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Development of an Outer Tube That Reduces Nasal Pain and Epistaxis during Transnasal Endoscopy

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Background: Transnasal endoscopy has recently become common in Japan. Although transnasal endoscopy has many advantages, nasal pain and epistaxis are common complaints. To reduce nasal pain and epistaxis, we developed a new tube sheath system for transnasal endoscopy. This new tube sheath system (outer sheath and inner tube), called the Nasal Slider, is produced by TOP Corporation, Japan.

Methods: A tube sheath longer than the nasal concha is inserted to reduce pain along the nasal turbinate. Because the sheath is left in place, tubes can be passed through the nose multiple times without causing additional pain. A total of 34 consecutive patients (mean age 68.1 years; 22 men and 12 females) who had undergone transnasal endoscopy in the past were selected for transnasal endoscopy with the Nasal Slider. After the transnasal endoscopy was completed, patients who gave consent for use of the Nasal Slider were interviewed by using 3 questionnaires on nasal discomfort, nasal pain, and epistaxis.

Results: Because the transnasal endoscope passes inside the sheath, epistaxis can be prevented. Thirty of 34 selected patients underwent transnasal endoscopy using the Nasal Slider. Twenty-seven and 28 patients reported feeling less nasal discomfort and pain, respectively, with the Nasal Slider than during examinations without the Nasal Slider. No epistaxis developed in any patient examined with the Nasal Slider.

Conclusions: The Nasal Slider appears to reduce nasal pain and epistaxis during transnasal endoscopy and is currently used in many hospitals in Japan. (J Nippon Med Sch 2021; 88: 516–523)

Key words: transnasal endoscopy, nasal pain, epistaxis, outer tube

Introduction

Diagnostic upper endoscopy using a standard endoscope without anesthesia is routinely performed outside the United States[1–3]. However, in the United States transoral esophagogastroduodenoscopy (EGD) is usually done with intravenous sedation, since manipulation of the hypopharynx causes a gagging reflex, which causes discomfort for the patient, thus increasing the difficulty and reducing the tolerability of the examination[4]. This procedure is routinely performed under full anesthesia in North America. A significant proportion of cases of morbidity and mortality associated with EGD are related to hypoxia due to general anesthesia[5]. The use of anesthesia is also associated with increased cost, lost work time by the patient on the day of endoscopy, and the need for someone to accompany the patient home after the procedure[6]. In transnasal EGD, an ultrathin endoscope is introduced via the naris along the choanae under visual control into the upper gastrointestinal tract, which can then be inspected in its entirety[7]. Transnasal endoscopy has been popular for many reasons, such as its small diameter, decreased throat irritation, the ability to speak during examination, and the low physical and mental burdens[1–8].

However, transnasal endoscopy has disadvantages. Na-

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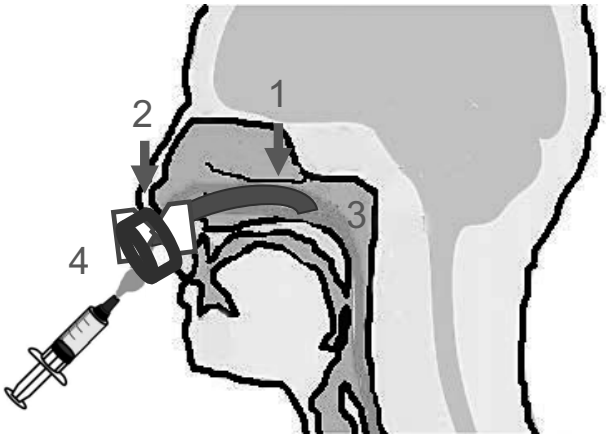

Fig. 1
Illustration of the important points in trial production of sheath as a measure against nasal pain and epistaxis.
1. The sheath should be longer than the nasal concha, as pain occurs while passing the nasal turbinate.
2. The shape of the sheath is wing-like, and a cushion is attached to protect the nostrils and avoid pain during operations after passage.
3. The sheath is inserted through the sinus turbinate and left in place. Tubes can subsequently be passed through the nose multiple times without additional pain.
4. The inner tube is an infusion form for additional injection of anesthesia. The tube is longer than the nasal concha.

sal pain and epistaxis are sometimes observed during examination[4,9–11]. The level of pain experienced throughout the procedure is comparatively low, and the only complication reported by patients is epistaxis. However, these are important patient concerns. A study of risk factors for epistaxis during transnasal endoscopy found that it occurred in 5.3% of patients undergoing transnasal endoscopy as part of a health checkup[9].

