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Ioan Florin Marchis , Claudiu Zdrehus , Sever Pop ,
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BJAN-D-21-00057 - Original Investigation**Awake nasotracheal intubation with a 300-mm working length fiberscope: a prospective observational feasibility trial****Ioan Florin Marchis^{a,*}, Claudiu Zdrehus, Sever Pop^b, Doinel Radeanu^b, Marcel Cosgarea^b, Calin Iosif Mitre^a**^a University of Medicine and Pharmacy “Iuliu Hatieganu”, Anaesthesia and Intensive Care Department, Cluj- Napoca, Romania^b University of Medicine and Pharmacy “Iuliu Hatieganu”, Otorhinolaryngology Department, Cluj- Napoca, Romania*** Corresponding author.**

E-mail: marchis.ioan@umfcluj.ro (I.F. Marchis).

ORCID ID: 0000-0002-1272-8272

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KEYWORDS

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Abstract

Background: Awake fiberoptic tracheal intubation is an established method of securing difficult airways, but there are some reservations about its use because many practitioners find it technically complicated, time-consuming, and unpleasant for patients. Our main goal was to test the safety and efficacy of a 300-mm working length fiberscope (video rhino-laryngoscope) when used for awake nasotracheal intubation in difficult airway cases.

Methods: This was a prospective, single-center study involving adult patients, having an ASA physical status between I and IV, with laryngopharyngeal pathology causing distorted airway anatomy. Awake nasotracheal intubation, using topical anesthesia and light sedation, was performed using a 300 mm long and 2.9 mm diameter fiberscope equipped with a lubricated reinforced endotracheal tube. The primary outcomes were the success and duration of the procedure. Patients' periprocedural satisfaction and other incidents were recorded.

Results: We successfully intubated all 25 patients included in this study. The mean \pm SD duration of the procedure, starting from the passage of the intubating tube through one of the nostrils until the endotracheal intubation, was 76 ± 36 seconds. Most of the patients showed no discomfort during the procedure with statistical significance between the No reaction Group with the Slight grimacing Group (95%CI 0.13, 0.53, $p = 0.047$) and the Heavy grimacing Group (95%CI 0.05, 0.83, $p = 0.003$). The mean \pm SD satisfaction score 24 hours post-intervention was 1.8 ± 0.86 – mild discomfort. No significant incidents occurred.

Conclusions: Our study showed that a 300-mm working length flexible endoscope is fast, safe, and well-tolerated for nasotracheal awake intubation under challenging airways.

Introduction

Patients with a tumoral or inflammatory pathology of the base of the tongue, epiglottis, and glottic aperture, or a history of prior surgery or radiotherapy are at risk of difficult or impossible facemask ventilation and tracheal intubation.[1,2] These lesions may not be fully appreciated during standard preoperative airway examination, as clinical signs and symptoms are often discrete.[2,3]

Awake fiberoptic intubation, with proper topical anesthesia and sedation, is the gold standard in securing the airway in such cases while maintaining spontaneous respiration and airway reflexes.[3-5] About 1% of all intubations are performed in an awake state, most of them for head and neck surgery, and the development of the new intubating tools did not affect this proportion.[5,6] The high safety profile and rate of success when performed by experienced practitioners, low incidence of complications, and, according to some reports, excellent cardiovascular tolerance result in an extensive presence of this technique in algorithms and guidelines.[5-7] Ultrasound and airway endoscopic evaluation could complete a standard pre-anesthetic airway exam, and it

could lead to proper airway control strategy: awake or not, supraglottic or invasive.[2,7] While some reports suggest that there is room for improvement in the majority of fatalities related to airway control, some reservation about the use of awake intubation persists for various reasons: fear of failure, new devices which improved airway control, lack of training, or time pressure of a busy operating room.[8,9] Apart from the conventional fiber bronchoscope, which is usually 600 mm long, some other tools also aid awake intubation, with the video laryngoscope gaining field.[9]

As it is a routine instrument in Otorhinolaryngology practice, office, or hospital, the flexible video rhino-laryngoscope has the advantage of being a minimally invasive easy to handle fiberscope because of its 300 mm working length and around 3 mm diameter.[10,11] We found few references in the literature, mostly case reports, regarding the use of a flexible fiberoptic rhino-laryngoscope for awake endotracheal intubation dating from the eighth decade of the last century.[12]

This study aims to show that awake nasotracheal intubation performed with a minimal invasive 2.9 mm diameter, 300 mm working length fiberscope, could offer safety and comfort to patients with challenging airways while using low dose titrated sedation and carefully applied topical anesthesia.

