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Research Article

Evaluation of Ambu® aScope™ 2 in awake nasotracheal intubation in anticipated difficult airway using conventional or facilitated technique: A randomized controlled trial

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KEYWORDS

Ambu® aScope™ 2;
Awake nasotracheal;
Conventional;
Facilitated technique

Abstract *Objectives:* Ambu® aScop2 (aScope2) is a new disposable flexible videoscope, that has several advantages compared with the reusable devices. The purpose of this study was to evaluate the efficacy of this device in awake nasotracheal intubation for patients with anticipated difficult airway and to compare the use of facilitated technique with the conventional technique in an attempt to fasten the nasotracheal intubation and to increase the likelihood of success.

Methods: Fifty adult patients aged 18–45 years of ASA I–III with anticipated difficult intubation were randomly allocated into two groups of awake nasotracheal intubation either by the conventional technique of videoscopic nasotracheal intubation (C group) or by facilitated technique (F group) where a lubricated nasal tube was introduced first into nasopharynx till the mark 18 in males and 16 in females acting as a conduit for the aScope, then the aScope 2 was inserted through it to visualize the vocal cords and then advanced into the trachea, finally the nasal tube railroaded over the aScope. Times needed to visualize vocal cords (Tvc), to complete the endotracheal intubation (Tti) and the sum of both were recorded. Also number of attempts, the need of facilitating maneuver, success rate and any complications were compared.

Results: The overall success rate of aScope-guided intubation was 84% and 92% in the control and the facilitated groups respectively with a higher 1st attempt success rate in the facilitated group. Both Tvc and total nasotracheal intubation time were significantly shorter in facilitated group (156 ± 0.81 and 198.6 ± 0.82 s) compared to (201.6 ± 1.15 and 244.8 ± 1.15 s) in control group.

Conclusion: The aScope 2 provided a high success rate in awake nasotracheal intubation in patients with anticipated difficult airway and the use of a facilitated technique shortened the time needed to perform successful videoscopic intubation.

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1. Introduction

Difficult intubations contribute to considerable morbidity and mortality in anesthesia [1]. Complications of difficult airways range from upper airway soft tissue trauma to hypoxic brain damage and death [2].

Nasotracheal fiberoptic intubation is the best option and is often the gold standard where oral route is impossible. It has certain advantages such as the route to larynx is easier than mouth and also the patient is unable to bite the scope [3]. The nasal route provides an easier view of the laryngeal opening as a result of decreased interference from the tongue. In addition, the gag reflex is less pronounced with nasal intubation than with oral intubation [4]. The conventional fiberoptic nasal intubation method in which the nasal tube is inserted in one step after visualization of the vocal cords by a flexible fiber-optic laryngoscope [5], two major problems are encountered, i.e. visualization of the glottis and the entry point at the level of vocal cords, and insertion of the fiberscope into the trachea [5,6]. Placing a lubricated endotracheal tube through the nostril can guide the fiberoptic scope toward the larynx. It would be helpful for optimal visualization of the vocal cords when the scope is passed through the endotracheal tube if the length of nares-vocal cord (NV length) could be predicted and the tip of the endotracheal tube could be placed close to the vocal cord [7].

Although fiberoptic scopes are well established in the management of difficult airways [8], these reusable devices need to be disinfected before each use. This cleaning process can take 20–60 min to complete [9]. In addition, some contamination may remain despite cleaning [10].

The Ambu aScope (Ambu A/S, Ballerup, Denmark) is a novel single-use video-endoscope designed to aid tracheal intubation. According to the manufacturer, it is designed with an outer diameter of 5.3 mm and a bending section that can be manipulated through an angle of 120 upwards and downward. The aScope has a built-in camera with a light-emitting diode (LED) and a channel with an inner diameter of 0.8 mm for administering local anesthetic. Before use, the scope has to be connected to a separate 6.5-inch color liquid crystal display (LCD) monitor [11]. It has several possible advantages: no requirement for cleaning or disinfection, no repair costs, avoidance of the small, but existing, risk of cross contamination and the possibility of always having access to a flexible scope, which is not the case with reusable scopes [12]. The aScope successfully had been used to facilitate tracheal intubation with anticipated or unanticipated difficult airways [11]. The purpose of this study was to evaluate this novel videoscope in nasotracheal intubation in anticipated difficult airways where oral route is impossible, through using the conventional method or a facilitated one by placing a lubricated endotracheal tube through the nostril that can guide the videoscope towards the larynx.

