Auris Nasus Larynx 48 (2021) 973–977

Contents lists available at ScienceDirect

Auris Nasus Larynx

journal homepage: www.elsevier.com/locate/anl

Factors associated with the occurrence of stomal stenosis after tracheostomy in adults

Megumi Koizumi[a,b,c,*], Miho Ishimaru[a], Hiroki Matsui[a], Kiyohide Fushimi[d], Tatsuya Yamasoba[b], Hideo Yasunaga[a]

[a] *Department of Clinical Epidemiology and Health Economics, School of Public Health, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan*

[b] *Department of Otolaryngology and Head and Neck Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan*

[c] *Department of Otolaryngology and Head and Neck Surgery, Sanraku Hospital, 2-5 Kandasurugadai, Chiyoda-ku, Tokyo 101-8326, Japan*

[d] *Department of Health Policy and Informatics, Graduate School of Medicine, Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, Japan*

ARTICLE INFO

Article history:
Received 20 October 2020
Accepted 25 March 2021
Available online 26 April 2021

Keywords:
Tracheostomy
Complication
Tracheal peristomal stenosis
Peristomal granulation

ABSTRACT

Objective: Although tracheal stomal stenosis can be life-threatening, factors associated with the occurrence of stomal stenosis remain unknown. This study was performed to evaluate these factors in adult patients.

Methods: We retrospectively identified adult patients who underwent tracheostomy from 2010 to 2016 using a Japanese national inpatient and outpatient database. We performed Cox proportional hazard regression analyses to evaluate factors associated with the occurrence of tracheal stomal stenosis.

Results: We obtained data on 25,436 eligible patients. The proportion of tracheal stomal stenosis was 0.9%. Tracheal stomal stenosis was significantly less likely to occur in patients with regular use of oral steroids [hazard ratio (HR), 0.28; 95% confidence interval (CI), 0.09–0.88; $P = 0.03$] and in male patients (HR, 0.75; 95% CI, 0.57–0.97; $P = 0.03$). The occurrence of tracheal stomal stenosis was significantly associated with use of a mechanical ventilator at home (HR, 2.54; 95% CI, 1.55–4.15; $P < 0.001$) and a body mass index of $<18.5\,kg/m^2$ (HR, 1.45; 95% CI, 1.06–1.99; $P = 0.02$).

Conclusion: Our study revealed several factors that are associated with tracheal stomal stenosis. These findings may help physicians to manage tracheal stomas.

1. Introduction

Tracheostomy complications are classified into early and late complications [1–4]. Early complications occur within 7 days after tracheostomy and include accidental decannulation, mucus plugging, bleeding, pneumothorax, and subcutaneous emphysema. Late complications occur after 7 days and include peristomal granulation, tracheal stenosis, tracheomala-

* Corresponding author at: Department of Otolaryngology and Head and Neck Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan.

E-mail address: imegumi-zao@umin.ac.jp (M. Koizumi).

https://doi.org/10.1016/j.anl.2021.03.023

cia, infection, stomal breakdown, tracheocutaneous fistula, tracheoinnominate artery fistula, tracheoesophageal fistula, and death [5]. A previous study showed that the causes of tracheal stenosis were classified into simple web stenosis with or without circumferential fibrosis and granulation [6]. Severe peristomal granulation often induces stomal stenosis and difficult cannula exchange because of bleeding or airway stenosis [7].

In several previous studies, peristomal granulation occurred in 6.1 to 24.0% of pediatric patients [4,8–11] and in 0.8 to 43.7% of adult patients after tracheostomy [3,12]. Another study showed that the most common late complication was peristomal granulation in institutionalized children with long-term tracheostomy and ventilator assistance [2].

Tracheal stomal stenosis due to peristomal granulation can induce difficulty in exchanging the cannula; however, factors associated with the occurrence of tracheal stomal stenosis remain unclarified. The present study was performed to investigate factors associated with the occurrence of stomal stenosis after tracheostomy in adult patients.