Methods

We designed a prospective, observational, single-center study with the agreement of the Ethics Committee no. 100/12.02.2018, in accordance with the Declaration of Helsinki, and registered with ClinicalTrials.gov, identification number NCT03546088. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were followed. Between February 20, 2018, and December 25, 2018, we included consecutive adult patients, ASA (American Society of Anesthesiologists) physical status I–IV, with a SARI (Simplified Airway Risk Index) score ≥ 4 , presented with distorted airway anatomy caused by laryngopharyngeal masses, previous radiotherapy, and acute inflammation, and referred for surgery under general anesthesia. An otorhinolaryngology and preanesthetic airway exam, which included flexible nasopharyngolaryngoscopy, concluded that awake fiberoptic nasal intubation is the safest choice for securing the airway, as the loss of spontaneous respiration or other approaches of the airway could present a vital risk.

The exclusion criteria were refusal for consent, obstructed nasal passage, bleeding disorders, patients allergic to the medication used within the trial, poor understanding and cooperation, marked stridor with obstructing respiratory failure.

Patient preparation

The patients were informed about the details of the procedure and were asked for consent. In the operative room, they were administered midazolam 0.5–1 mg IV (intravenously), atropine 0.4 mg IV and nebulized lidocaine 2% via facial mask for ten minutes. If the airway could have been compromised by tissue edema, hydrocortisone 100 mg IV was administered.[13] The following step was to transfer the patients to the operating theatre, where they were placed in a sitting position on the adjusted operating table and monitored. Oxygenation was supplemented via nasal cannula, as they were administered xylometazoline 0.1% and lidocaine 10% nasal spray. We decided on a final management plan after the trans-nasal fiberoptic airway evaluation with the fiberoptic video rhino-laryngoscope (TELE PACK X LED 11101 VP, Karl Storz, Germany). We identified the most suitable nostril and evaluated if the passage of the tube through the supraglottic and glottic space until mid-trachea was possible.[14] If the decision of awake intubation was still considered the best option after this exam, the preparation continued with midazolam 0.5–1 mg IV, fentanyl 0.05–0.1 mg IV in titrated doses over 5 minutes until an Observer's Assessment of Alertness/Sedation Scale (OAA/S) of 4–5 was achieved: cooperative, oriented, and calm patient. We omitted or titrated the sedation dose carefully in patients for whom sedative medication was likely to worsen airway obstruction. Then we topically administered 2% lidocaine, first gargling, and then dripping with a curved oropharyngeal catheter under trans-nasal fiberoptic guidance as the subject was encouraged to inspire and vocalize during instilment. If the patient did not cough while dripping local anesthetic in the larynx, we considered that we had achieved a good level of anesthesia. We inserted a cotton gauze soaked with lidocaine 4% in the chosen nostril along the septum. We took care that the total dose of lidocaine would not exceed $7 \text{ mg}\cdot\text{kg}^{-1}$ in total (nebulized and topically).

Intervention

After 5–7 minutes from sedation and topical anesthesia, the maneuver started with the flexible rhino-laryngoscope (2.9 mm diameter, 300 mm working length) armed with a cuffed reinforced intubating tube with 5.5–6.5 mm internal diameter (ID), lubricated

with 2% lidocaine gel. Training for using the flexible rhino-laryngoscope consisted of performing perioperative endoscopic airway examination and awake intubation to five patients before starting this research under the guidance of an otorhinolaryngologist.

Although the working length (the flexible optical cord) of the rhino-laryngoscope is 300 mm, an intubating tube, which is 300 mm long, will fit perfectly and will not cover the articulated tip of the fiberscope because the handle of the transition part of the fiberscope will get covered by the tube. It will help to hold the tube in a fixed position on the endoscope while advancing the tube-fiberscope assemble (Fig. 1). As the 6.5-mm ID intubating tube is 32 cm long and it would block the free movement of the fiberscope tip, we removed the connecting piece during awake intubation and placed it back when we connected the intubating tube to the anesthesia machine, if we used an intubating tube of that size.