A new tube sheath system that can be inserted into the nose to reduce subsequent nasal pain and epistaxis risk has been developed. A sheath with an inner tube, called the Nasal Slider (TOP Corporation; Japan), has been produced to reduce these complications. We examined its usefulness during treatment.

Materials and Methods

This study was approved by the Ethics Review Board of Nippon Medical School Tama Nagayama Hospital (Reception number: 676).

Development of the Outer Tube through Transnasal Endoscopy

Development of a sheath through which a transnasal endoscope can be inserted

Nasal airway tubes and nasal trachea tubes can be inserted from the nose. The shape of these were considered when developing the Nasal Slider. To protect against nasal pain, the length of the sheath is longer than the nasal concha, and rigidity was ensured by using a polyvinyl chloride tube with a shape that can be easily adjusted (**Fig. 1**). Since the sheath is longer than the nasal concha and is left in place, pain when passing through the nasal turbinate is experienced once, and subsequent insertion of tubes is painless. A cushion has been designed to protect the nostrils and reduce nasal pain during and after passage. For additional injection of anesthesia, the inner tube is designed in an infusion form. The tube is longer than the nasal concha, to avoid epistaxis.

In normal nasal endoscopy, a catheter is inserted during preceding treatment procedures and then removed, after which the nasal endoscope is inserted and removed. This results in repeated insertions and removals along the nasal turbinate. However, the Nasal Slider is inserted only once and left in place after removing the inner tube. This tube sheath system was configured to be comfortable and shaped so that drugs can be injected through the inner tube, which reaches the back of the nasal cavity.

The Nasal Slider comprises an outer sheath, an inner tube, a sponge, and a belt (**Fig. 2**). The material of the sheath and inner tube is polyvinyl chloride. The sheath was examined and improved 3 times to fit the nasal meatus (**Fig. 3**; **Table 1**). The system has been patented and marketed.

The outer and inner diameters of the sheath are 8 mm and 7 mm, respectively. The outer diameter measurement was set so that the sheath can pass through the nasal meatus, and the inner diameter was set so that a nasal endoscope can be inserted inside the sheath. The effective length of the sheath was set at 70 mm so that it could be placed in the nasal cavity.

The outer diameter of the inner tube is 6.5 mm, which is larger than the diameter of a transnasal endoscope (5.8 to 5.9 mm). The effective length of the inner tube is 85 mm, which is almost the same as that of the nasal pretreatment catheter (length, 90 mm; diameter, 14 or 16 Fr; Fujifilm, Japan). The inner tube is removed during endoscopic examination, and examination is performed by inserting a transnasal endoscope inside the feather-shaped sheath, to affix the tube and prevent unintentional removal. A sponge is applied to the area corresponding to the nostrils.

Method for Using the Nasal Slider (Fig. 4)

(i) Premedication and anesthesia: Patients are asked to fast from 20:00 the day before undergoing EGD, although