2. Materials and methods

2.1. Data source

We used the Japanese Diagnosis Procedure Combination database. We only used data from 255 hospitals that had both inpatient and outpatient data. The database consists of inpatient claims data and discharge abstract data, including the hospital identifier; patient's sex, age, height, and weight; dates of admission and discharge; surgical procedures; main diagnosis and International Statistical Classification of Disease (ICD)-10 codes; comorbidities on admission coded with ICD-10 codes; surgical procedures coded with Japanese procedure codes; performance of bacterial culture testing; drugs used; and mechanical ventilation. Outpatient data included the dates of medical examinations, drug prescriptions, and procedures. A previous study reported the validity of the diagnostic records in the Diagnosis Procedure Combination database and indicated that the specificity of diagnoses exceeded 96% [13].

This study was approved by the review board of The University of Tokyo. The requirement for informed consent was waived because the study data were anonymous.

2.2. Patient selection

We enrolled patients who underwent tracheostomy from July 2010 to March 2017. We excluded patients with laryngeal or hypopharyngeal cancer who underwent laryngectomy or pharyngolaryngectomy, patients with incomplete data, and patients aged <20 years. We selected the first operation if the same patients underwent tracheostomy multiple times.

2.3. Independent variables

The independent variables were the patient's sex, age, regular use of oral steroids, use of a mechanical ventilator at home, body mass index (BMI) (<18.5, 18.5–24.9, 25.0–29.9, and $\geq 30.0\,kg/m^2$), performance of respiratory specimen culture, and comorbidities. We classified BMI according to the definition established by the World Health Organization. Comorbidities included chronic heart failure, chronic pulmonary disease, malignancy, and diabetes mellitus with or without complications. These comorbidities include components of the Charlson comorbidity index [14,15]. A previous study showed that the Charlson comorbidity index was associated with tracheostomy-related mortality [16].

2.4. Outcomes

The primary outcome was tracheal stomal stenosis. We identified tracheal stomal stenosis using the written diagnoses in Japanese text and ICD-10 code (J950) or records of stomal stenosis extension surgery (operation procedure code).

2.5. Statistical analysis

We performed Cox proportional hazard regression and checked for the absence of a violation of the proportional hazard assumption using Schoenfeld residuals and a log-log plot. We checked variance inflation factors for each variable and considered that variance inflation factors of >10 indicated multicollinearity. Variables that indicated multicollinearity were excluded from the analyses.

A P value of <0.05 was considered statistically significant. All analyses were performed by STATA version 15.0 (StataCorp, College Station, TX, USA).

3. Results

We obtained data on 27,988 patients from 255 hospitals. We excluded 1240 patients who underwent laryngectomy or pharyngolaryngectomy and 5 patients with incomplete data. We also excluded 1307 patients aged <20 years. Finally, we included 25,436 eligible patients in the present study.

Table 1 shows the baseline characteristics and the proportions of stomal stenosis after tracheostomy. The overall proportion of stomal stenosis was 0.9%. The median interval from tracheostomy to the onset of stomal stenosis was 75 days (interquartile range, 28.0–270.5 days). Age indicated multicollinearity, and the performance of respiratory specimen culture indicated the absence of the proportional hazard assumption.

Table 2 shows the factors associated with the occurrence of stomal stenosis. Tracheal stomal stenosis was significantly less likely to occur in patients with regular use of oral steroids [hazard ratio (HR), 0.25; 95% confidence interval (CI), 0.08–0.78; $P = 0.02$] and in male patients (HR, 0.75; 95% CI, 0.57–0.97; $P = 0.03$). The occurrence of tracheal stomal stenosis was significantly associated with use of a mechanical ventilator at home (HR, 2.54; 95% CI, 1.55–4.15; $P < 0.001$) and BMI of $<18.5\,kg/m^2$ (HR, 1.45; 95% CI, 1.06–1.99; $P = 0.02$).

Table 1. Characteristics and proportions of stomal stenosis after tracheostomy.

