure 1: Study flow chart
Patients receiving TIV at the study hospital in October 2020 were screened for eligibility. Patients who did not meet the Gold Coast criteria for ALS, those with tracheomalacia or emphysema, and those without chest CT performed within 3 months before patient selection were excluded. No patient was excluded because of tracheomalacia. The final cohort was classified into the leak and non-leak groups according to peri-cuff air leakage status. ALS, amyotrophic lateral sclerosis; CT, computed tomography; TIV, tracheostomy invasive ventilation.

Table 1: Patient characteristics according to peri-cuff air-leakage status

		All	Leak group	Non-leak group	P value
Number of patients		26	10	16	
Age (years)		72.5 (65.3-79.0)	74.5 (69.3-78.0)	70.5 (63.8-79.3)	0.342
Sex (n)	Male	15	7	8	0.428
	Female	11	3	8	
Duration of TIV use (months)		91.5 (38.3-133.5)	96.5 (53.0-141.0)	77.0 (33.5-132.5)	0.960
Communication impairment stage (n)	Stage 1	11	4	7	0.868
	Stage 2	3	1	2	
	Stage 3	3	3	0	
	Stage 4	3	0	3	
	Stage 5	6	2	4	
Height (cm)		161.5 (153.5-166.0	161.5 (156.0-169.0	161.0 (153.0-163.8	0.598
Weight (kg)		47.1 (39.7-51.6)	47.1 (44.4-49.2)	47.4 (39.5-51.9)	0.854
Body mass index		18.0 (16.0-19.3)	17.8 (16.5-18.5)	18.0 (15.8-19.7)	0.673

Values are presented as median (interquartile range) or number. P values were calculated using Fisher's exact test for nominal categorical variables and the Mann–Whitney U test for continuous and ordinal variables. TIV, tracheostomy invasive ventilation.

Table 2: Tracheostomy tube and cuff characteristics according to peri-cuff air-leak status

		All	Leak group	Non-leak group	P value
Tracheostomy tube type	GB Tracheostomy Tube	13	5	8	1.000
	Aspir-Ace™ Tracheostomy	9	4	5	
	Koken double-suction cannula	3	1	2	
	GB Adjustfit Tracheostomy Tube	1	0	1	
Cuff pressure (cmH_2O)		30.0 (30.0-30.0)	31.5 (30.0-34.9)	30.0 (30.0-30.0)	0.005
Cuff diameter (mm)		26.5 (26.5-29.4)	26.5 (26.5-27.6)	28.0 (26.0-29.6)	0.438

Values are presented as median (interquartile range) or number. P values were calculated using Fisher's exact test or the Fisher–Freeman–Halton exact test for nominal categorical variables and the Mann–Whitney U test for continuous and ordinal variables.

Table 3: Computed tomography-derived tracheal dimensions and ventilator monitoring data according to peri-cuff air-leak status

	All	Leak group	Non-leak group	P value
Major tracheal diameter (mm)	26.4 (25.0-28.6)	29.0 (28.1-30.9)	26.5 (26.1-27.6)	<0.001
Minor tracheal diameter (mm)	22.7 (21.4-25.3)	24.5 (22.7-26.9)	22.0 (21.2-24.5)	0.008
Tidal volume (mL)	375.0 (290.0-400.0)	345.0 (262.5-392.5)	383.5 (342.5-412.5)	0.132
Peak inspiratory pressure (cmH_2O)	23.0 (18.0-29.1)	27.0 (22.8-31.3)	18.5 (17.0-24.0)	0.019
Positive end-expiratory pressure (cmH_2O)	4.0 (4.0-5.0)	4.0 (4.0-4.75)	4.0 (4.0-5.0)	0.584
Dynamic compliance (mL/cmH_2O)	19.2 (12.9-29.6)	14.3 (9.7-21.9)	24.6 (15.2-33.1)	0.020
Difference between major and minor tracheal diameters (mm)	3.5 (1.6-5.5)	5.7 (2.9-6.8)	2.3 (1.3-4.4)	0.037
Major-to-minor tracheal diameter ratio	1.2 (1.1-1.2)	1.2 (1.1-1.3)	1.1 (1.1-1.2)	0.068
Difference between cuff diameter and major tracheal diameter (mm)	0.55 (-1.6-2.6)	-2.3 (-4.1- -1.6)	1.8 (0.7-3.0)	<0.001

Values are presented as median (interquartile range). P values were calculated using the Mann–Whitney U test for continuous variables.

