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Title page

Dilation Eustachian Tuboplasty with Visual Eustachian Tube Endoscope and Supporting Balloon.

Short running title: Feasibility and Safety Assessment

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Abstract

Objective: To evaluate the feasibility and safety of employing a visual Eustachian tube endoscope (VETE) with a supporting balloon as a viable treatment and examination option for patients with Eustachian tube dysfunction (ETD).

Methods: A study involving 9 fresh human cadaver heads was conducted to investigate the potential of balloon dilation Eustachian tuboplasty (BET) utilizing the supporting balloon catheter, and the ET cavity was examined using VETE during the procedure, which involved the dilation of the cartilaginous portion of the ET with the supporting balloon catheter.

Results: The utilization of VETE in conjunction with the supporting balloon catheter demonstrated technical ease during the procedure, with no observed damage to essential structures, particularly the ET cavity.

Conclusion: This newly introduced method of dilation and examination of the ET cavity using VETE and the supporting balloon is a feasible, safe procedure.

Key Words: Dilation; Eustachian Tube; Visual endoscope; Supporting balloon; Feasibility and safety.

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Introduction

The Eustachian tube (ET) serves as the sole channel for middle ear ventilation and drainage (1-3), playing a crucial role in regulating middle ear pressure, clearing the middle ear space, and preventing diseases(4, 5). So, the ET plays an important role in the middle ear.

Eustachian tube dysfunction (ETD) includes obstructive ETD, baro-challenge-induced ETD and patulous ETD (4), can persist into adulthood and have various causes, such as anatomical derangements, chronic sinusitis, allergic rhinitis, adenoid hypertrophy and gastroesophageal reflux (1). The incidence rate in adults is approximately 5% (6-8), and 70% of children experience at least one acute episode of ETD before the age of 10 (9, 10), indicating the significant impact of ETD on health.

Various medical and surgical treatments have been explored for obstructive ETD, including balloon dilation of Eustachian tube (BET), laser Eustachian tuboplasty (11), and topical application of medications (12). Among these treatments, BET has shown promising effect (13, 14). Indications for BET may include symptoms such as aural fullness lasting for more than 3 months; type B/C tympanogram; Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) score > 2; and failure of medical treatment (15). Previous studies have demonstrated that BET can improve ET function based on subjective and objective measurement in patients with ETD (16). Additionally, BET appears to have no significant impact on taste function, but may improve olfactory function (17). However, the lack of high-level evidence to support its use has led to some ENT consultants in the UK not practicing BET (18). We believe that the existing BET techniques lack accurate operation markers and may not be performed at the optimal position of the balloon.

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In this study, we designed a **V**isual **E**ustachian **T**ube **E**ndoscope (**VETE**) and its supporting balloon, and examined the feasibility of visual BET in cadavers. The objective of this study was to assess the safety and optimize its clinical application of this novel technique.

MATERIALS AND METHODS

Cadavers Study

Ethical approval was obtained from the Ethical Committee of the Second People's Hospital of Foshan (KJ2022007) for this study. In order to assess the feasibility of using the VETE and its supporting balloon for accurate positioning in the cartilaginous portion of the ET, we developed a procedure for BET under visual guidance using the VETE. A total of 9 ETs from 9 cadavers, aged between 30 and 70, were included in the study, with an approximately equal distribution of left ETs (4/9) and right ETs (5/9). All 9 cadavers maintained their shape and integrity, and being filled with colophony glue. Prior to the procedure, the cadavers were fully thawed to avoid damage to the ET mucosa and prevent adverse effects during the operation. The cadavers were selected for this study after being filled with color glue to aid in assessing any damage during the procedure.

The VETE used in this study was a 1.2mm-diameter soft segment endoscope (Shaanxi FeiMiao Medical Equipment Co., LTD, China). A supporting balloon, sheathed outside the VETE, had a diameter of 3.5mm and a length of 16mm, which was advanced through the working channel of the VETE to ensure accurate positioning of the balloon

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in the video (Fig. 1). Once the narrowest position of the ET was visualized, the supporting balloon was inflated to a pressure of 10 bars (7.501 mm Hg) for 2 minutes using a pressure applicator (Shaanxi FeiMiao Medical Equipment Co., LTD, China).

