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Clinical Study Protocol

Development of an Oropharyngeal Scope with an Integrated Tongue Depressor: NTOP2013 Study

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The oropharynx is examined with a light source such as an electric light, a penlight, or a forehead mirror based on an acquired visual field using a tongue depressor. However, it is extremely difficult to obtain objective and reproducible images of tissue within the pharynx required in recent years with these methods, and insufficient progress in the examination tools has been made. There is an increasing need to develop a method for display during oropharyngeal examination. We conducted the present study to develop a novel oropharyngeal endoscope as an objective observation method.

Key words: tongue depressor, oropharyngeal scope, oral, pharyngeal, otorhinolaryngology

There has been no dramatic progress in the design of tools used for oropharynx examinations, which are currently done using a light source such as an electric light, a pen light, or a forehead mirror based on an acquired visual field using a tongue depressor. With these methods, it is extremely difficult to obtain objective and reproducible images of tissue within the pharynx, as required in recent years.

A condition that can be confirmed at an initial assessment through careful observation of the oropharynx is aberrant (tortuosity) change of the internal carotid artery associated with a change in posture due to aging [1], and its incidence in the elderly has been increasing. We have thus examined the clinical significance of aberrant tortuosity change in the oropharynx [2-7]. However, posture change is initially reversible, and it is recognized only in the sitting and standing positions. In contrast, a return to the original posture/position is noted in the supine position where the neck portion is extended, along with the disappearance of the posture change [6,7]. For this reason, the posture change cannot be identified during an outpatient examination using magnetic resonance angiography, computed tomography, or magnetic resonance imaging, which require the patients to lie in a supine position [6].

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It is therefore necessary to observe the oropharynx with the patient in a sitting or standing posture while the pulse is measured. The aberrant tortuosity change of the internal carotid is a newly identified risk factor for cerebral infarction [3], with an odds ratio of 23.4 [5]. However, the discovery of the lesion depends on the experience of the physician, and thus the differences in rates of discovery are large [8].

In children, careful pharyngeal observation is an important procedure for finding a foreign body [8], which is only made possible with the voluntary participation of the child. An examination of the pharynx/oral cavity of a child can thus be challenging compared to that of the body trunk, limbs, ears, or nasal cavities. Forcing the mouth to open with a device can be difficult because the masseter muscle is so strong that it requires considerable force. Moreover, the use of force can result in vomiting due to the pharyngeal reflex and is a risk factor for tooth injury [9].

Notably, diseases in the pharynx and oral cavity are particularly difficult to diagnose and treat, not just in children or elderly patients. The display and recording of data during examinations is indispensable for medical education and evaluation [10], and such data are currently lacking in otolaryngology clinical practice. In response to these problems, our study group has assessed the usefulness of an exclusive attachment with an integrated tongue depressor using the Pentax Airway Scope (AWS), which is a video intubation device, and we evaluated the Pentax AWS as a simple oropharyngeal endoscope (unpublished data) based on the following criteria during the observation of 50 volunteers by 10 otolaryngologists: observation, treatment, recording, display, safety, convenience, possibility of future use, discomfort of examination, anxiety during examination, and recording/display explanation.

As a result, all 10 otolaryngologists confirmed the usefulness of the Pentax AWS for observation, treatment, recording, display, safety, and convenience compared with a light source such as an electric light, penlight, or forehead mirror based on an acquired visual field using a tongue depressor. On the other hand, for the possibility of future use, all 10 otolaryngologists stated that improvement was necessary for the use of the Pentax device as an exclusive oropharyngeal endoscope, not as an AWS. According to all 50 subjects and their families, the device was significantly positive for the items 'possibility of future use,' 'discomfort of examination,' 'anxiety during examination,' and 'recording/display explanation.' Based on these results, we reported the usefulness of the device [11].

Endpoints

Primary endpoints. The primary endpoints of this trial are the safety and usefulness of the investigational device based on an evaluation by physicians who used the investigational device as an oral laryngoscope (evaluation items A to G in Table 1) by the physicians.