2. Methodology

After approval of institutional ethics committee of Faculty of Medicine, Minia University and a small pilot study performed on 10 patients with normal airway for initial evaluation of the device and to predict the nares to vocal cord distance in either sex, this prospective, randomized, parallel study was conducted in the period from June 2013 till December 2014, on fifty patients, aged 18–45 yrs of both sex, ASA physical status I–III underwent elective maxillofacial surgery under general anesthesia with an anticipated difficult airway requiring nasotracheal intubation as the oral route was impossible. The patients were randomly allocated into two groups by using a computer-generated table and the randomization sequence was concealed in sealed envelopes assignment held by an assistance who not involved with the clinical management or data collection. According to the method of nasal intubation used, the two groups were either, a conventional group (control) or facilitated group of 25 patients in each with an allocation ratio of 1:1. We explained the procedure during the pre-operative visit and all the included patients gave their consent for awake videoscopic intubation. Exclusion was for those with any contraindication for nasal intubation, bleeding disorder, reactive airway disease and gastroesophageal reflux (see Fig. 1). Pre-operative airway evaluation was performed in terms of the previous history of difficult intubation; pathologies and symptoms associated with difficult intubation; inter-incisor gap and mandible movement; thyromental distance; head and neck movement; and the modified Mallampati score Table 1.

Pathologies associated with the difficult intubation varied between intra-oral tumor, ankylosis of temporomandibular joint or burn with neck contracture and limited mouth opening. Patient age, weight, height and body mass index were recorded. All patients fasted for at least 6 h before surgery. Each patient received 500 mL of Ringer's solution IV 1 h before surgery.

In the operative room, routine monitoring with ECG, noninvasive blood pressure, pulse oximetry and capnography commenced. These vital parameters were recorded at baseline, and every 5 min thereafter, then a cannula was sited and all patients were premedicated with metoclopramide 10 mg IV, midazolam 0.05 mg/kg IV, atropine 0.5 mg IV to reduce the secretions of airways and phenylephrine drops (3 drops in each nostril) 15 min before airway manipulation. Topical anesthesia was achieved by nebulizer for 10 min using 10 ml lidocaine 2%. The larger nostril was selected for intubation while through the other nostril a nasal cannula was inserted to administer 100% oxygen (2 L/min) was started 3 min before and then along the procedure. A fentanyl bolus of 1 μg/kg and propofol infusion at the rate of 30–35 μg/kg/min. were administered before manipulation.

With the patients in supine position, intubation was performed by the same anesthetist with help of three attendants one for suctioning and oxygenation, another for administering local anesthetic through the channel of the videoscope and the intravenous drugs, and the third for monitoring the patients and recording the data.

In the conventional group, the cord of the aScope was inserted through the nostril and advanced into the nasopharynx till the vocal cords were visualized. Then, a lubricated nasal tube, which had been mounted and fitted on the scope beforehand, was glided over the videoscope and advanced through the vocal cords into the trachea. Whereas in the facilitated group, or the tube-first approach, the lubricated nasal tube was inserted into the nasal cavity and advanced through it into the nasopharynx till the mark 18 in men and 16 in women reached the level of alae of the nose. At this level, the tube tip is nearly placed just above the larynx, then the