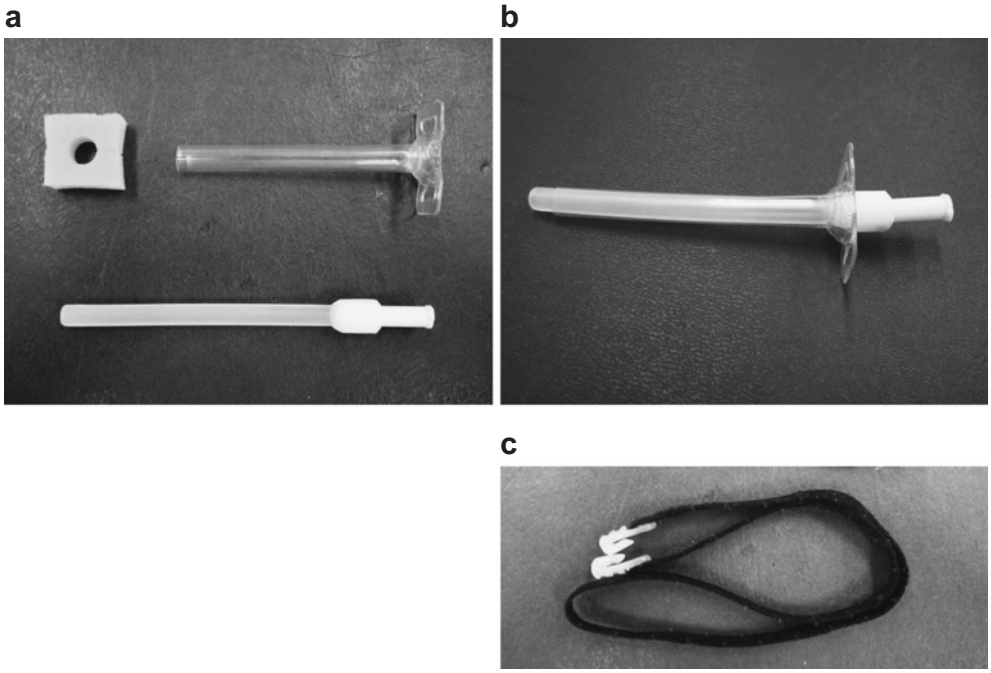

Fig. 2
The course of prototype production. Fourth generation tube: Nasal Slider.
The tube sheath system is called the Nasal Slider (TOP Corporation; Japan) and comprises an outer sheath, an inner tube, a sponge (a, b), and a belt (c).