The bevel of the intubating tube was oriented laterally during nasal passage to lower the chance of injuring the inferior concha. After the nasal passage of the fiberscope armed with the tube, the fiberscope and tube slowly advanced, with gentle movements, while maintaining verbal contact with the subject until we visualized the glottis. This proved to be challenging to achieve in some circumstances, such as large oropharyngeal tumors or distorted anatomy, so we had to reposition the subject's head, either by rotating it left-right or by flexion-extension movements until we could visualize the glottis and achieve an alignment so we could advance with the fiberscope and the tube through the glottis. If the tube reaches the laryngeal inlet at a too sharp angle, it is useful to withdraw and slowly rotate the tube 90° counter-clockwise or reposition the subject's head, either by rotating left-right or flexion-extension.[15] We decided that the investigator should have a single attempt for tracheal intubation, during which the intubating tube should not be withdrawn above the nasopharynx unless major complications occurred or the patient requested so. In such cases, we considered that the procedure failed. Once it passed the vocal cords, the tube is advanced to the level of the mid-trachea, and the successful tracheal intubation is confirmed by fiberscope view, spontaneous bag ventilation movement, and capnography. Most studies state that the depth at which the intubating tube should be inserted in case of nasotracheal intubation is 26 cm for women and 28 cm for men, a recommendation that we generally followed.[16]

Data collection

The primary outcome measure was the duration of the successful procedure, starting from the beginning of the nasal passage with the intubating tube until the confirmation of the tracheal intubation, noticing the anesthesia machine bag free movement and capnography waveform. During the maneuver, we monitored blood pressure every minute during the procedure, electrocardiogram, oxygen saturation and kept continuous verbal contact with the subject. We used a scale to mark the subject's reaction during the process as follows: 0, no response; 1, slight grimacing; 2, heavy grimacing; 3, verbal protest; and 4, head and body movement. We noted the results as markers of subject discomfort, which was the second outcome measure. We also documented the complications – epistaxis, pharyngolaryngeal bleeding or injury, laryngospasm, heart rate disturbances, over-sedation, respiratory or cardiac arrest, as well as incidents occurring during the maintenance of anesthesia: intubating tube displacement or inadequate lung ventilation.

Patients were asked to complete a satisfaction score of the intubation procedure 24 hours after surgery in the form of a visual analog scale (VAS). The scale was a line marked with five grades of their discomfort during the procedure: none, mild, moderate, very bad, and unbearable. Above these written words, there was a 1 to 10 scale on which the subjects noted their satisfaction score: 1, no discomfort; 10, unbearable discomfort.

All patients at risk of post-extubation complications followed a extubating protocol, which included the ENT surgeon's opinion, the leak test of the uncuffed tracheal tube, and a fully awake and responsive patient. If the risk of edema or bleeding was substantial, the tube was maintained for 24–48 hours with the patient sedated. We were prepared to place an Airway Exchange Catheter, and the fiberoptic was at hand for airway evaluation and reintubation.[17] An experienced team in anterior neck access was also on stand-by.

Sample size

An audit of sample sizes for feasibility trials carried out in the United Kingdom revealed a median (IQR) [Range] of 36 (20, 60) [10, 300].[18] Starting from these results, we calculated the sample size based on the presumed success rate of the procedure. Awake fiberoptic intubation carries a failure risk of 1–1.5% in most large trials.[5,6,19] We assumed that our feasibility trial would have a failure rate of 10%, because of the challenging airways and the lack of experience with a new device.

Therefore, the resulting sample size was 25, considering an alpha level of 5%, a study power of 80%, and a failure rate of 1% from the literature. Sample size calculations were performed with the help of the web platform <https://clincalc.com/stats/samplesize.aspx>.

Statistical analysis

The variables studied were categorical except for the duration of intervention, which is numerical. We performed frequency analysis and calculated the mean, median, standard deviation (SD), and interquartile range (IQR) for all appropriate variables. A value of $p < 0.05$ was considered statistically significant. We tried to find correlations between the discomfort during the procedure and the other variables and between the satisfaction at 24 hours and the other variables. The statistical tests used were Fisher's exact test, Pearson's R, ANOVA, Spearman's, and t-tests.

To provide statistical analysis, we used SPSS[®] version 21 as well as JASP[®].

Results

Over the eleven months, we recruited 32 consecutive patients for this study. Seven of them were excluded from the study during the preoperative trans-nasal fiberoptic examination, because they pleaded for another type of airway approach. Table 1 presents the general features of the patients included in the study.

Main outcome

All 25 patients included in this study, aged between 34 and 82 years, had their tracheas successfully intubated with the flexible rhino-laryngoscope. The mean \pm SD duration of the procedure, starting from the passage of the intubating tube through one of the nostrils until the endotracheal intubation confirmation by free bag movement and capnography, was 76 ± 36 seconds (Table 2).

