Received: 22 May 2023 | Accepted: 12 June 2023

DOI: 10.1002/lio2.1105

ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Usefulness of a newly developed endoscope for the observation of the posterior tracheal wall

Tomoe Tamai DDS, PhD[1] | Kanako Yoshimi DDS, PhD[1] | Kazuharu Nakagawa DDS, PhD[1] | Ryosuke Yanagida DDS[1] | Takuma Okumura DDS, PhD[1,2] | Kohei Yamaguchi DDS, PhD[1] | Miki Ishii DDS, PhD[1] | Yuki Nagasawa DDS, PhD[1] | Haruka Tohara DDS, PhD[1]

[1]Department of Dysphagia Rehabilitation, Division of Gerontology and Gerodontology, Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University (TMDU), Tokyo, Japan

[2]Department of Dentistry and Oral Surgery, Hokuto Hospital, Obihiro-shi, Japan

Correspondence
Kanako Yoshimi, Department of Dysphagia Rehabilitation, Division of Gerontology and Gerodontology, Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, Japan.
Email: k.yoshimi.gerd@tmd.ac.jp

Abstract

Objective: Videoendoscopic evaluation of swallowing is an objective swallowing function evaluation method used in dysphagia rehabilitation. However, it is anatomically difficult to detect the entry of foreign substances through the posterior tracheal wall using a conventional endoscope (CE). In this study, we developed an endoscope that can observe the posterior tracheal wall and investigated its reliability and validity in healthy adults.

Methods: Twenty healthy adults were included. The trachea was observed from inside the larynx using a CE and a portable, flexible two-step angulation endoscope (two-AE) with a two-step curved shaft tip. The visibility of the anterior and posterior walls was recorded. The time from the endoscope tip entering the larynx to the posterior tracheal wall was measured. Additionally, discomfort events were assessed after the examination. McNemar's test and a paired *t*-test were used for statistical analysis. Kappa coefficients and concordance rates were calculated.

Results: The anterior tracheal wall was observed using both endoscopes. The posterior tracheal wall was significantly observed in 18 participants with the two-AE ($p < .001$), compared to only three of 20 participants with the CE. The time to observation of the posterior tracheal wall for examiners 1 and 2 was 13.3 ± 6.5 and 12.0 ± 6.7 s, respectively, with no difference between groups ($p = .400$). The kappa coefficients of examiners 1 and 2 and between the examiners were 0.444, 0.643, and 0.643, respectively, with concordance rates of 90%, 95%, and 95%, respectively.

Conclusion: Regardless of the examiner's years of experience, we observed that the two-AE could observe the posterior tracheal wall.

Level of Evidence: Step 5.

KEYWORDS
dysphagia, swallowing disorders, trachea, videoendoscopy

1 | INTRODUCTION

Videoendoscopic evaluation of swallowing (VE) is an objective method for evaluating swallowing function during dysphagia rehabilitation. However, the form and examination methods have only changed slightly since the method was reported.[1] The examination uses a swallowing endoscope, in which a fiber is inserted through the nasal cavity to observe the morphology and structure of the pharynx, swallowing dynamics, and aspiration or pharyngeal residues to evaluate swallowing function.[2] Many studies have reported that the detection of aspiration by VE is comparable to that by videofluoroscopic examination of swallowing (VF).[2–12] Some have reported that the specificity and sensitivity of VE and VF tend to coincide,[2,5,6] while others have reported that VE is more sensitive than VF for penetration and aspiration.[13,14] In other words, the detection rate of aspiration in VE is debatable. Although the anterior tracheal wall can be identified during VE, the posterior tracheal wall is almost impossible to observe. Moreover, aspiration is inferred from the residues in the piriform synus, penetration, and dripping from the interarytenoid notch.[5] Therefore, the accuracy of aspiration detection is limited.

The difficulty in observing the posterior wall of the trachea is caused by the structure of the larynx and pharynx and the position of the tip of the endoscopic shaft. A typical endoscope has one bending portion on the shaft that extends from the body. The endoscope is usually inserted ventrally beyond the soft palate. After the tip of the shaft crosses the oropharynx, a lever on the body is used to bend the bent part further ventrally over the epiglottis, allowing it to reach a position where the inside of the larynx can be observed. Therefore, the tip of the shaft tends to point toward the anterior wall of the trachea, and it is often difficult to see the posterior wall of the trachea because of the structure of the interarytenoid notch, vocal folds, and false vocal cords. In other words, if the aspiration dripping from the interarytenoid notch is silent, the detectability of aspiration in VE is likely to be reduced. This means there is room for improvement in the structure of the endoscope.