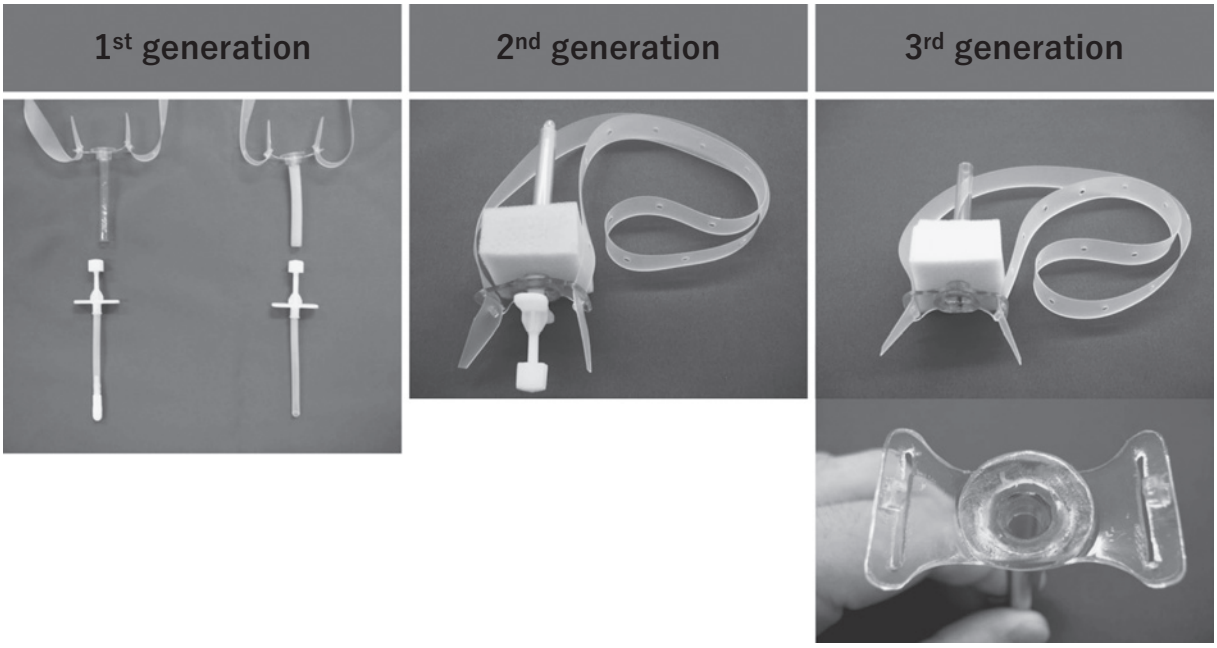

Fig. 3
Development of the tube sheath system.
The Nasal Slider consists of a sheath and inner tube, which are produced from polyvinyl chloride and a sponge. The inner tube fits into the sheath. A belt is used to attach the Nasal Slider to the face.

they can drink water and other fluids. On the day of the examination, patients are given a mixture of Gascon Drops 5 mL and water 50 mL approximately 15 minutes before the procedure (**Fig. 4a**). They are then asked to lie down on the endoscopy table in the supine position. About 10 minutes before starting, several drops of 0.05% naphazoline solution are added to the local anesthesia, to reduce congestion and swelling of the nasal mucosa, pre-

Table 1 Development of the tube sheath system

Unit: mm		1st generation		2nd generation			3rd generation		4th generation
Outer cylinder	length	60	60	50	60	70	50	70	70
	Outer diameter	8	8	8	8	8	7	7	7.5
	inner diameter	6	6	6	6	6	6	6	6.5
	Possible diameter of TNE	5.5	5.5	5.5	5.5	5.5	5.5	5.5	5.5-5.9
	thickness	1	1	1	1	1	0.5	0.5	0.5
Inner cylinder	Outer diameter								6
	tip	closed	closed	closed	closed	closed	closed	closed	open
sponge		–	–	+	+	+	+	+	+