Table 4: Patient and tracheostomy tube characteristics according to sex

		Male	Female	P value
Number of patients		15	11	
Age (years)		73.0 (69.0-75.0)	71.0 (62.5-79.5)	0.835
Peri-cuff air leakage (n)	Yes	7	3	0.428
	No	8	8	
Duration of TIV use (months)		120.0 (71.5-141.0)	26.0 (11.5-97.5)	0.052
Communication impairment stage (n)	Stage 1	6	5	0.568
	Stage 2	3	0	
	Stage 3	2	1	
	Stage 4	2	1	
	Stage 5	2	4	
Height (cm)		163.0 (160.5-169.0)	153.0 (148.5-160.0)	0.006
Weight (kg)		49.6 (47.1-52.5)	39.4 (35.8-44.8)	0.006
Body mass index		18.3 (16.8-19.7)	16.8 (15.1-18.5)	0.139
Tracheostomy tube type	GB Tracheostomy Tube	5	8	0.193
	Aspir-Ace™ Tracheostomy	7	2	
	Koken double-suction cannula	2	1	
	GB Adjustfit Tracheostomy Tube	1	0	
Cuff pressure (cmH_2O)		30.0 (30.0-33.25)	30.0 (28.0-30.0)	0.026
Cuff diameter (mm)		28.0 (26.5-30.0)	26.0 (24.6-28.7)	0.038

Values are presented as median (interquartile range) or number. P values were calculated using Fisher's exact test or the Fisher–Freeman–Halton exact test, as appropriate, for nominal categorical variables and the Mann–Whitney U test for continuous and ordinal variables. TIV, tracheostomy invasive ventilation.

Table 5: Computed tomography-derived tracheal dimensions and ventilator monitoring data according to sex

	Male (n=15)	Female (n=11)	P value
Major tracheal diameter (mm)	28.1 (26.0-29.6)	25.1 (23.5-27.0)	0.033
Minor tracheal diameter (mm)	24.9 (22.1-27.1)	21.9 (20.3-22.7)	0.010
Tidal volume (mL)	370.0 (290.0-425.0)	387.0 (316.5-400.0)	0.640
Peak inspiratory pressure (cmH_2O)	24.0 (23.0-30.5)	18.0 (16.9-21.7)	0.012
Positive end-expiratory pressure (cmH_2O)	4.0 (4.0-4.5)	4.0 (4.0-5.0)	0.267
Dynamic compliance (mL/cmH_2O)	15.4 (11.0-21.5)	29.4 (19.5-31.7)	0.055
Difference between major and minor tracheal diameters (mm)	2.3 (1.3-5.2)	3.8 (2.7-5.6)	0.363
Major-to-minor tracheal diameter ratio	1.1 (1.0-1.2)	1.2 (1.1-1.3)	0.169
Difference between cuff diameter and major tracheal diameter (mm)	0.2 (-2.5-2.3)	1.1 (-0.45-2.4)	0.350

Values are presented as median (interquartile range). P values were calculated using the Mann–Whitney U test.