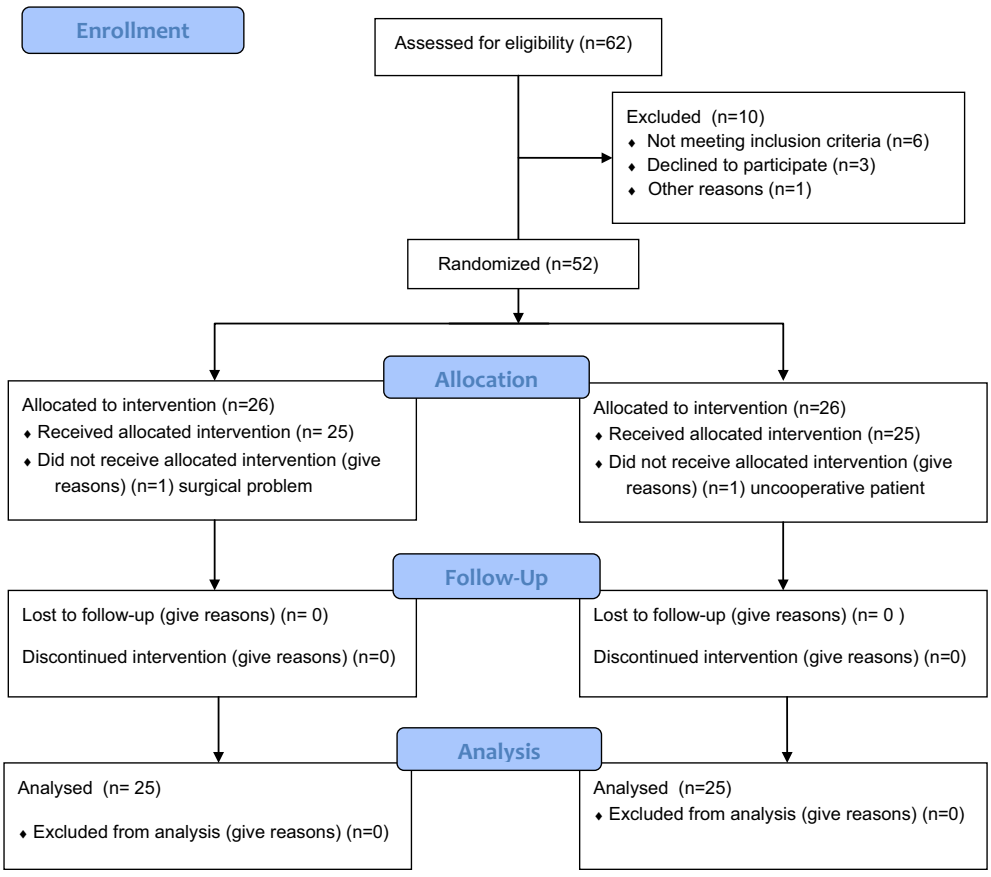

Figure 1 Participant flow diagram.

Table 1 Modified Mallampati score grading of the upper airway (Samsoon and Young) [13].

- Class I: everything visible (tonsillar pillars)
- Class II: uvula fully visible, fauces visible
- Class III: soft palate and base of uvula visible only
- Class IV: cannot see soft palate

lubricated cord of the aScope was glided through the tube and passed the tip of it to visualize the larynx, and then inserted between the cords toward the trachea followed by sliding the tube over the cord into the trachea. Repositioning of the tube to optimize visualization and suctioning with an oral catheter were needed in some cases.

After successful passage of the tube through the vocal cords into the trachea and after identification of the carina, the tube was positioned approximately 3 cm above the carina which corresponds to the mark of 26–28 cm at the nares, then the scope was withdrawn and the cuff of the tube was inflated and the tube was sealed with adhesive tape.

Correct placement of the tube was confirmed by the end-expiratory CO_2 curve on capnography and by bilateral auscultation. Immediately propofol 1–2 mg/kg IV was administered to induce general anesthesia and to establish mechanical ventilation. During the procedure, patients were awake and most of them were co-operative with the anesthetist. If it was necessary, facilitating techniques such as head flexion, and jaw thrust were utilized.

2.1. Parameters assessed

In addition to the parameters of assessment mentioned above (mouth opening, Mallampati class, neck movement, thyromental distance, and prognathism ability), the following data were recorded:

1. Primary outcomes:
   a. The time from the start of insertion of the aScope in the nares till visualization of vocal cords (Tvc) and from this till successful endotracheal intubation and cuff inflation (Tti), then the total time of nasotracheal intubation which is the sum of the previous two times were recorded in seconds.
   b. success rate
2. Secondary outcomes:
   The number of attempts, the need of facilitating maneuvers, the incidence of esophageal intubation or any complications were recorded.

Intubation was considered failed if desaturation (S_pO_2 < 95%) occurred before identification of the carina in spite of the precautions taken to provide oxygen.

3. Statistical method

The collected data were coded, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 20.

Descriptive statistics were done for numerical data by mean, standard deviation and minimum and maximum of the range, while they were done for categorical data by number and percentage.

- Analyses were done for quantitative variables using independent sample t test, and for qualitative variables using Chi square test.
- The level of significance was taken at P-value $\leqslant 0.05$.