Secondary endpoints. The secondary endpoints

Table 1 Evaluation items

Evaluation by the attending physicians and display viewers (physicians and medical staff):

Item	Score				
A. Observation	1. Poor	2. Inferior	3. No change	4. Superior	5. Excellent
B. Treatment	1. Poor	2. Inferior	3. No change	4. Superior	5. Excellent
C. Recording	1. Poor	2. Inferior	3. No change	4. Superior	5. Excellent
D. Display	1. Poor	2. Inferior	3. No change	4. Superior	5. Excellent
E. Safety	1. Poor	2. Inferior	3. No change	4. Superior	5. Excellent
F. Convenience	1. Poor	2. Inferior	3. No change	4. Superior	5. Excellent
G. Possibility of Future Use	1. Never	2. Probably not	3. Yes, if available	4. Probably yes	5. Yes, definitely

Evaluation by patients and their family members:

Item	Score
H. Discomfort of Examination	1. Felt discomfort 2. Slight discomfort 3. No change 4. Fairly comfortable 5. Comfortable
I. Anxiety of Examination	1. Anxious 2. Slightly anxious 3. No change 4. Slightly relieved 5. Relieved
J. Recording/Display Explanation	1. Difficult to understand 2. Slightly difficult to understand 3. No change 4. Fairly easy to understand 5. Easy to understand

are the patient's satisfaction and family satisfaction (evaluation items H-J in Table 1) and the display viewer satisfaction (among physicians and other medical staff; evaluation items A-G in Table 1).

Eligibility Criteria

The inclusion criteria for the trial are as follows. (1) Inpatients or outpatients who require observation and treatment of the oral cavity, palate, or pharynx; and (2) those who provide written consent. The exclusion criteria for the trial are: patients who are unable to communicate, provide an allograph, and respond to a questionnaire.

Methods

Study design. After the acquisition of written consent, the observation and treatment of the patient's oropharynx will be performed using the investigational device. After the observation/treatment, the physician, the display viewer, the patient, and the patien's family member(s) if present will evaluate the efficacy of the device based on the items listed in Table 1. By comparing the device with conventional methods such as a light source and fiber or electronic scope, they will select the most efficient evaluation method for each item. This study was approved by the National Hospital Organization Tokyo Medical Center Research Ethics Committee on May 1, 2014 (approval no. R14-004). This study was registered in the Clinical Trial Registry (UMIN-CTR) on July 18, 2014 (UMIN000014586). In connection with this study, we have carried compensation liability insurance and liability insurance as compensation measures for health damage caused to the subjects.

Outline of the investigational device. An oropharyngeal endoscope with an integrated tongue depressor is composed of a body part for displaying an image and a blade part. Although the body grip of the airway scope is designed to lift the epiglottis for tracheal intubation, the body grip of this device can be used for observation in the mouth. In addition, this device has functions to record and to enlarge by optical zooming. The tongue depressor is designed to prevent the gag reflex.

The blade is removable and may be adjusted to fit a wide range of age groups. The device is also compact and portable, making it suitable for home medical care. In this study, we will use the improved type I device (Fig. 1) that has a lightweight, miniaturized blade for the oral cavity or pharyngeal observation. The reduced weight and size of the detachable blade makes the device usable for a wide range of age groups. The applications of the device are as follows: (1) oral cavity/pharynx observation (Fig. 2), (2) suction of sputum, (3) carotid artery echo for finding risk factors for cerebral infarction, (4) airway management (tracheal intubation), and (5) confirmation of insertion of a stomach tube.

Statistical Considerations

Sample size. The number of registered patients was planned as 200. As the purpose of this study is to assess the safety and usefulness of the improved type I device for development and the number of devices is limited, the number of patients was based on feasibility rather than on the statistical hypothesis testing.

Statistical analysis. The number of patients enrolled in a study and who are observed using the investigational device is considered an analysis set. The frequency distribution of the ratings of each evaluation item will be calculated. The patient age, gender, disease, and treatment, and the number of years of experience of the examining physician, and the physicians' department will be examined.