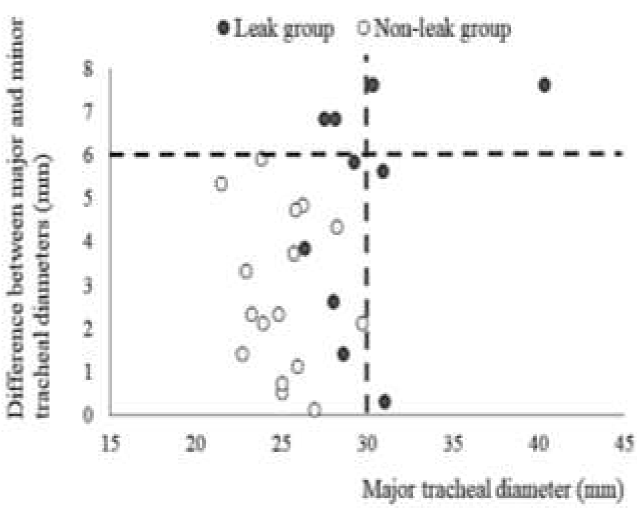

Figure 2. Scatter plot of major tracheal diameter and the difference between major and minor tracheal diameters
Closed circles indicate patients in the leak group, and open circles indicate patients in the non-leak group. The vertical and horizontal reference lines indicate a major tracheal diameter of 30.0 mm and a difference between major and minor tracheal diameters of 6.0 mm, respectively. All patients with a difference between major and minor tracheal diameters ≥ 6.0 mm were in the leak group. Similarly, all patients with a major tracheal diameter ≥ 30.0 mm were in the leak group.

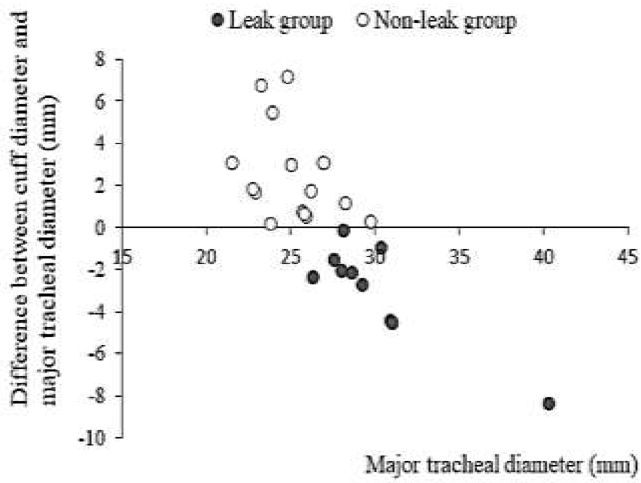

Figure 3. Scatter plot of major tracheal diameter and the difference between cuff diameter and major tracheal diameter
Closed circles indicate patients in the leak group, and open circles indicate patients in the non-leak group. The difference between cuff diameter and major tracheal diameter was calculated as cuff diameter minus major tracheal diameter. The horizontal reference line indicates 0 mm. A negative value indicates that the cuff diameter was smaller than the major tracheal diameter. All patients with a negative value were in the leak group.

Discussion

The most important finding of this study was that, among patients with ALS receiving long-term TIV, those with peri-cuff air leakage had larger tracheal diameters on CT images and a significantly smaller difference between cuff diameter and major tracheal diameter. In particular, all patients in whom the cuff diameter was smaller than the major tracheal diameter were classified into the leak group. This finding suggests that peri-cuff air leakage in patients receiving long-term TIV may be related not only to cuff pressure but also to tracheal enlargement at the cuff level and cuff–trachea diameter mismatch.

Peri-cuff air leakage may be managed by increasing cuff pressure, adding injected air volume, or replacing the tracheostomy tube.[4] However, in this study, peri-cuff air leakage was observed in the leak group despite significantly higher cuff pressure than in the non-leak group. This finding suggests that, in some patients with ALS receiving long-term TIV, air leakage cannot be explained solely by insufficient cuff pressure. A clinical study of adult patients with endotracheal intubation reported that the smaller the difference between cuff area and airway area, the higher the cuff pressure required to achieve adequate airway sealing.[7] In patients with ALS, case reports have also described tracheal enlargement at the cuff level and peri-cuff air leakage.[8–10] Similarly, in the present study, the leak group had larger tracheal diameters and a greater difference between the major and minor tracheal diameters, suggesting that tracheal enlargement and non-circular deformation at the cuff level may have resulted in nonuniform contact between the cuff and the tracheal wall.