Exclusion criteria for cadavers were as follows: a) Severely narrow nasal cavity, abnormal development of the nasal cavity or the ET, hyperplasia, or cancer, or severely deformed nasal cavity or ET due to injury before death; b) Unknown source of the cadaver head, or if the infectious disease virus had not been inactivated.

Efficacy evaluation:

a) Highly Effective: The advancement of the supporting Balloon is smooth with moderate hand feel. The internal tissue of the human body where the lens reaches can be clearly observed during the endoscope push process, allowing for adjustment of the push direction based on this image. The balloon can be successfully advanced into the ET without any issues. The endoscope can be used to safely exit the inflating balloon. No device-related damage occurs during the test. The regression process after the test can be observed in the ET and nasal cavity.

b) Effective: The advancement of the supporting Balloon is moderately laborious with moderate hand feel. The tissue condition in the human body where the lens reaches can be partially observed during the endoscope push process, or can be observed after processing, allowing for adjustment of the push direction and completion of the push based on this image. The endoscope can be used to safely exit the inflating balloon. No device-related damage occurs during the test. The regression process after the test can be observed in the ET and nasal cavity.

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c) Ineffective: The advancement process of the supporting Balloon is laborious, possibly due to a sharp front end of the combined instrument, or inability to observe the tissue condition in the human body where the lens reaches during the endoscope push process. The VETE cannot be adjusted and advanced properly. The supporting Balloon cannot be withdrawn using the endoscope, or the lens body is broken (non-human factors), the balloon falls off during the operation, the balloon leaks or breaks, or the cavity of the cadavers head is severely damaged during the operation. The regression process after the test cannot be observed in the ET and nasal cavity.

Statistics:

Statistical analysis was conducted with GraphPad Prism 8.0 statistical software (GraphPad Software, USA). A 2-tailed paired-samples test and Chi square test were performed using $P < 0.05$ for significance.

Results

Clinical Features of the Study Cohort

A total of nine cadavers (7 male, 2 female) aged 30 to 70 years who had previous tympanostomy tubes, underwent examination with visual ET and BET of the cartilaginous portion of their ET at October 10, 2020. Among the nine ETs, six required the use of a 45° catheter, three required both 45° and 60° catheters, and one ET necessitated the use of catheters with three angles (30°, 45°, and 60°). ~~Preoperative findings are summarized in Table 1.~~

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Structure of VETE and Supporting Balloon

The VETE consists of a hard segment and a soft segment (Fig. 2A). The catheter has three angles: 30 °, 45 ° and 60 °, which can be adjusted to change the angle of the endoscopic soft segment to adapt to different ETs (Fig. 2B). The supporting balloon can be sleeved on the VETE soft segment (Fig. 2C), and used with the catheter to advance the matching balloon along the VETE soft segment to the appropriate position of the ET (Fig. 2D). The schematic diagram and operational illustration of this equipment are shown in Fig. 2E.

Practical Application

The VETE instrument was inserted into the ET to observe the position reached, with the supporting balloon installed in the front section (soft section) of the endoscope. We encountered no technical difficulties in identifying the pharyngeal ET orifice in the 9 human cadavers. The endoscope tip was advanced into the pharyngeal ostium of the ET, and the ET cavity was examined (Fig. 3A). Then, the balloon catheter was gently advanced through the working channel with the endoscope until the narrowest position of the ET (Fig. 3B).

Once the balloon was correctly positioned, dilation was implemented using NaCl solution up to a pressure of 10 bars for 2 minutes. Then, the solution from the balloon was aspirated, and the catheter, endoscopic, and balloon were carefully removed under endoscope control.

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In all cases, the catheter and balloon was correctly positioned as confirmed by the endoscope video. After being correctly positioned in the ostium, the balloon catheter was advanced by an assistant without resistance. After the balloon was dilated, it was remove from the soft segment of the VETE, and then the VETE was pushed forward to observe the state of the ET cavity. The narrowest segment of ET was clearly observed (Fig. 3C-D).