Therefore, we developed an endoscope with a two-step shaft curvature. Evaluation methods used in research and clinical practice must have high instrumental validity and reliability. Moreover, when non-standardized evaluation methods are used, it is necessary to examine their reliability in advance. In this study, we investigated the validity and reliability of a newly developed portable, flexible two-step angulation endoscope (two-AE) for the observation of the posterior tracheal wall in healthy adults.

2 | MATERIALS AND METHODS

This cross-sectional study was conducted in June and July 2022. Twenty healthy adult volunteers (seven males and 13 females [median (interquartile range) age: 29.5 (28.0–40.0) years]) were included. Patients with a history of diseases causing dysphagia (cerebrovascular disorders, neuromuscular diseases, and head and neck cancer) and those who did not consent to participate in this study were excluded. All the study participants were fully informed about the study, verbally and in writing, and provided written consent. This study was approved by the Ethics Committee of Tokyo Medical and Dental University (ref: D2021-067). This was a human observational study, and the manuscript conforms to the STROBE guidelines. The survey was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

2.1 | Equipment

A conventional portable fiber naso-pharyngo-endoscope (CE) (ENT-30PC; Machida Endoscope Co., Ltd., Japan) and a newly developed two-AE (ENT-30DA08; Machida Endoscope Co., Ltd., Japan) were used. The characteristics of the endoscopes are presented in Table 1.

The two-AE consisted of a shaft part that could be inserted through the nasal cavity and an operation part on the eyepiece side, similar to the CE. At the tip of the shaft section was bend part 1 with a lens (Angle 1), and bend part 2 (Angle 2) was located closer to the control part. In the operation part, the angle levers for operating the bending mechanism were located separately on two different surfaces (Levers 1 and 2). Bend parts 1 and 2 could be operated independently of each other. The bending angle of the shaft was ±40° to the central axis of the shaft section for bend part 1 and ± 90° for bend part 2 (Figure 1).

2.2 | Measurements

The participants underwent VE using the CE and two-AE, examined by examiners 1 and 2. During the examination, the participants were instructed to sit with their heads in the midline position. Examiners 1 and 2 were dentists who had been engaged in VE for over 3 years and 6 years, respectively. They performed VE after learning the two-AE operation for approximately 30 min.

The examination procedure consisted of an observation of the anterior tracheal wall when the endoscope tip entered the larynx and an observation of the posterior tracheal wall by bending the shaft tip to the dorsal side. We evaluated whether the anterior or posterior tracheal wall could be observed (Figure 2) or not (Figure 3). An

TABLE 1 The structural differences between the portable, flexible two-step angulation endoscope and the conventional endoscope.

	Unit	Conventional endoscope	Portable, flexible two-step angulation endoscope
Diameter of tip	(mm)	3.2	3.2
Diameter of shaft	(mm)	3.2	3.2
Angle 1 up/down	(°)	130/100	40/40
Angle 2 up/down	(°)	Non	90/90
Angle view	(°)	80	80
Number of pixels		Same	

acceptable observation of the posterior tracheal wall was defined as the visualization of the membranous wall of the superior portion of the posterior cricoid wall just below the transverse and oblique arytenoid muscles. As an indication of the burden of the examination, the observation time (s) was recorded as the time from the point when the epiglottis disappeared from the endoscope's field of view and entered the larynx to the point when the posterior tracheal wall was visible. After the examination, the participants were asked about any unpleasant events during the examination.

Examiner 1 carried out two VEs using the CE and two-AE, while examiner 2 carried out only two VEs using the two-AE. Both examinations were performed again on the same participant 1 week after the initial examination. In the VE using the CE, the posterior tracheal wall was considered observable if it could be observed at least once during one of the two examinations.