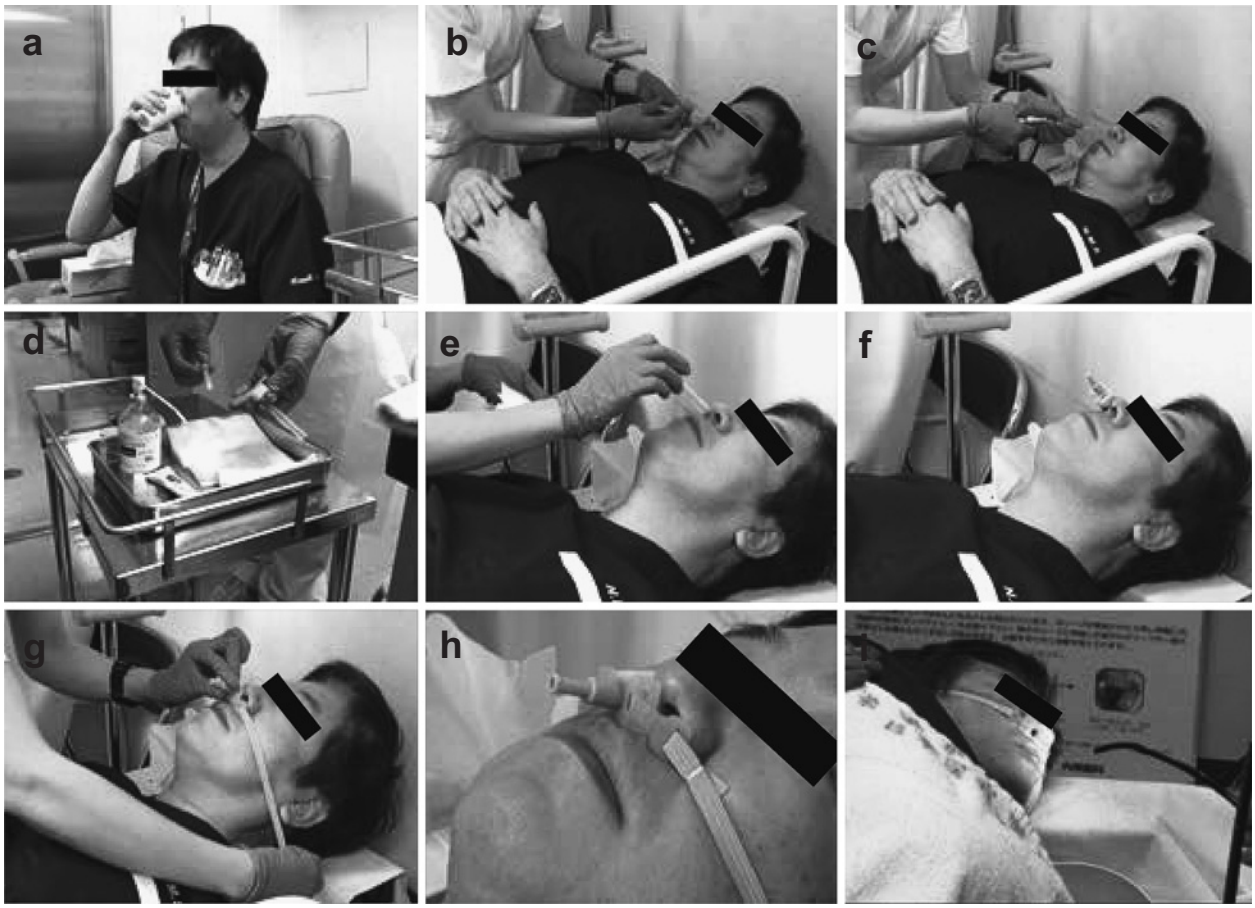

Fig. 4
How to use the Nasal Slider.

vent epistaxis, and prolong the anesthetic effect of lidocaine sprayed in the nasal cavity (**Fig. 4b**). Local anesthesia of the pharynx and nasal mucosa is achieved by 2 applications each of 2% lidocaine spray and application of lidocaine gel (Xylocaine gel 2%; AstraZeneca) in the naris intubated with the inner tube (**Fig. 4c**). Because the local anesthesia is sprayed into the nasal cavity and reaches the pharynx, there is no need to spray the pharynx directly through the mouth. Routine transnasal endoscopy is performed with the patient in left lateral position.

(ii) The lubricant is applied to the outer surface of the inner tube (**Fig. 4d**).

(iii) The sheath and inner tube are inserted into the nasal cavity in combination with the sponge (1 minute is allowed for acclimation in the nose) (**Fig. 4e and f**).

(iv) The belt is secured at the rear of the patient's head and hooked to the wing on the sheath (**Fig. 4g and h**).