The leak group had higher PIP and lower Cdyn. However, because ventilator modes and settings were not standardized or controlled, it remains unclear whether these differences reflected the patients' underlying condition or differences in clinician-selected ventilator settings. The cross-sectional design also precluded determination of whether these findings were consequences of peri-cuff air leakage. Nevertheless,

Inada et al. reported that the "just-seal" intracuff pressure required to prevent air leakage increased as airway inflation pressure increased.[17] Accordingly, although causality cannot be inferred, the higher PIP observed in the leak group may have represented a condition unfavorable for maintaining airway sealing. In patients with air leakage despite management with high cuff pressure, it may be appropriate to reassess cuff pressure, cuff–trachea diameter compatibility, cuff position, tracheostomy tube type and size, and ventilator settings, rather than simply increasing cuff pressure further.

Because sex differences in tracheal diameter have been reported previously,[18–21] we performed an exploratory analysis by sex. Height, weight, cuff pressure, cuff diameter, major tracheal diameter, minor tracheal diameter, and PIP were significantly higher in male patients than in female patients, and the findings for major and minor tracheal diameters were consistent with previous reports. In contrast, sex was not significantly associated with peri-cuff air-leak status, and the difference between cuff diameter and major tracheal diameter did not differ significantly between male and female patients. These findings suggest that cuff–trachea diameter compatibility may be relevant to peri-cuff air leakage despite the observed sex differences in tracheal dimensions. However, because this analysis was exploratory and included a limited number of patients, the findings should be interpreted with caution.

This study has several limitations. First, because this was a single-center, retrospective, cross-sectional study with a limited number of patients, causal relationships could not be determined. Given the small sample size, multivariable analysis could not be performed reliably; therefore, residual confounding by sex, body size, duration of TIV use, tracheostomy tube type, or ventilator settings cannot be excluded. Second, CT images were obtained for clinical indications, and patients without an index CT examination were excluded; therefore, selection bias may have occurred. Third, peri-cuff air leakage was determined retrospectively from medical record entries, and the amount, frequency, and severity of leakage were not quantitatively assessed under standardized conditions. This may have led to misclassification between the leak and non-leak groups, potentially biasing the observed associations. Although peri-cuff air-leak status was retrospectively determined based on clinical findings observed during the period from 1 month before to 1 month after the index CT examination, short-term changes in tracheal dimensions during this interval cannot be excluded. Fourth, cuff diameter was based on manufacturer-reported nominal values rather than in vivo measurements. Because actual cuff dimensions and shape may vary with cuff pressure, tracheal geometry, and tissue compliance, the degree of cuff–trachea diameter mismatch may have been over- or underestimated, and the direction of this bias cannot be determined. Fifth, the 5-mm CT slice thickness may have reduced the precision of tracheal diameter measurements, particularly when interpreting sub-millimeter differences. In addition, CT image measurements were performed by a single evaluator, and inter-rater reliability was not assessed. Future multicenter prospective studies or longitudinal evaluations are needed to examine the temporal relationships among tracheal enlargement, increased cuff pressure, and peri-cuff air leakage.

Conclusion

This study examined the relationship between peri-cuff air leakage and CT-derived tracheal dimensions and cuff diameter in patients with ALS receiving long-term TIV. The leak group had larger CT-derived tracheal dimensions and a significantly smaller difference between cuff diameter and major tracheal diameter, and all patients in whom the cuff diameter was smaller than the major tracheal diameter were classified into the leak group. These findings suggest that cuff–trachea diameter compatibility, in addition to cuff pressure, may be relevant when evaluating peri-cuff air leakage in patients with ALS receiving long-term TIV.

References

1. Rimmer KP, Kaminska M, Nonoyama M, et al. Home mechanical ventilation for patients with Amyotrophic Lateral Sclerosis: A Canadian Thoracic Society clinical practice guideline. Canadian Journal of Respiratory, Critical Care, and Sleep Medicine 2019; 3(1):9-27.

2. Kimura F. Tracheostomy and invasive mechanical ventilation in amyotrophic lateral sclerosis: decision-making factors and survival analysis. Rinsho Shinkeigaku 2016; 56(4):241-247.