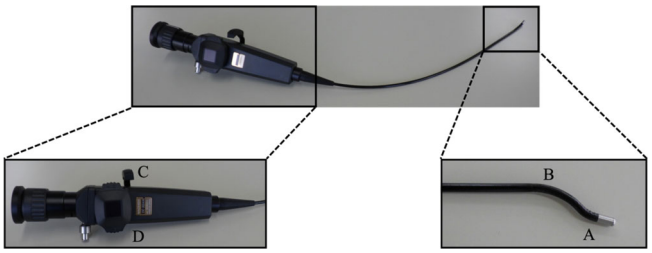

FIGURE 1 The components of the portable, flexible 2-step angulation endoscope. A: Angle 1; B: Angle 2; C: Lever 1; D: Lever 2.

2.3 | Statistical analysis

McNemar's test was used to examine whether the posterior tracheal wall could be observed with the CE and two-AE. The time taken by examiners 1 and 2 from the time the endoscope tip entered the larynx

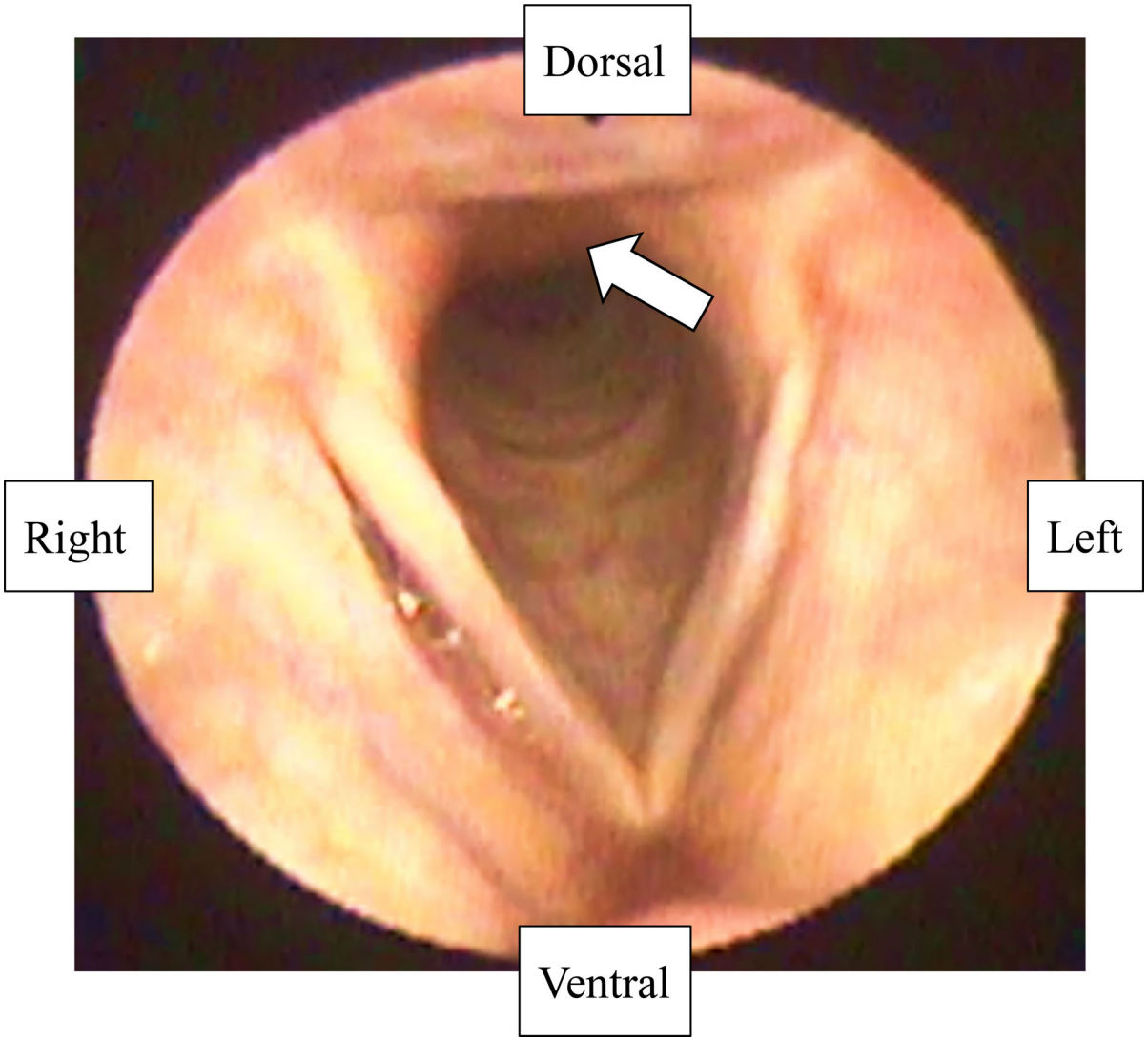

FIGURE 2 The image of the larynx and trachea observed using the portable, flexible two-step angulation endoscope. The posterior wall of the trachea was observed using the portable, flexible two-step angulation endoscope (arrow).