	Patients		Outcome		*P* value
Total	25,436	234	(0.9)		
Sex					
Male	16,666	(65.5)	136	(0.8)	0.02
Female	8770	(34.5)	98	(1.1)	
Age (years)					
20–29	566	(2.2)	15	(2.7)	<0.001
30–39	816	(3.2)	13	(1.6)	
40–49	1556	(6.1)	14	(0.9)	
50–59	2934	(11.5)	34	(1.2)	
60–69	6427	(25.3)	69	(1.1)	
70–79	7852	(30.9)	68	(0.9)	
80–89	4823	(19.0)	19	(0.4)	
≥90	462	(1.8)	2	(0.4)	
Body mass index (kg/m^2)					
<18.5	5958	(23.4)	65	(1.1)	0.31
18.5–24.9	12,643	(49.7)	102	(0.8)	
25.0–29.9	3407	(13.4)	32	(0.9)	
≥30.0	875	(3.4)	11	(1.3)	
Unspecified	2553	(10.0)	24	(0.9)	
Regular use of oral steroids	3257	(12.8)	3	(0.1)	<0.001
Use of a ventilator at home	362	(1.4)	18	(5.0)	<0.001
Respiratory specimen culture	15,809	(62.2)	112	(0.7)	<0.001
Comorbidities on admission					
Chronic heart failure	2175	(8.6)	11	(0.5)	0.03
Chronic pulmonary disease	1548	(6.1)	21	(1.4)	0.06
Malignancy	2207	(8.7)	27	(1.2)	0.12
Diabetes mellitus without complications	3437	(13.5)	26	(0.8)	0.28
Diabetes mellitus with complications	735	(2.9)	7	(1.0)	0.93

Data are presented as *n* (%).

Table 2. Hazard ratios for tracheal stomal stenosis by Cox proportional hazard regression.

Variables	Hazard ratio	95% Confidence interval	*P* value
Sex (male)	0.75	0.57–0.97	0.03
Body mass index (kg/m^2)			
<18.5	1.45	1.06–1.99	0.02
18.5–24.9		Reference	
25.0–29.9	1.18	0.80–1.76	0.42
≥30.0	1.47	0.79–2.75	0.23
Unspecified	1.73	1.11–2.71	0.02
Regular use of oral steroids	0.28	0.09–0.88	0.03
Use of a ventilator at home	2.54	1.55–4.15	<0.001
Comorbidities on admission			
Chronic heart failure	0.62	0.34–1.14	0.12
Chronic pulmonary disease	1.28	0.82–2.02	0.28
Malignancy	1.26	0.84–1.89	0.26
Diabetes mellitus without complications	0.84	0.56–1.27	0.41
Diabetes mellitus with complications	1.36	0.64–2.91	0.42

4. Discussion

In the present study, tracheal stomal stenosis was significantly associated with the use of a mechanical ventilator at home and an underweight status (BMI of <18.5 kg/m^2). Regular use of oral steroids and male sex were associated with a lower incidence of tracheal stomal stenosis.

In previous studies, younger age and long-term tracheostomy were associated with peristomal granulation [4,12]. In the present study, younger patients were more likely to develop tracheal stomal stenosis than older patients, which is consistent with the findings in these previous studies. The reasons for the higher likelihood of stomal stenosis in younger patients than older patients are unknown. In another previous study, the reason for the negative correlation between instances of hypergranulation in adult patients and age was also unclear [12]. Additionally, the use of a mechanical ventilator at home can be a surrogate variable of long-term tracheostomy; therefore, our results are also compatible with those of previous studies.

We identified an association between an underweight status and the occurrence of stomal stenosis. A previous study showed an inverse relationship between BMI and tracheal size [17]. Underweight patients may have a larger tracheal size. Therefore, commonly used endotracheal tubes may be too small for underweight patients, and a larger endotracheal tube may be needed to ensure an adequate fit within their endotracheal lumen. A larger endotracheal tube may be too tight for patients with a tracheal stoma.