(v) The inner tube is removed while carefully ensuring

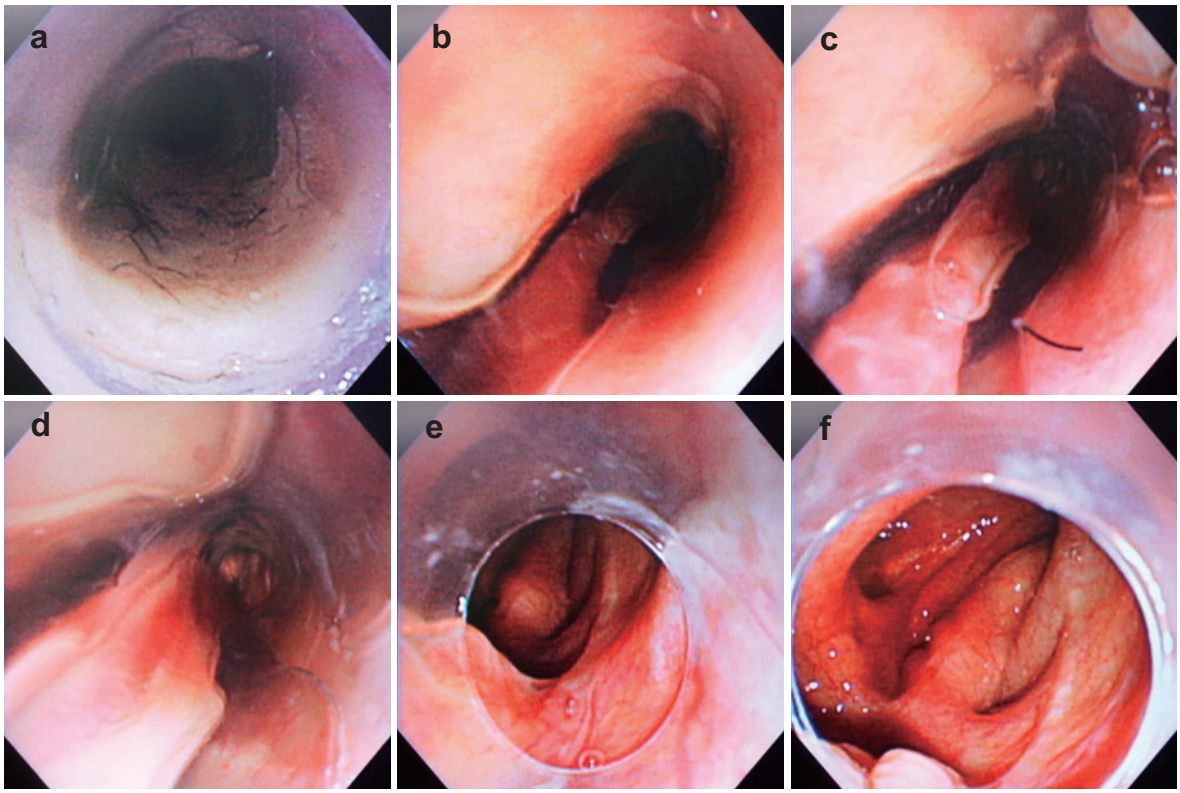

Fig. 5
Intranasal endoscopic image of middle turbinate route for the Nasal Slider.
a. Insert the transnasal endoscope into the left or right nostril.
b. The right inferior turbinate can be identified in the center of the image.
c. On the left and right, the nasal septum and inferior turbinate can be seen, and in the lower part of the image the middle turbinate can be seen.
d. The sheath prevents contact bleeding by the endoscope.
e. The transnasal endoscope reaches the end of the turbinate.
f. The transnasal endoscopy reaches the nasopharynx.

that the sheath remains in place.

(vi) The lubricant is applied to the endoscope, which is inserted into the sheath. The transnasal endoscope is coated with additional lidocaine gel and inserted into the nasal meatus via the sheath (**Fig. 4i**).

Intranasal Observation Images

On of the present authors underwent transnasal EGD examination using the Nasal Slider. Intranasal observation images are shown in **Figure 5**. The transnasal endoscope was inserted into the left or right nostril (**Fig. 5a**). **Figure 5b** shows the right inferior turbinate route. The sheath presses against the turbinate as it is deeply inserted ((**Fig. 5c**) and is observed in order to prevent contact bleeding with the scope (**Fig. 5d**). The transnasal endoscope reaches the end of the turbinate (**Fig. 5e**) and the nasopharynx (**Fig. 5f**).

Routine EGD Examination

No sedation is used, and a nurse is present to assist in biopsies and oral suction. The diameter of transnasal endoscopes ranges from 5.3 mm to 6.0 mm, whereas standard endoscopes have a diameter of 9.0 mm to 9.4 mm. During a typical examination, the transnasal endoscope is inserted through the nose and upper esophageal sphincter under direct vision (**Fig. 5**) and passes the esophagus and stomach, down to the second section of the duodenum. A biopsy is taken when clinically indicated, although maneuverability is reported to be poorer than that of a standard endoscope. Transnasal endoscopy without anesthesia is generally well tolerated and affords a similar diagnostic yield when compared with conventional transoral endoscopy, which uses a larger-caliber endoscope with full anesthesia.

Participants and Questionnaire

The effectiveness of the Nasal Slider was evaluated in 34 consecutive patients (mean age 68.1 years; 22 men [64.7%] and 12 women [35.3%]) who had undergone transnasal endoscopy and were scheduled to undergo the procedure again.