Postoperative results are summarized in Table 1. Two preoperative ETs were open or semi-open (22.22%), and the others were closed (77.78%). All postoperative ETs were open. After the operation, the ET cavity was opened, and the VETE could enter and exit the ET cavity very smoothly for observation. Moreover, the operation did not damage the mucosa of the ET cavity, and the entire operation process was not terminated due to accidents.

With the application of VETE, it took 2.22 ± 1.20 minutes to position the balloon, and the whole operation process was easy to implement. Eight (88.89%) ETs showed significantly effectiveness and one (11.11%) ET showed effectiveness in BET.

Discussion

Clinical studies has showed that BET is an effective and efficient treatment for diseases caused by ETD(13, 14, 19-21). However, some studies have reported that BET may not always yield ideal results. For instance, balloon placement may result in ET injury(22-24)due to failure to accurately observe the position of the balloon during advancement, and failure to promptly stop the procedure when mucosal damage occurs. Although computed tomography (CT) has been used in some studies to determine the position of the balloon (23, 25), it is not possible to use CT to guide balloon placement during

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surgery (26). Some studies have also used navigation for BET, but navigation is not available in all hospitals and may not be easily applicable on a wide scale (24, 27). The present study aimed to verify a new design of VETE that can be used to directly inspect the ET, observe the correct placement of the balloon, and examine the ET cavity after BET.

Patients with ETD often exhibit submucosal inflammatory infiltration and even follicle formation in the ET prior to surgery. Lymphatic follicles have been described as tonsils of the fallopian tube or Gerlach`s tonsil, and are part of the Waldyer`s ring of lymphoid tissue surrounding the oropharynx and nasopharynx. Some studies have shown that adenoid hypertrophic tissue with "cobblestoning" typically corresponds to lymphoid hyperplasia(28, 29). Many patients who require BET may also suffer from conditions such as allergic rhinitis, chronic rhinosinusitis, local biofilms, and edema of pharyngeal orifice(19, 28, 30, 31), which can make balloon placement challenging. Therefore, it is necessary to develop an instrument that can directly inspect and visualize the ET cavity for accurate balloon placement.

In traditional BET, the suitable position of the balloon is not directly observed during advancement, which can make it challenging for the balloon to enter the ET in many cases (23). Moreover, traditional BET may be associated with complications such as mucosal injury, caling, pathological ETD, epistaxis (nosebleeds), carotid artery injury (tear or pseudoaneurysm), subcutanous emphysima from mucosal injury, infection, and anesthesia-related complications (22). These complications often arise from failure to accurately observe the position reached by the balloon.

Prior to the operation, only a part of the ET cavity at the pharyngeal orifice is observable in most cases, even when both ETs are partially open. This means that the observation

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of the ET is limited without the use of VETE. Although the structure of the supporting balloon used in VETE is different from that of traditional balloon, their working principle is the same. In this study, all ETs were open after BET using the supporting balloon, demonstrating that the expansion ability of the supporting balloon for ETs is comparable to that of the traditional balloon. With the guidance of VETE, the average time taken for the balloon to reach the suitable position was only 2.22 minutes, except for the first operation which took 5 minutes, and the others did not exceed 3 minutes. The success rate of complete ET opening after BET was 100% in the 9 cases, and the entire process was completed without any accidental termination, and no mucosal damage was observed before or after BET, indicating the high safety of the VETE procedure. After BET, the entire ET cavity could be clearly observed with VETE, enabling effective evaluation of the ET after the procedure.

In terms of the angle of the external catheter used in the operation, 45° was used for 6 out of the 9 ETs (66.67%), 45° and 60° were used for 2 of the 9 ETs (22.22%), and 30°, 45°, and 60° were used for only one ET (11.11%), which is consistent with data indicating that the ET axis with reference to the sagittal plane is approximately 42°(32, 33). The design of multiple catheters in the new VETE can cater to the needs of different patients during the procedure.