Patients' satisfaction

The patients tolerated the procedure well, remaining calm and cooperative, and most of them showed no reaction during the passage of the intubating tube, with statistical significance when comparing the group with no reaction with the slight grimacing group (95%CI – 0.13 to 0.53, $p = 0.047$) and the heavy grimacing group (95%CI – 0.05 to 0.83, $p = 0.003$). The patients rated the maneuver with a mean \pm SD score of $1.8 \pm$

0.86 – none to mild discomfort during the post-intervention satisfaction score. Statistically, the 24-hour satisfaction was not correlated with momentary discomfort but with the duration of the procedure ($p = 0.001$).

Complications and incidents

We did not encounter any significant complications. Patients were hemodynamically stable during the procedure with no significant variation of heart rate or arterial pressure, the lowest oxygen saturation recorded being 90%. One subject presented transient epistaxis following the intubating tube nasal passage, and one patient became slightly over sedated with the possibility of airway compromise. The airway pathology of the patients included in the study was in the majority of tumoral nature (Fig. 2).

Discussion

Many anesthesiologists have reservations about using awake intubation because of the fear of failing, the lack of training, or a previous bad experience with this technique.[9,19] We think that a 600-mm fiberscope may be challenging to maneuver for some practitioners, considering that an essential part of practitioners' attention focuses on how to hold the fiberscope in position, which alters their capacity to concentrate on advancing and introducing the fiberscope and intubating tube between the vocal cords. Another undesired scenario is to advance the fiberscope into the trachea only to realize that the intubating tube does not fit the nostril, or if one chooses the blind nasal passage, epistaxis or concha injury may occur. "Railroading", the only blind maneuver when awake fiberoptic intubation is performed, is a critical moment that carries some risks of impingement, airway trauma, esophageal or bronchial intubation.[20] When using a 300-mm fiberscope, there is no need to railroad the tube over the fiberscope as they enter the glottis together, and the fiberscope is extracted once the tube reaches the trachea. If there is a pathology of the anterior airway or trismus, other alternatives of awake intubation, besides the fiberscope, may not be suitable.[21]

The sitting position is ideal for awake intubation, offering both the practitioner and the patient more safety and comfort.[22] More than that, in the case of lesions of the anterior airway or large neck masses, chances are that the supine position compromises an already reduced respiratory space.

Preoperative endoscopy performed with a flexible video laryngoscope could bring valuable information regarding the patency of the nasal cavity, the risks associated with tracheal intubation when an airway pathology is present or if the awake intubation is the best choice, and it could help the practitioner to plan the steps for a successful procedure.[2,14] Ultrasonography and other imagistic examinations could complete the airway exam.[23]

We believe that a patient with obstructive pathology of the base of tongue, supraglottic and glottic structures with a respiratory space large enough to accommodate a 5–5.5 mm diameter tube is an appropriate candidate for our technique. The device was practical and versatile in case of large pharyngeal, supraglottic, or glottic tumors where it is necessary to advance the intubating tube very gently without producing bleeding or swelling of the tumoral tissue. On the other hand, when a 7-mm ID or larger tube is needed, a longer fiberscope may be the first choice.

Because the flexible rhino-laryngoscope is thin, usually around 3 mm in diameter, and easy to handle due to its length, the procedure is well-perceived by patients with little to no risk of hemorrhage and trauma.[11]

A shorter fiberscope is easy to manipulate with one hand, leaving the other hand available for positioning the patient's head in a manner that aligns the glottis and the armed fiberscope. Urging the subject to protrude the tongue and to take deep breaths during the glottis passage also proved helpful in this matter. The fact that the tube is closely following the tip of the fiberscope helps practitioners through the nasal passage and to anticipate the moment when the tube is passing the glottis as the tip of the endoscope reaches the larynx. Therefore, they may timely apply the above-described measures or slightly rotate the tube when an obstacle is encountered.

The maneuver was straightforward in most cases, with a significant advantage concerning intubation time when compared to a study by Kramer and colleagues involving patients with comparable airway pathology and experienced investigators.[24] They reported a median (IQR) intubation time of 100 (50–300) s with a 96% success rate in a study involving 50 patients. In our study, the median (IQR) duration of the procedure was 63 (56–88), statistically faster with a (95% CI – 38.9 to -9, $p = 0,003$) and a mean difference of 23.96 seconds. This suggests that our results are encouraging, but not necessarily better since our study was carried out in different conditions.