Table 2 Questionnaire results

	Q1. Nasal discomfort		Q2. Nasal pain		Q3. Epistaxis	
	Yes	No	Yes	No	Yes	No
M 21/30	3/21 (14.3%)	18/21 (85.7%)	2/21 (9.5%)	19/21 (90.5%)	0/21 (0%)	21/21 (100%)
Transnasal endoscopy	phase before 3/21 (14.3%) during 2/21 (9.5%) after		phase before 2/21 (9.5%) during 2/21 (9.5%) after			
F 9/30	0/9 (0%)	9/9 (100%)	0/9 (0%)	9/9 (100%)	0/9 (0%)	9/9 (100%)
Total	3/30 (10%)	27/30 (90%)	2/30 (6.7%)	28/30 (93.3%)	0/30 (0%)	30/30 (100%)

Questionnaire

The questionnaire comprised 3 questions on discomfort, nasal pain, and epistaxis, and the phase of these conditions among the examined patients was determined.

After transnasal endoscopy was completed, patients who gave consent for use of the nasal slider were interviewed by asking the following questions.

As compared with your past transnasal endoscopy experience, "(1) Did you experience more discomfort? (Yes, No)". If yes, "(2) When did you experience discomfort? (Before examination, During examination, After examination)." Regarding nasal pain, "(1) Did you experience nasal pain (Yes, No)." If yes, "(2) When did you experience the pain? (Before examination, During examination, After examination)." Regarding epistaxis, "(1) Did you experience a nosebleed? (Yes, No)." If yes, "(2) When did you experience the nosebleed? (Before examination, During examination, After examination)."

Results

In this study, 34 patients were enrolled, and 30 patients (88.2%) underwent transnasal endoscopy using the Nasal Slider. The other 4 patients underwent standard transnasal endoscopy. The questionnaire results are summarized in **Table 2**; 27 (90%) and 28 (93.3%) patients examined with the Nasal Slider reported less nasal discomfort and less pain, respectively, as compared with an examination performed without the Nasal Slider. Only 1 patient (4.3%) reported nasal discomfort before transnasal endoscopy and 2 patients (9.5%) reported both nasal discomfort and pain before and during transnasal endoscopy with the Nasal Slider. No epistaxis was detected in any patient examined with the Nasal Slider. These results suggest that the Nasal Slider results in lower incidences of nasal pain and epistaxis.

Endoscopist skill varies, and the transnasal endoscope was difficult to insert with the Nasal Slider in 3 (25%) of the female patients. These patients were younger (age: 48, 48, and 60 years). No female patient examined with the Nasal Slider reported nasal discomfort or pain. One disadvantage of the nasal slider is difficulty in inserting the transnasal endoscope into the nasal meatus, especially in women. Another disadvantage is that the sheath sometimes moves with the endoscope.

Discussion

Transnasal endoscopy is more acceptable than standard transoral endoscopy for patients. Most importantly, a significant proportion of transnasal endoscopy patients reported that transnasal endoscopy was more tolerable than previous transoral endoscopies without anesthesia. Transnasal endoscopy was significantly better tolerated than transoral endoscopy without general anesthesia.

The endoscope is passed transnasally along the floor of the nostril, while avoiding compression of the turbinate, to minimize discomfort. The pharynx and larynx are well visualized by this route. Because the patient is conscious, the pharyngeal phase of swallowing can be evaluated for the presence of aspiration and pharyngeal residue. Pharyngeal sensory testing may also be performed.

Alexandridis et al. reported visual analogue scale (VAS) scores that rated aspects of the procedure from 0 to 10, with 0 denoting discomfort and 10 denoting high comfort and tolerability. Endoscopic VAS scoring was done for visualization of the upper digestive system. Views of the hypopharynx, epiglottis, vocal cords, and cricopharyngeal region by transnasal endoscopy are better than those in conventional images. VAS scores for patient comfort were significantly better in the transnasal endoscopy group than in the standard transoral endoscopy group. Almost all patients who previously underwent standard endoscopy and randomly received a transnasal endoscopy at this time preferred transnasal endo-

scopy[1]. Gagging and cardiovascular stress, irrespective of the degree of gagging or comfort, was significantly lower in the transnasal endoscopy group.