3. Mussa CC, Gomaa D, Rowley DD, et al. AARC clinical practice guideline: management of adult patients with tracheostomy in the acute care setting. Respir Care 2021; 66(1):156-169.

4. Gould E, Carlsen KM, Trask J, et al. Under pressure: Tracheostomy cuff over inflation leading to tissue necrosis and cuff rupture. In: WebM&M: Case Studies. AHRQ patient safety network (PSNet) collection. Agency for healthcare research and quality (US); 2019. Accessed May 20, 2026. http://www.ncbi.nlm.nih.gov/books/NBK612705/

5. Seegobin RD, van Hasselt GL. Endotracheal cuff pressure and tracheal mucosal blood flow: endoscopic study of effects of four large volume cuffs. Br Med J (Clin Res Ed) 1984; 288(6422):965-968

6. Sengupta P, Sessler DI, Maglinger P, et al. Endotracheal tube cuff pressure in three hospitals, and the volume required to produce an appropriate cuff pressure. BMC Anesthesiol 2004; 4(1):8.

7. Wu HL, Wu YH, Shen WQ, et al. Relationship between difference in endotracheal tube cuff area and airway area with minimum cuff pressure for adequate airway sealing: a prospective observational study. Sci Rep 2025; 15(1):5875.

8. Yang JH, Kim TW, Lee BJ, et al. Successful management of acquired tracheomalacia of patients with Amyotrophic Lateral Sclerosis: A report of three cases. Ann Rehabil Med 2018; 42(2):368.

9. Lee DH, Yoon TM, Lee JK, et al. Tracheomegaly secondary to tracheotomy tube cuff in Amyotrophic Lateral Sclerosis: A case report. Medicine (Baltimore) 2015; 94(42):e1763.

10. Shibasaki N, Konishi K, Nishiyama Y, et al. A case of Amyotrophic Lateral Sclerosis managed by tracheostomy

and invasive ventilation in which air leaks occurred at the cuff. Rinsho Shinkeigaku 2024; 64(11):789-793.

11. Shefner JM, Al-Chalabi A, Baker MR, et al. A proposal for new diagnostic criteria for ALS. Clin Neurophysiol 2020; 131(8):1975-1978.

12. Shepard JAO, Flores EJ, Abbott GF. Imaging of the trachea. Ann Cardiothorac Surg 2018; 7(2):197-209.

13. Tsao TC, Shieh WB. Intrathoracic tracheal dimensions and shape changes in chronic obstructive pulmonary disease. J Formos Med Assoc 1994; 93(1):30-34.

14. Hayashi K, Mochizuki Y, Nakayama Y, et al. Communication disorder in amyotrophic lateral sclerosis after ventilation - A proposal of staging and a study of predictive factor. Rinsho Shinkeigaku 2013; 53(2):98-103.

15. Yan Y, Du Z, Chen H, et al. The relationship between mechanical power normalized to dynamic lung compliance and weaning outcomes in mechanically ventilated patients. PLoS One 2024; 19(8):e0306116.

16. Kanda Y. Investigation of the freely available easy-to-use software 'EZR' for medical statistics. Bone Marrow Transplant 2013; 48(3):452-458.

17. Inada T, Uesugi F, Kawachi S, et al. The tracheal tube with a high-volume, low-pressure cuff at various airway inflation pressures. Eur J Anaesthesiol 1998; 15(6):629-632.

18. Breatnach E, Abbott GC, Fraser RG. Dimensions of the normal human trachea. AJR Am J Roentgenol 1984; 142(5):903-906.

19. Karmakar A, Pate MB, Solowski NL, et al. Tracheal size variability is associated with sex: implications for endotracheal tube selection. Ann Otol Rhinol Laryngol 2015; 124(2):132-136.

20. Dominelli PB, Ripoll JG, Cross TJ, et al. Sex differences in large conducting airway anatomy. J Appl Physiol (1985) 2018; 125(3):960-965.

21. El-Anwar MW, El-Hussiny A, Osman H, et al. Tracheal and subglottic dimensions: a computed tomography cross section study of adult population. Egypt J Otolaryngol 2024; 40(1):25.