The sample size was based on an initial pilot observation and previous studies, in order to ensure a power of 0.80 for detecting clinically meaningful difference in intubation time with a type-1 error of 0.05. Assuming a 5% dropout rate, 25 patients in each group were studied with an allocation ratio 1.

4. Results

Statistical analysis showed there were no significant differences between the two groups regarding age, sex, weight, height, body mass index (BMI) and ASA class as well as the parameters of the airway assessment (Tables 2 and 3).

As shown in (Table 4) the time to vocal cord visualization (Tvc) as well as the total time of nasotracheal intubation was significantly shorter in the facilitated group than in the control group, however there was no significant difference between the two groups regarding the time of tracheal intubation (Ti).

The overall success rate of aScope-guided intubation was 84% and 92% in the control and the facilitated groups respectively but it was statistically insignificant. Nasotracheal intubation achieved at the first attempt in 48% and 84% of cases, at 2nd attempt in 24% and 8% and at the 3rd attempt in 28% and 8% of cases in the control and facilitated groups respectively with a significant difference in favor of the facilitated group (Table 5).

Also the need for jaw thrust and neck flexion was significantly more often in the conventional group (20% and 30% respectively) in comparison with the facilitated group (12% and 8% respectively). The incidence of esophageal intubation (P-value 0.637) or any complication in terms of bleeding or desaturation (P-value 0.919) was insignificant between the two groups (Table 5).

Table 2 Demographic Profile of the studied groups (data expressed as Mean ± SD or number and percentage).

Variable	Group C (n = 25)	Group F (n = 25)	P value
Age	(18–45) 31.84 ± 8.39	(18–43) 28.96 ± 7.99	0.220
Sex:			
Female	14 (56%)	13 (52%)	0.777
Male	11 (44%)	12 (48%)	
Weight	(58–88) 74.4 ± 10.49	(55–90) 70.32 ± 9.07	0.148
Height	(150–172) 164 ± 9.27	(145–178) 164.88 ± 10.26	0.752
BMI	(19–41) 27.6 ± 4.97	(20–39) 26.16 ± 4.85	0.305
ASA:			
Class I	13 (52%)	13 (52%)	1
Class II	10 (40%)	10 (40%)	
Class III	2 (8%)	2 (8%)	

No significance difference p-value > 0.05.
BMI = Body Mass Index.

Table 3 Airway Assessment in the studied groups (data expressed as number and percentage).

Variable	Group C (n = 25)	Group F (n = 25)	P value
Mallampati class:			
Class III	8 (32%)	7 (28%)	0.758
Class IV	17 (68%)	18 (72%)	
Mouth opening:			
> 4 cm	8 (32%)	7 (28%)	0.758
< 4 cm	17 (68%)	18 (72%)	
Neck movement:			1
90°	10 (40%)	10 (40%)	
80–90°	9 (36%)	9 (36%)	
< 80°	6 (24%)	6 (24%)	
Thyromental distance:			
> 6.5	10 (40%)	10 (40%)	0.931
6–6.5	9 (36%)	10 (40%)	
< 6	6 (24%)	5 (20%)	
Prognathism ability:			
Yes	19 (76%)	18 (72%)	0.747
No	6 (24%)	7 (28%)	

Table 4 Times of nasotracheal intubation (data expressed as mean ± SD).

Variable	GC (n = 25)	GF (n = 25)	P value
Time to VC visualization (s)	(60–300) 201.6 ± 1.15	(60–240) 156 ± 0.81	0.010*
Time to Ti (s)	(30–54) 43.2 ± 0.1	(30–54) 42.6 ± 0.12	0.802
Total time of nasotrach. (s)	(108–348) 244.8 ± 1.15	(90–288) 198.6 ± 0.82	0.010*

Time to vc = time to vocal cord visualization
Time to Tti = time to tracheal intubation.
Total time of nasotrach. = Total time of nasotracheal intubation.
* Significant difference p-value $\leqslant 0.05$.

5. Discussion

In this study, the use of aScope 2 provided a high success rate in awake nasotracheal intubation in patients with anticipated difficult airway and the use of a facilitated technique shortened the time needed to perform this videoscopic nasotracheal

Table 5 No. of attempts, the need of facilitating maneuver, success rating, incidence of esophageal intubation or complications in the studied groups (data expressed as number and percentage).