If the VETE and its supporting balloon are demonstrated to be clinically effective with sustained benefits over time, they could serve as a useful and minimally invasive alternative for patients with ETD. The findings of the present study, along with previous studies, suggest that VETE may result in lower injury compared to traditional balloon, particularly in patients with ETD and patients with nasopharyngeal carcinoma after radiotherapy, who may not be suitable candidates for traditional balloon treatment.

Summary

Wide-ranging outcomes have been reported on the surgery and surgical complications of eustachian tube balloon

This attempt to perform Visual Eustachian Tube Endoscope and Supporting Balloon on 9 corpses

Visual Eustachian Tube Endoscope and Supporting Balloon was easy to perform, and no damage to essential structures, particularly the ET cavity, was observed

The ET cavity using VETE and the supporting balloon is a feasible, safe procedure

Conclusions

In conclusion, the use of the VETE technique, with its supporting balloon, offers a promising and minimally invasive approach for treating ETD. The VETE procedure allows for direct observation of the balloon as it is advanced, reducing the risk of complications associated with traditional balloon techniques. The expansion ability of the supporting balloon for Eustachian tubes is comparable to that of traditional balloons, as demonstrated by successful opening of all ETs in the study. The use of VETE also allows for better visualization of the entire Eustachian tube cavity before and after the procedure, facilitating more effective evaluation. Additionally, the

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multiple catheter design of the VETE allows for flexibility in choosing the appropriate angle for catheter insertion.

Furthermore, the VETE technique may be particularly beneficial for patients with ETD and those with nasopharyngeal carcinoma after radiotherapy, who may not be suitable candidates for traditional balloon treatments due to increased risks of complications. However, further clinical studies are needed to validate the clinical effectiveness and long-term benefits of VETE. Overall, the VETE procedure shows promise as a safe and effective alternative for treating ETD, with potential advantages over traditional balloon techniques, and warrants further investigation and consideration in clinical practice.

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Conflict of interest

The authors declare no competing interests.

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Author contributions

S. Chen, and H. Zhang designed the study. H. Zhang performed the analyses with assistance from S. Chen. H. Zhang, S. Chen, Q. Zhang, K. He, Y. Chen, D Su, H Tang and W Lin contributed to experimental design and experimental operation. H. Zhang and S. Chen wrote the manuscript. H. Zhang and S. Chen supervised the study. All authors discussed the results and interpretation, and contributed to the final version of the paper.

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Figure Legend

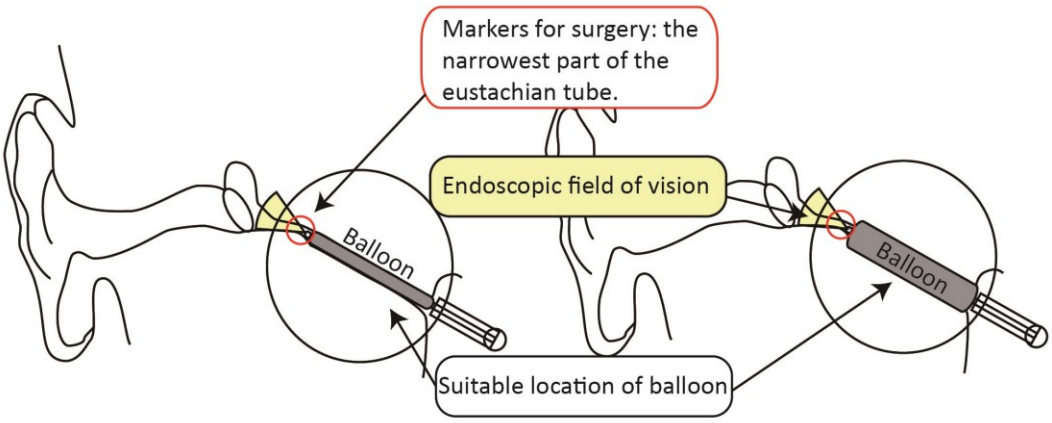

Fig. 1. Operating principle of VETE.