Abe et al. reported successful insertion rates of 98.8% for transnasal endoscopy and 99.1% for transoral endoscopy. There was no significant difference in these rates[12]. The incidences of nausea and vomiting were 8.6% and 0.8%, respectively, for transnasal endoscopy and 60.7% and 25.4%, respectively, for transoral endoscopy[12]. According to patient evaluations, 94.4% of patients who previously underwent transoral endoscopy reported that transnasal endoscopy was more comfortable, and 94.7% of the same group reported that premedication for transnasal endoscopy was less unpleasant than that for a transoral endoscopy[12]. When discomfort during transoral endoscopy was set at 10, the average score for transnasal endoscopy was 3.2 ± 1.1—a considerable decrease in discomfort[12].

The total cost of upper endoscopy with anesthesia is increased by the cost of medication and patient monitoring associated with such anesthesia[13]. Transnasal endoscopy can be a cost-effective alternative to transoral endoscopy with anesthesia.

The diagnostic performance of transnasal endoscopy is less than optimal for cancer screening, particularly for patients with *Helicobacter pylori*-related non-atrophic gastritis[14]. Transnasal endoscopy is now widely used in gastric cancer screening in Japan. NBI close examination using ultrathin transnasal endoscopy enables mucosal diagnosis even without magnification and is reasonably effective for endoscopic diagnosis[15]. Transnasal endoscopic biopsies are smaller but sufficient for definitive diagnosis, like standard endoscopy[1].

Among treatments that involve endoscopy, transnasal endoscopy is widely used. An ileus tube is inserted through a guide wire and threaded through the forceps hole in the transnasal endoscope[16]. Transnasal endoscopy is sometimes useful during submucosal dissection of the pyloric area[17] and duodenum[18] during endoscopy and can be used as one of the double endoscopes during peroral endoscopic myotomy (POEM)[19]. The Nasal Slider can be used during those examinations.

Patients who had not previously undergone transnasal endoscopy were more likely to report nasal pain than those who had. Nasal pain occurred in 42.9% of patients[12]. In a US study, other drawbacks to transnasal endoscopy were raised, and the most significant complaint regarding transnasal endoscopy from the patient perspective was nasal pain[20]. Zaman et al. reported that transnasal endoscopy patients experienced significantly more pain during insertion of a 6-mm videoscope than did oral EGD patients, although other procedures involving endoscopy without anesthesia by a transnasal or oral route were generally well tolerated[20].

Regarding limitations of the Nasal Slider in this study, the rate of insertion failure (25%) was somewhat higher for transnasal endoscopy. The relatively large diameter of the Nasal Slider is one possible cause. Compared with male and older female patients, young female patients have a narrower common nasal meatus. When using the Nasal Slider, the pathway for the transnasal endoscope becomes smaller because of its additional thickness. For some female patients with a narrow common nasal meatus, insertion failure of the transnasal endoscope with the Nasal Slider may occur. Improvement for women with smaller nasal passages is needed.

Epistaxis occurred in 1.1% of patients, and recovery was observed within 10 minutes in all patients[12]. Multivariate logistic regression revealed that the risk factors for epistaxis were age and sex: the odds ratio was 2.31 (95% CI: 1.746-3.167) for younger age and 2.02 (95% CI: 1.542-2.659) for females[11]. There was no case of epistaxis associated with Nasal Slider in this study.

In conclusion, a newly developed supplementary device, the Nasal Slider, can help reduce nasal pain and epistaxis in patients undergoing transnasal endoscopy. The transnasal endoscope is coated with gel and inserted into the sheath, and nasal pain is reduced by subsequent insertions performed within the sheath of Nasal Slider. Contact bleeding can also be prevented.

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Conflict of Interest: This research of product and improvement of Nasal Slider was supported by TOP Corporation. The first author and Nippon Medical School get 1% of their sales as a reward.

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