Variable	Group C (n = 25)	Group F (n = 25)	P value
No of attempts:			
1 time	12 (48%)	21 (84%)	0.027*
2 times	6 (24%)	2 (8%)	
3 times	7 (28%)	2 (8%)	
Facilitating manoveur:			
No	12 (48%)	20 (80%)	0.047*
Jaw thrust	5 (20%)	3 (12%)	
Neck flexion	8 (32%)	2 (8%)	
Success rating:			
Failed	4 (16%)	2 (8%)	0.384
Success	21 (84%)	23 (92%)	
Esophageal intubation:			
No	22 (88%)	23 (92%)	0.637
Yes	3 (12%)	2 (8%)	
Complications:			
No	20 (80%)	19 (76%)	0.919
Bleeding	3 (12%)	4 (16%)	
Desaturation	2 (8%)	2 (8%)	

* Significant difference p-value $\leqslant 0.05$.

intubation with a higher 1st attempt success rate than with the conventional technique.

The evolving technology of miniature digital cameras has led to flexible optics without typical fiberoptic bundle technology. These videoscopes have to be connected to a separate monitor to generate a picture. The Ambu aScope is a novel single-use video-endoscope designed to aid tracheal intubation [11]. The availability of this disposable flexible optical scope has several possible advantages for the anesthesiologist: No cumbersome cleaning, no repair costs, avoidance of the small, but existing, risk of cross-contamination [14] and the possibility of always having access to a flexible scope, which is not the case with the expensive reusable scopes [15].

However, it is mandatory to evaluate the clinical performance of a disposable flexible scope to make sure of its efficiency in managing patients presenting with severely difficult airways. Some studied had performed in simulated difficult intubation in a manikin and others are limited to some case reports [11,12,16] and they found that it was successfully used for awake intubation in patients with difficult airways and seems to offer a valuable supplement, or maybe even alternative, to the existing reusable flexible fiberoptic and recommended further evaluation. As a very limited published evidence regarding the value of the aScope in nasotracheal intubation in anticipated difficult airway as the oral route is impossible, this study conducted on fifty patients where awake nasotracheal intubation performed using two techniques, the conventional method and a facilitated method in which a lubricated nasal tube was placed firstly into the nasopharynx till the mark 18 in males and 16 in females reached the level of alae of the nose. The detection of nares to vocal cord distance depended on our pilot study and the revision of the previous studies.

Han et al., 2005 estimated the nasal to vocal cord length of the males was 18.3 ± 0.8 cm, and that of the females was 16.3 ± 0.7.

Techanivate and his colleagues [17] in a study to predict the proper depth of placement of endotracheal tubes, oral and nasal estimated the distance from the right external naris to the vocal cords distance to be 15.00 ± 0.84 cm with no relation to the gender.

Also the study conducted by Mohammadzadeh et al. [18] on patients allocated for elective maxillofacial operation of miniplate insertion in the upper and lower jaws with fiberscopic nasal intubation using either the conventional method or NASAL-18 technique where they insert the nasal tube to a fixed mark of 18 at the alae irrespective of the gender.

The major reason for difficulty in advancing an endotracheal tube over a fiberscope is considered to be deviation of the course of the tube from that of the fiberscope (because of the gap between the two) toward the epiglottis, arytenoid cartilage, pyriform fossae, or esophagus [19,20]. Another contributing factor in difficult exposures was decreased space between the edge of the epiglottis and posterior pharyngeal wall [19].

In the current research, the aScope had achieved a good success rate (84% in conventional group and 92% in facilitated group) in awake nasotracheal intubation for patients with difficult and sometimes extremely difficult airway. Also the handling of the aScope and its transportation were easy due its light weight and the image of the airway structures was considerably good. This is consistent with the findings of Kristensen and Fredensborg [21] where 40 patients with predicted difficult tracheal intubation were randomly assigned to be intubated awake with either the aScope or the reusable Olympus videobronchoscope. They concluded that both aScope and Olympus videoscope allowed safe awake intubation in those elective patients with difficult, but uncompromised, airways. Also Scutt et al. [22] who compared the Ambu aScope™ with a conventional fibrescope in three airway training manikins for oral intubation, nasal intubation and intubation via three supraglottic airway devices concluded that the performance of the aScope was good with few failures and infrequent problems in simulated fiberoptic intubation and (if adapted for untimed use) would be a useful training tool for both simulated fiberoptic intubation and conduit-assisted intubation but as manikin study does not predict the performance in humans they recommended clinical studies. On the other hand, Krugel and his colleagues [23] in comparing the second generation single-use Ambu(®) aScope™ 2 videoscope with a standard re-usable flexible fibrescope in 50 patients with a difficult airway simulated by a semirigid collar, although all the patients were intubated successfully with the aScope 2 or the re-usable fiberscope, they do not support the use of the single-use aScope 2 videoscope as an alternative to the re-usable fiberscope due to longer time and poorer scores for quality of vision.