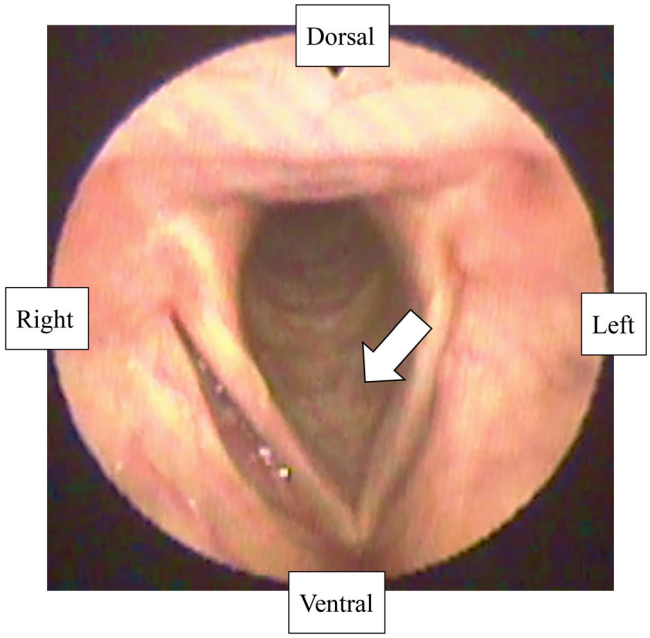

FIGURE 3 The image of the larynx and trachea observed using the conventional endoscope. The posterior wall of the trachea could not be observed using the conventional endoscope, only the anterior wall (arrow).

to the time the posterior tracheal wall was observed was compared using paired *t*-test. The kappa coefficient, concordance rate, bias index (BI), and prevalence index (PI) were calculated for intra- and inter-examiner reproducibility.[15] The significance level was set at $p < .05$. SPSS version 28.0 J (IBM Inc., Tokyo, Japan) was used for statistical analysis.

3 | RESULTS

All the participants agreed to participate in the study. VE using both CE and two-AE was possible in all cases, and all data were analyzed.

The anterior tracheal wall was visible in all participants using both endoscopes. On the other hand, the posterior tracheal wall was observed in 18 subjects with the two-AE, but only in three subjects with the CE (Table 2). In one of the 20 participants, examiners 1 and 2 were able to reach the endoscopic tip into the larynx but were unable to bend angle 1 within the larynx due to the strangulation reflex and could not see the posterior tracheal wall. The results of McNemar's test showed that examiner 1 was able to observe the posterior tracheal wall significantly ($p < .001$) when using the two-AE compared to the CE (Table 3).

TABLE 2 The results of the videoendoscopic evaluation of swallowing of the posterior wall of the trachea for examiners 1 and 2.

			Examiner 1				Examiner 2	
			Conventional endoscope		Portable, flexible 2-step angulation endoscope		Portable, flexible 2-step angulation endoscope	
Participants (No.)	Age (years)	Sex	First	Second	First	Second	First	Second
1	28	M	−	−	+	+	+	+
2	29	F	−	−	+	−	+	+
3	30	M	−	−	+	+	+	+
4	31	M	−	−	+	+	+	+
5	26	M	−	−	+	+	+	+
6	62	F	−	−	+	+	+	+
7	42	F	−	−	+	+	+	+
8	26	F	−	−	+	+	+	+
9	29	M	−	+	+	+	+	+
10	29	F	−	−	+	+	+	+
11	30	F	−	−	+	+	+	+
12	29	F	−	−	+	+	+	+
13	34	F	−	−	−	+	+	−
14	28	F	−	−	−	−	−	−
15	30	F	−	−	+	+	+	+
16	42	F	−	+	+	+	+	+
17	49	F	−	−	+	+	+	+
18	45	F	−	−	+	+	+	+
19	26	M	+	+	+	+	+	+
20	26	M	−	−	+	+	+	+

Note: "+" and "−" show that the posterior wall of the trachea was observed and not observed, respectively, during the videoendoscopic evaluation of swallowing.
Abbreviations: F, female; M, male.