The red ring represents the surgical markers of the VETE and its supporting Balloon surgery. The yellow area indicates the field of vision of the VETE. The gray area represents the supporting Balloon of the VETE. The black ring indicates the main operative area of the VETE.

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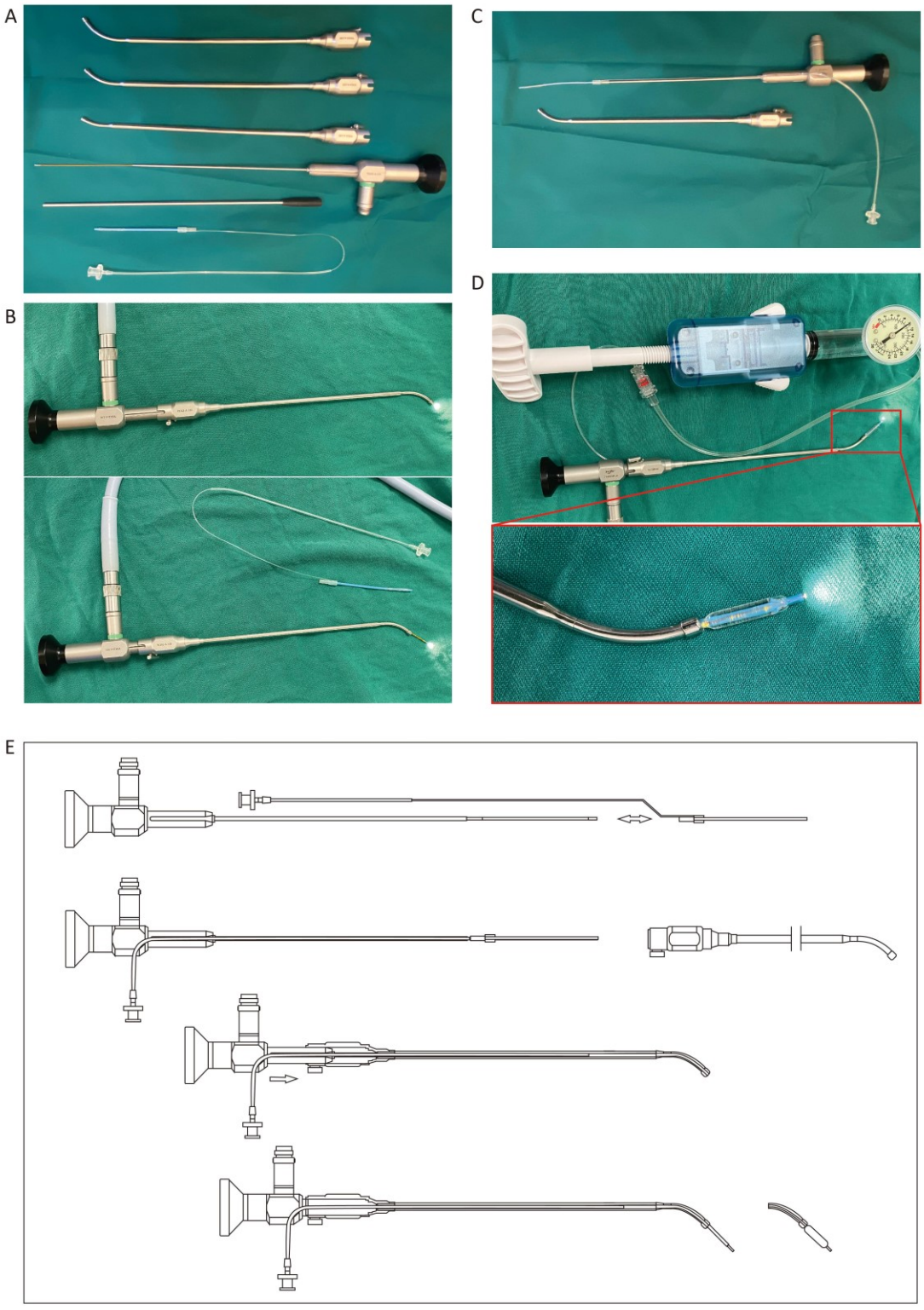

Fig. 2. Structure of VETE and its supporting Balloon.