Discussion

There is an increasing need to develop a display method during oropharyngeal examination, which would entail (1) the cooperation of patients at all participating medical institutions, (2) a display to third parties, and (3) the use by physicians for recording and treating. However, except for a few devices described in previous studies, there are currently no devices that can enable the recording of observations during an examination. The present study is planned in order to develop an oropharyngeal endoscope as an objective observation method. The device (Improved Type I) will be assessed using the items from the previous study, *i.e.*, observation, treatment, recording, display, safety, convenience, possibility of future use, discomfort of examination, anxiety during examination, and recording/display explanation. Problems encountered during

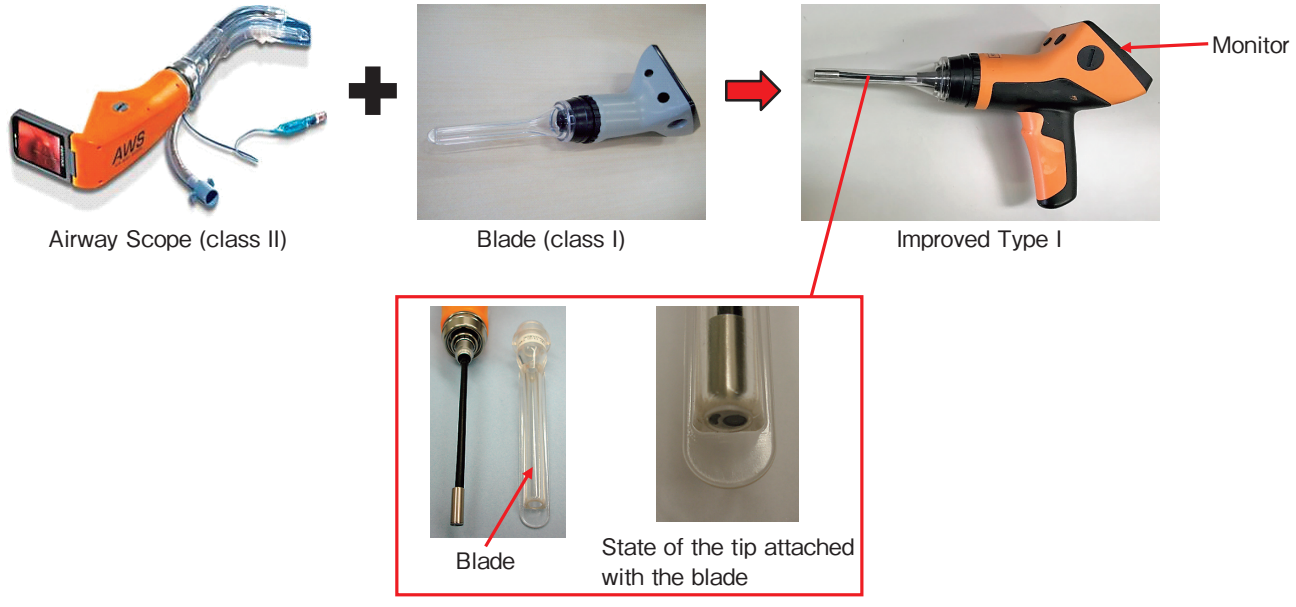

Fig. 1 Improved Type I device

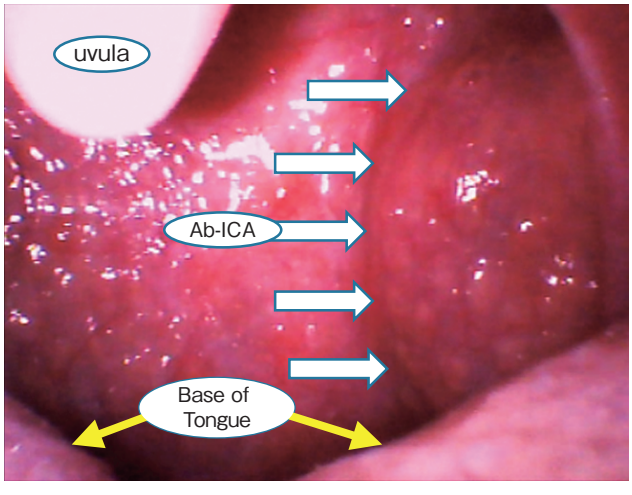

Fig. 2 Monitor view of posterior pharyngeal wall

the evaluations will be addressed and discussed.

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