TABLE 3 The observability of the posterior wall of the trachea with the portable, flexible two-step angulation endoscope and the conventional endoscope.

		Conventional endoscope			
		Observable	Unobservable	Total	*p*-value
Portable, flexible 2-step angulation endoscope	Observable	3	15	18	<.001**
	Unobservable	0	2	2	
	Total	3	17	20	

Note: **$p < .01$. McNemar's test was performed.

TABLE 4 The time required to observe the posterior wall of the trachea.

Participants (No.)	Age (years)	Examiner 1 Observing time (s)	Examiner 2
1	28	20	13
2	29	8	8
3	30	13	23
4	31	6	6
5	26	15	4
6	62	14	19
7	42	5	6
8	26	13	11
9	29	10	2
10	29	23	18
11	30	8	8
12	29	15	14
13	34	22	28
14	28	(–)	(–)
15	30	11	16
16	42	6	8
17	49	28	8
18	45	10	14
19	26	7	7
20	26	19	14
	29.5 (28.0–40.0)[a]	13.3 ± 6.5[b]	12.0 ± 6.7[b]

Abbreviations: F, female; M, Male; SD, standard deviation.
[a]Median (interquartile range).
[b]Mean ± deviation.

The time from when the endoscope tip entered the larynx until the posterior tracheal wall was identified was 13.3 ± 6.5 s for examiner 1 and 12.0 ± 6.7 s for examiner 2, with no difference between the groups ($p = .400$; Table 4). Regarding discomfort during examination with the two-AE, eight of the 20 participants complained of mild discomfort in the nasopharyngeal cavity, but no nasal bleeding or pain was observed.

The intra-rater reliability was 0.444 for examiner 1 and 0.643 for examiner 2 for the kappa coefficient of the second test compared to that of the first test as a reference. The concordance rate was 90.0% and 95.0%, respectively. The BI was 0 and 0.05, respectively, and the PI was 0.8 and 0.85, respectively. The inter-rater reliability was based on the first examination of examiner 2, who had more years of experience, with a kappa coefficient of 0.643, a concordance rate of 95.0%, a BI of 0.05, and a PI of 0.85 for examiner 1's first examination compared to that of examiner 2 (Table 5).

TABLE 5 Intra-rater and inter-rater reliabilities regarding examiners 1 and 2.

	Kappa value (κ)	Concordance rate (%)	Bias Index	Prevalence Index
Intra-rater reliability (Examiner 1)	0.444	90	0	0.80
Intra-rater reliability (Examiner 2)	0.643	95	0.05	0.85
Inter-rater reliability	0.643	95	0.05	0.85

4 | DISCUSSION

The results of McNemar's test showed that the two-AE significantly allowed for the observation of the posterior tracheal wall from within the larynx compared to the CE. The CE has only one bend in the endoscope shaft. Because of the positional relationship between the epiglottis and the posterior wall of the pharynx, the endoscope shaft tends to contact each structure, causing strangulation reflex, discomfort, and damage to the mucosa. Additionally, the anatomical structure of the laryngopharynx makes it difficult to observe the posterior wall of the trachea from the larynx. However, the two-AE has two bend sections on the endoscope shaft, and the endoscope tip (bend part 1) can be curved ±40° to the shaft within the larynx. This allows the observation of the inside of the larynx with a field of view different from that of the CE, and the posterior wall of the trachea can also be seen. To observe the posterior tracheal wall using the two-AE, it is necessary to curve the tip of the endoscope toward the back from the anterior wall and look into the posterior tracheal wall. Although the observation range has improved compared to that of the CE, it is difficult to observe only the posterior wall, and the anterior wall is also visualized simultaneously.