Although an animal study and a case report showed a potential effect of steroids on granulation [18,19], large clinical data are lacking. Our study showed that tracheal stomal stenosis including granulation was less common when systemic steroids were regularly used. Previous studies have suggested that infection may contribute to the pathogenesis of tracheal stenosis [20–22]. Regular use of systemic steroids may improve mucosal inflammation and edema, resulting in a lower incidence of stenosis.

Male patients had a lower incidence of stenosis in our study, but the reason for this remains unknown. Although a previous study showed that sex was not associated with tracheal stenosis [20], the association between tracheal stomal stenosis or granulation and sex has not been thoroughly evaluated and needs further investigation.

The findings in the current study could help physicians to manage problems in patients with tracheostomy because patients and their families can be informed of the various risk factors, allowing patients to be more watchful.

This study indicates that effective prevention of stomal stenosis includes regular use of oral steroids and attention to infection. Previous studies have implicated that granulation tissue can be caused by bacterial infection, gastroesophageal reflex, suture material, the presence of powder from surgical gloves, and use of stents in laryngotracheal reconstruction [23]. Therefore, prevention of granulation may be achieved by topical or systemic antibiotics, anti-gastroesophageal reflex measures, creation of a formal skin-to-trachea stoma, and regular changes of the tracheostomy tube [21,23].

Many previous reports have described treatments of granulation, including topical steroid cream, topical steroid injection, topical antibiotic cream, silver nitrate, steroid inhalation therapy, bronchoscopy with carbon dioxide laser therapy, bronchoscopy with YAG laser therapy, bronchoscopic-guided excision through the stoma, electrocautery, external exploration, and polyurethane foam dressing [7,23–29]. Changing the tracheostomy tube every 2 weeks after tracheostomy can decrease the need for surgical treatment of granulation tissue [23]. Additionally, the use of large endotracheal tubes (size of >7.5) has been shown to be associated with the development of airway stenosis [3].

Our study had several limitations. First, we were unable to obtain data when patients were transferred to other hospitals. Second, we were unable to determine the causes of stomal stenosis and the sites of granulation because of the lack of data. Analyses stratified by the causes of stomal stenosis and by the sites of granulation are needed to clarify the factors in more detail. Third, we could not differentiate between surgical tracheostomy and percutaneous tracheostomy. Fourth, the database did not contain detailed information on surgical procedures such as stoma maturation techniques and use of a Bjork flap. A previous study showed no relationship between stoma maturation and the development of pediatric tracheostomy-related granulation tissue [4]. Other studies have indicated that the use of Bjork's inferiorly based flap increased the incidence of stomal granulations [10,30]. Formation of stomal granulation was not associated with tracheostomy techniques, a vertical tracheal incision, or a horizontal tracheal incision with creation of an inferiorly base tracheal flap [31]. Studies on the relationship between percutaneous dilatational tracheostomy and tracheostomy-related granulation have shown conflicting results. Some studies revealed that the risk of severe suprastomal tracheal stenosis increased after dilatational tracheostomy [32,33], while others showed no significant difference between percutaneous dilational tracheostomy and hypergranulation [12,34]. Further evaluation of the relationship between surgical procedures and stomal stenosis is needed.

5. CONCLUSION

We identified several factors associated with the occurrence of tracheal stomal stenosis in adults. These findings will be helpful for physicians to manage patients with tracheal stomas.

6. Author Contributions

Drs Koizumi and Yasunaga had full access to all of the data in the study and take responsibility for the integrity of the data and accuracy of the data analysis.