In our study, the insertion of lubricated flexible tube firstly in the facilitated group used as a conduit that guided the aScope 2 through the nasal cavity toward the vocal cords and reduced the probability of the aScope twisting with the accompanying traumatization of the upper airway which improved the overall success rate of intubation in this group than the other even though the difference was not statistically significant. This may explain the significant shorter time to

predict and visualize the vocal cords (Tvc) and the shorter total time of nasotracheal intubation in the facilitated group.

Also the tube placement at the first attempt was significantly more successful in the facilitated group (84%) than in the conventional group (48%) and the need for using Jaw thrust or neck flexion was significantly lower (20%).

Our results agree with those of Mohammadzadeh et al. [18] whom found that NASAL-18 method reduces the time needed for successful fiberoptic intubation with higher success rate with the NASAL-18 method (83.3%), while this rate in the conventional method was at 67%, with an emphasis on the aScope 2 not the fiberscope was used in our research and all the studied cases had difficult or extremely difficult airway, still the success rate was higher in our study.

It is obvious that the use of a facilitating technique allows the anesthetist to perform fiberscopy with greater ease and speed. Scutt et al. [22] in their study mentioned before concluded that, the intubation times were faster when using a conduit than without and the type of fiberscope had no statistically significant effect on intubation speed, but the type of conduit had, thus, the intubation via the i-gel was 12 s faster than the cLMA (31 s) and 5 s faster than the ILMA (24 s). Hughes and Smith [24] assessed the effectiveness of three tracheal tube rotational movements in assisting nasotracheal tube placement over the fiberoptic laryngoscope and recommended that 90 degrees anticlockwise or overcorrected 90 degrees anticlockwise tube rotation is used to facilitate nasotracheal tube placement during fiberoptic intubation.

Relative long mean time of nasotracheal insertion in this research may be attributed to the clinical condition of some patients as ASA class III was included in this study where cautious and gentle manipulation was a must as that in a case of severe hyperparathyroidism where pathological fractures were present in most parts of the body including the mandible together with cardiac problems, another explanation, some burn patients with limited mouth opening and neck contracture were not fully cooperative due to the psychic state of those patients, also about 10 patients had recurrent ankylosis with redundant soft palate and some were suffering from obstructive sleep apnea. Due to lack of a large suction port in the aScope 2, frequent suction was needed to clear the secretions which can cause fogging of the camera, this together with limited angulation of the tip of the device were other cumbersome causes with more time consumed.

Krugel et al. [23], explained the longer intubation times with the aScope 2 in their study essentially due to a lesser range of movement of the tip, with a limited angulation (120° up and down, whereas the standard fibrescopes presents a tip mobility of 180° up and 130° down) which makes it difficult to pass under the tongue or a falling epiglottis.

This research has some limitations, first the aScope was not compared to the standard fiberscope to clarify the performance of each, second, all of the intubations were performed by the same anesthetist, if different experiences provided the intubation and the rate of success and the times involved might be different. Lastly we did not evaluate the efficiency of the device in the unanticipated difficult airway.

In conclusion, the aScope 2 provided a high success rate in awake nasotracheal intubation in patients with anticipated difficult airway and the use of a facilitated technique shortened the time to visualize the vocal and the total time of nasotracheal intubation with less need of facilitating maneuvers and higher 1st attempt success.

Since outer diameter of the aScope-2 (5.3 mm) is larger than that of adult reusable fiber-optic scopes (3.5–4.2 mm), we could not deal with some cases that required smaller tube size, so we recommend manufacturing aScope with different cord sizes.

Conflict of interest

The author declare that there is no conflict of interest.

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