According to previous studies, the kappa coefficient of concordance is "Moderate" from 0.41 to 0.60, and "Substantial" from 0.61 to 0.80.[16] Both the intra-examiner kappa coefficient for examiner

2 and the inter-examiner kappa coefficient for examiner 1 based on examiner 2, who had more years of experience, were above 0.6, indicating that the observation of the posterior tracheal wall was highly reliable. On the other hand, the intra-examiner kappa coefficient for examiner 1 was 0.444, which might be interpreted as less reliable than for examiner 2. This may be due to the smaller BI and larger PI, resulting in a smaller kappa coefficient.[17] We believe that the effect of coincidence was small in the analysis of this study, and the high agreement rate of 90.0% between the first and second examinations can be used in clinical practice with some degree of reliability.

Regarding the handling of the two-AE, the two examiners were able to establish the endoscopic technique after approximately 30 min of use, and the reliability of intratracheal observation was assured. This was presumably because the shaft part diameter, tip diameter, and viewing angle of the two-AE were the same as those of the CE, and the two-AE could easily be operated with only an additional lever operation (lever 1). Therefore, the possibility of operability affecting the inspection quality can be considered small.

Although no previous study provides a guideline for examination time, the time required to observe the posterior wall of the trachea after the tip of the endoscope entered the larynx was 28 s at the longest and 2 s at the shortest, showing a large individual difference. On average, examiners 1 and 2 took approximately the same amount of time, and there was no difference between the groups, suggesting that examiners of any experience level can carry out the assessments at the same time. In one of the 20 participants, the posterior tracheal wall was not observed because of the participant's vomiting reflex during the VE by examiners 1 and 2. This may have been due to the fact that the subject was a healthy adult with sensitive pharyngeal sensations. However, there were no adverse events, such as pain or bleeding, in any of the participants. Therefore, we considered that the difference in the structure of the endoscope fiber tip has little effect on the invasiveness of the examination.

4.1 | Limitation

If the posterior wall of the trachea can be observed, it would improve the detection of aspiration that occurs when saliva or food accumulated in the pyriform sinus enters the larynx and then passes through the posterior wall of the trachea. However, the participants in this study were healthy adults, not patients with dysphagia. Therefore, only the presence of confirmation of the posterior tracheal wall at rest was examined, and actual evaluation of swallowing and aspiration detection were not performed. VE chronologically evaluates changes in disease status and training effects, and two or more examiners may evaluate the swallowing function in the same patient. Therefore, further studies should test the feasibility of significantly detecting aspiration adherent to the posterior tracheal wall compared to the CE in patients with dysphagia who are at high risk of aspiration and the occurrence of discomfort or adverse events associated with the examination. In addition, since aspiration during pharyngeal contraction cannot be detected during the "whiteout" by VE,[13,18] it is necessary to observe and evaluate the presence or absence of aspirated materials in the trachea. Improving the field of view with the two-AE may enhance the sensitivity of VE.

In addition, healthy adults could maintain a stable posture during the examination, and intratracheal confirmation from the inside of the larynx could be performed without problems. However, in actual clinical practice, it may be difficult to hold the posture, and the examination of patients with involuntary movements, such as those with Parkinson's disease, may be anticipated. Furthermore, in the reclining and neck retroflexed positions, clinicians sometimes encounter cases in which it is difficult to confirm the posterior tracheal wall owing to anatomical features. Therefore, it is necessary to examine the limitations of the two-AE and the optimal posture during the examination.

5 | CONCLUSION

Examination using the two-AE was almost identical to that with the CE, with high reproducibility of intra- and inter-examiner examinations. It was suggested that the two-AE might facilitate observation of the posterior tracheal wall regardless of the examiner's years of experience.

ACKNOWLEDGMENTS

The authors thank all the staff members and participants who participated in this study. Moreover, Machida Endoscope Co., Ltd. (Japan) loaned us a portable, flexible two-step angulation endoscope free of charge.

FUNDING INFORMATION

No funding was received for this study.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

The datasets generated and analyzed during the current study are not publicly available because they contain information that could compromise the privacy of the participants but are available from the corresponding author upon reasonable request.