A faster and smooth procedure would reflect itself in patients' satisfaction, as proved by our study, with patients reporting only minor discomfort or no discomfort,

even those cases with a particularly difficult airway, which required more time for intubation.

Limitations

This study has some specific limitations. The number of patients included in the study may be insufficient. We compared the results of our study with other study results and not with a control group; the patients' satisfaction score has been influenced by sedation and general anesthesia. It is an observational single-center study that relies on personal perception and the skill of a limited number of investigators.

Conclusion

Our study showed that a 300-mm working length, 2.9-mm diameter flexible rhinolaryngoscope could be efficient and well-tolerated when used for nasal awake intubation in problematic airway patients who benefit from this kind of airway approach. This tool is now widely available, and it may be used for both airway assessment and control. More elaborate trials are necessary to confirm our findings.

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Conflicts of interest

The authors declare no conflicts of interest.

Presentations

Preliminary data for this study were presented at The National Congress of Otorhinolaryngology and Cervico-Facial Surgery, Arad, Romania, 6-9 June 2018 and at The Fifth Difficult Airway Conference, Cluj Napoca, Romania, 21-23 June 2018

ClinicalTrials.gov identifier

NCT03546088, Registered 20 February 2018 - Retrospectively registered, <https://clinicaltrials.gov/ct2/show/NCT03546088>

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Table 1 Patients' characteristics.

Age mean \pm SD, years	60.7 \pm 11.6
Body mass index mean \pm SD, kg.m⁻²	22.6 \pm 3.6

Height mean \pm SD, m	1.76 \pm 0.06
Female sex, n (%)	3 (12)
Inter incisors gap < 2 cm, n (%)	6 (24)
ASA mean \pm SD	2.56 \pm 0.76
SARI mean \pm SD	5.16 \pm 0.98

Duration of the procedure, s	Mean 76.04	Less than 60 s, n (%) 7 (28), $p = 0.043$ Between 60 and 90 s 13 (52), $p = 1.000$ More than 90 s 5 (20), $p = 0.004$
	95% Confidence Interval for Mean	
	Lower Bound 61.11	
	Upper Bound 90.96	
	5% Trimmed Mean 70.52	
	Median 63.00	
	SD 36.15	
	Minimum 47.00	
	Maximum 227.00	
	Range 180.00	
Interquartile Range 32.00		

Primary diagnoses, n (%)	
Ludwig's Angina	2 (8)
Epiglottis tumor	4 (16)
Larynx tumor	6 (24)
Hypopharynx tumor	2 (8)
Previous radiotherapy	2 (8)
Tongue base tumor	9 (36)

SD, standard deviation; ASA, American Society of Anesthesiologists physical status;
SARI, Simplified Airway Risk Index.

Table 2 Results.

Momentary discomfort 0, no response 1, slight grimacing 2, heavy grimacing 3, verbal protest 4, head and body movement	Mean 0.60 95% Confidence Interval for Mean Lower Bound 0.28 Upper Bound 0.91 5% Trimmed Mean 0.55 Median 0.00 Std. Deviation 0.76 Minimum 0.00 Maximum 2.00 Range 2.00 Interquartile Range 1.00	No reaction, n (%) 14 (56), $p = 0.690$ Slight grimacing 7 (28), $p = 0.043$ Heavy grimacing 4 (16), $p < 0.001$
24-hour satisfaction score 1, no discomfort 2, mild discomfort 3,4,5, moderate discomfort 6,7,8, very bad discomfort 9,10, unbearable discomfort	Mean 1.80 95% Confidence Interval for Mean Lower Bound 1.44 Upper Bound 2.15 5% Trimmed Mean 1.73 Median 2.00 Std. Deviation 0.86 Minimum 1.00 Maximum 4.00 Range 3.00 Interquartile Range 1.00	No discomfort, n (%) 11 (44), $p = 0.069$ Mild discomfort 9 (36), $p = 0.023$ Moderate discomfort 5 (20), $p = 0.004$

Figure 1 The fiber rhino-laryngoscope armed with a 6.0 reinforced intubating tube. The articulated tip is continuing the tube, guiding it through the nasal passage until the trachea.



Figure 2 one of the challenging cases. A) Glottis tumor, B) Laryngeal tumor in a subject associating ankylosing spondylitis, C) Epiglottic cyst, D) Base of tongue tumor.