Study concept and design: Koizumi, Ishimaru, Yasunaga, Fushimi

Acquisition, analysis, or interpretation of data: Koizumi, Ishimaru, Matsui, Fushimi, Yasunaga, Yamasoba

Drafting of manuscript: Koizumi, Yasunaga, Yamasoba

Critical revision of the manuscript for important intellectual content: Koizumi, Yasunaga, Yamasoba

Statistical analysis: Koizumi, Ishimaru, Yasunaga

Obtained funding: Yasunaga, Fushimi

Administrative, technical, or material support: Ishimaru, Matsui, Fushimi, Yasunaga, Yamasoba

Study supervision: Ishimaru, Matsui, Fushimi, Yasunaga, Yamasoba

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

CRediT authorship contribution statement

Megumi Koizumi: Conceptualization, Funding acquisition, Writing - original draft, Writing - review & editing, Formal analysis. **Miho Ishimaru:** Conceptualization, Funding acquisition, Supervision, Project administration. **Hiroki Matsui:** Funding acquisition, Formal analysis, Supervision, Project administration. **Kiyohide Fushimi:** Conceptualization, Funding acquisition, Supervision, Project administration. **Tatsuya Yamasoba:** Funding acquisition, Writing - original draft, Writing - review & editing, Supervision, Project administration. **Hideo Yasunaga:** Conceptualization, Funding acquisition, Writing - original draft, Writing - review & editing, Formal analysis, Supervision, Project administration.

Funding sources

This work was supported by grants from the Ministry of Health, Labour and Welfare, Japan (H30-Policy-Designated-004 and 19AA2007) and the Ministry of Education, Culture, Sports, Science and Technology, Japan (17H04141).