(A) The shape characteristics of VETE. (B) The catheter changing the angle of the VETE soft segment. (C) Combination mode of VETE and its supporting Balloon. (D)

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The angle of the supporting Balloon can change with VETE under the catheter. (E) The diagram of the equipment.

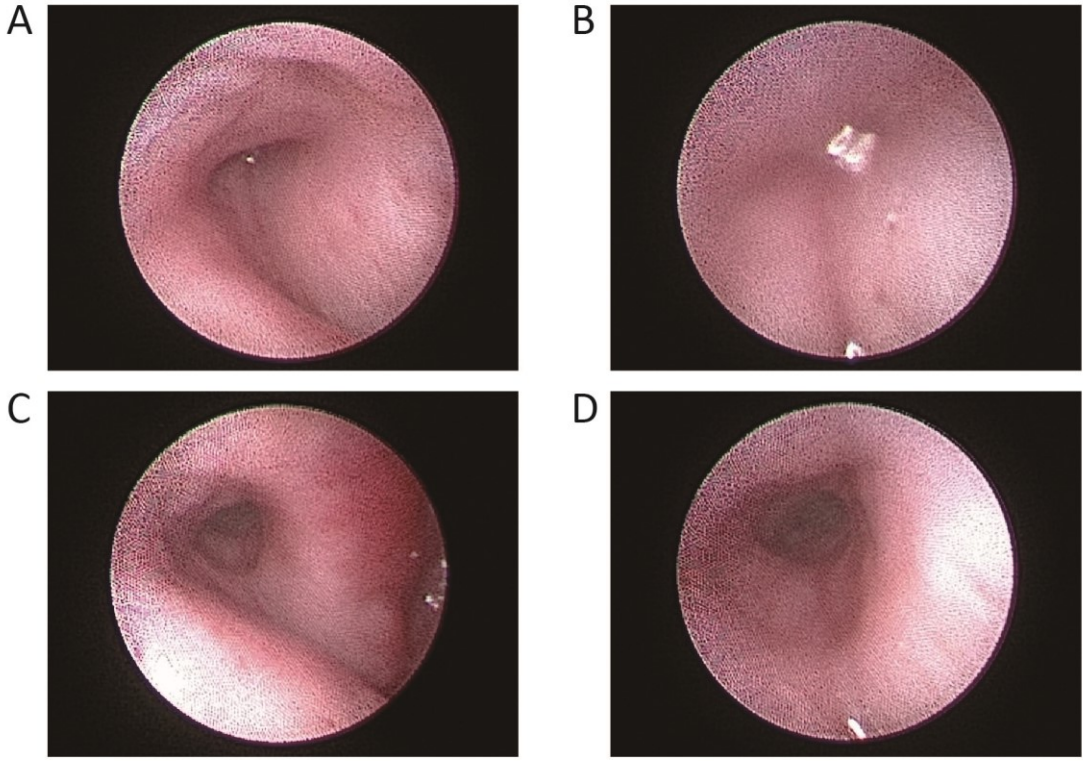

Fig. 3. The preoperative and postoperative ET in VETE.

(A) The pharyngeal ostium of the ET in VETE. (B) The narrowest position of the ET in VETE. (C) The postoperative ET cavity in VETE. (D) The narrowest segment of postoperative ET in VETE.

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Table 1. Postoperative results

	Preoperative	Postoperative	P Value
Morphology of ET			0.0007
Open	2 (22.22%)	9 (100%)	
Close	7 (77.78%)	0	
Observe the tube			<0.0001
Whole	0	9 (100%)	
Part	9 (100%)	0	
Cavity damage			>0.9999
Yes	0	0	
No	9 (100%)	9 (100%)	
Accidents			>0.9999
Yes	0	0	
No	9 (100%)	9 (100%)	
Time for balloon placement (min)	2.22±1.20		
Effect evaluation			
Significantly effective	8(88.89%)		
Effective	1 (11.11%)		
Invalid	0		

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