ORCID

Kanako Yoshimi https://orcid.org/0000-0002-5005-036X
Kazuharu Nakagawa https://orcid.org/0000-0002-5572-4159
Ryosuke Yanagida https://orcid.org/0000-0002-5752-5946
Kohei Yamaguchi https://orcid.org/0000-0002-7034-4402
Haruka Tohara https://orcid.org/0000-0001-5514-6419

REFERENCES

1. Bastian RW. Videoendoscopic evaluation of patients with dysphagia: an adjunct to the modified barium swallow. *Otolaryngol Head Neck Surg*. 1991;104(3):339-350. doi:10.1177/019459989110400309

2. Langmore SE, Schatz K, Olson N. Endoscopic and videofluoroscopic evaluations of swallowing and aspiration. *Ann Otol Rhinol Laryngol*. 1991;100(8):678-681. doi:10.1177/000348949110000815
3. Langmore SE, Schatz K, Olsen N. Fiberoptic endoscopic examination of swallowing safety: a new procedure. *Dysphagia*. 1988;2(4):216-219. doi:10.1007/bf02414429
4. Leder SB, Sasaki CT, Burrell MI. Fiberoptic endoscopic evaluation of dysphagia to identify silent aspiration. *Dysphagia Winter*. 1998;13(1):19-21. doi:10.1007/pl00009544
5. Wu CH, Hsiao TY, Chen JC, Chang YC, Lee SY. Evaluation of swallowing safety with fiberoptic endoscope: comparison with videofluoroscopic technique. *Laryngoscope*. 1997;107(3):396-401. doi:10.1097/00005537-199703000-00023
6. Kaye GM, Zorowitz RD, Baredes S. Role of flexible laryngoscopy in evaluating aspiration. *Ann Otol Rhinol Laryngol*. 1997;106(8):705-709. doi:10.1177/000348949710600817
7. Logemann JA, Rademaker AW, Pauloski BR, Ohmae Y, Kahrilas PJ. Normal swallowing physiology as viewed by videofluoroscopy and videoendoscopy. *Folia Phoniatr Logop*. 1998;50(6):311-319. doi:10.1159/000021473
8. Bastian RW. The videoendoscopic swallowing study: an alternative and partner to the videofluoroscopic swallowing study. *Dysphagia Fall*. 1993;8(4):359-367. doi:10.1007/bf01321780
9. Murray J, Langmore SE, Ginsberg S, Dostie A. The significance of accumulated oropharyngeal secretions and swallowing frequency in predicting aspiration. *Dysphagia Spring*. 1996;11(2):99-103. doi:10.1007/bf00417898
10. Butler SG, Markley L, Sanders B, Stuart A. Reliability of the penetration aspiration scale with flexible endoscopic evaluation of swallowing. *Ann Otol Rhinol Laryngol*. 2015;124(6):480-483. doi:10.1177/0003489414566267
11. Pilz W, Vanbelle S, Kremer B, et al. Observers' agreement on measurements in fiberoptic endoscopic evaluation of swallowing. *Dysphagia*. 2016;31(2):180-187. doi:10.1007/s00455-015-9673-7
12. Baijens L, Barikroo A, Pilz W. Intrarater and interrater reliability for measurements in videofluoroscopy of swallowing. *Eur J Radiol*. 2013;82(10):1683-1695. doi:10.1016/j.ejrad.2013.05.009
13. Giraldo-Cadavid LF, Leal-Leaño LR, Leon-Basantes GA, et al. Accuracy of endoscopic and videofluoroscopic evaluations of swallowing for oropharyngeal dysphagia. *Laryngoscope*. 2017;127(9):2002-2010. doi:10.1002/lary.26419
14. Kelly AM, Drinnan MJ, Leslie P. Assessing Penetration and Aspiration: How Do Videofluoroscopy and Fiberoptic Endoscopic Evaluation of Swallowing Compare?.
15. Cohen J. A coefficient of agreement for nominal scales. *Educ Psychol Meas*. 1960;20(1):37-46. doi:10.1177/001316446002000104
16. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33(1):159-174.
17. Byrt T, Bishop J, Carlin JB. Bias, prevalence and kappa. *J Clin Epidemiol*. 1993;46(5):423-429. doi:10.1016/0895-4356(93)90018-v
18. Mirrett PL, Riski JE, Glascott J, Johnson V. Videofluoroscopic assessment of dysphagia in children with severe spastic cerebral palsy. *Dysphagia Summer*. 1994;9(3):174-179. doi:10.1007/bf00341262

How to cite this article: Tamai T, Yoshimi K, Nakagawa K, et al. Usefulness of a newly developed endoscope for the observation of the posterior tracheal wall. *Laryngoscope Investigative Otolaryngology*. 2023;8(4):963-969. doi:10.1002/lio2.1105