References

[1] Ilan O, Gross M, Zaltzman Y, Sasson A, Marcus EL. Diagnosis and conservative management of late tracheotomy complications in chronic ventilator-dependent patients. Head Neck 2015;37:716–21.
[2] Wilcox LJ, Weber BC, Cunningham TD, Baldassari CM. Tracheostomy complications in institutionalized children with long-term tracheostomy and ventilator dependence. Otolaryngol Head Neck Surg 2016;154:725–30.
[3] Halum SL, Ting JY, Plowman EK, Belafsky PC, Harbarger CF, Postma GN, et al. A multi-institutional analysis of tracheostomy complications. Laryngoscope 2012;122:38–45.
[4] Colman KL, Mandell DL, Simons JP. Impact of stoma maturation on pediatric tracheostomy-related complications. Arch Otolaryngol Head Neck Surg 2010;136:471–4.
[5] Das P, Zhu H, Shah RK, Roberson DW, Berry J, Skinner ML. Tracheotomy-related catastrophic events: results of a national survey. Laryngoscope 2012;122:30–7.
[6] Nair S, Mohan S, Mandal G, Nilakantan A. Tracheal stenosis: our experience at a tertiary care centre in India with special regard to cause and management. Indian J Otolaryngol Head Neck Surg 2014;66:51–6.
[7] Inagi K, Okubo K, Ikari Y, Mitsuhashi M. A study on tracheostomy with resection of the cricoid cartilage for subglottic stenosis. J Jpn Bronchoesophagol 2018;69:236–43 (in Japanese).
[8] Wetmore RF, Thompson ME, Marsh RR, Tom LWC. Pediatric tracheostomy: a changing procedure? Ann Otol Rhinol Laryngol 1999;108:695–9.
[9] Tantinikorn W, Alper CM, Bluestone CD, Casselbrant ML. Outcome in pediatric tracheostomy. Am J Otolaryngol Head Neck Med Surg 2003;24:131–7.
[10] Syed KA, Naina P, Pokharel A, John M, Varghese AM. Paediatric tracheostomy: a modified technique and its outcomes, results from a South Indian tertiary care. Int J Pediatr Otorhinolaryngol 2019;118:6–10.
[11] D'Souza JN, Levi JR, Park BA, Shah UK. Complications following pediatric tracheotomy. JAMA Otolaryngol Head Neck Surg 2016;142:484–8.
[12] Ledl C, Mertl-Roetzer M. Tracheal and tracheostomal hypergranulation and related stenosis in long-term cannulated patients: does the tracheostomy procedure make a difference? Ann Otol Rhinol Laryngol 2009;118:876–80.
[13] Yamana H, Moriwaki M, Horiguchi H, Kodan M, Fushimi K, Yasunaga H. Validity of diagnoses, procedures, and laboratory data in Japanese administrative data. J Epidemiol 2017;27:476–82.
[14] Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 1987;40:373–83.
[15] Quan H, Sundararajan V, Halfon P, Fong A, Burnand B, Luthi JC, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. Med Care 2005;43:1130–9.
[16] Kashlan KN, Williams AM, Chang SS, Yaremchuk KL, Mayerhoff R. Analysis of patient factors associated with 30-day mortality after tracheostomy. Laryngoscope 2019;129:847–51.
[17] D'Anza B, Knight J, Greene JS. Does body mass index predict tracheal airway size? Laryngoscope 2015;125:1093–7.
[18] Braidy J, Breton G, Clement L. Effect of corticosteroids on post-intubation tracheal stenosis. Thorax 1989;44:753–5.
[19] Croft CB, Zub K, Borowiecki B. Therapy of iatrogenic subglottic stenosis: a steroid/antibiotic regimen. Laryngoscope 1979;89:482–9.
[20] Johnson RF, Saadeh C. Nationwide estimations of tracheal stenosis due to tracheostomies. Laryngoscope 2019;129:1623–6.
[21] Prescott CA. Peristomal complications of paediatric tracheostomy. Int J Pediatr Otorhinolaryngol 1992;23:141–9.
[22] Mathur NN, Sohliya LM. Pre-decannulation peristomal findings in tracheostomaized cases and their effect on the success of decannulation. Indian J Otolaryngol Head Neck Surg 2015;67(Suppl 1):91–7.
[23] Yaremchuk K. Regular tracheostomy tube changes to prevent formation of granulation tissue. Laryngoscope 2003;113:1–10.
[24] Michelson SA. Upper airway bypass surgery for obstructive sleep apnea syndrome. Otolaryngol Clin North Am 1998;31:1013–23.
[25] Eliachar I, Oringher S. Performance and management of long-term tracheostomy. Operative Techn Otolaryngol Head Neck Surg 1990;1:56–63.
[26] Abo M, Fujimuar M, Kibe Y, Kida H, Matsuda T. Beclomethasone diproprionate inhalation as a treatment for post-intubation tracheal stenosis. Int J Clin Pract 1999;53:217–18.
[27] Werkhaven J, Maddern BR, Stool SE. Posttracheostomy granulation tissue managed by carbon dioxide laser excision. Ann Otol Rhinol Laryngol 1989;98:828–30.
[28] Merritt RM, Bent JP, Smith RJH. Suprastomal granulation tissue and pediatric tracheostomy decannulation. Laryngoscope 1997;107:868–71.
[29] Reilly JS. Myer 3rd CM. Excision of suprastomal granulation tissue. Laryngoscope 1985;95:1545–6.
[30] Waki EY, Madgy DN, Zablocki H, Belenky WM, Hotaling AJ. An analysis of the inferior based tracheal flap for pediatric tracheotomy. Int J Pediatri Otorhinolaryngol 1993;27:47–54.
[31] Rozsasi A, Kuhnemann S, Gronau S, Keck T. A single-center 6-year experience with two types of pediatric tracheostomy. Inter Pediatri Otorhinolaryngol 2005;69:607–13.
[32] Koitschev A, Simon C, Blumenstock G, Mach H, Graumuller S. Suprastomal tracheal stenosis after dilational and surgical tracheostomy in critically ill patients. Anaesthesia 2006;61:832–7.
[33] Koitschev A, Graumuller S, Zenner HP, Dommerich S, Simon C. Tracheal stenosis and obliteration above the tracheostoma after percutaneous dilational tracheostomy. Crit Care Med 2003;31:1574–6.
[34] Melloni G, Muttini S, Gallioli G, Carretta A, Cozzi S, Gemma M, et al. Surgical tracheostomy versus percutaneous dilation tracheostomy. A prospective-randomized study with long-term follow-up. J Cardiovasc Surg 2002;43:113–21 (Torino).