Brief Communication Application of "twelve-step" approach based on SEEK^{flex} for difficult awake tracheal intubation in patients with cervical spinal tumor

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Abstract: Difficult airway always occurs in patients with cervical spinal tumor. Awake tracheal intubation (ATI) is usually a primary safe approach for clinical doctors in these intractable difficult airways. It is of great significance to establish specific strategies to reduce related acute airway accidents. A novel "twelve-step" approach of awake tracheal intubation based on an improved introducer (Safe Easy Endotracheal Kit-flexible, "SEEK^{flex}") was developed and practiced in model successfully. Patients with cervical spinal tumor in a single tertiary hospital were chosen to secure airway with this approach. Primary outcomes were safety and feasibility, defined as completion of ATI without serious adverse events, Secondary outcome was the first intubation attempt rate, total intubation time, satisfaction of patients in the whole process and relevant complications. We performed awake tracheal intubation with this approach to solve the difficult airway in five patients with cervical spinal tumor. The courses went successfully in all patients without any relevant complications. This novel "twelve-step" approach based on SEEK^{flex} for ATI can be considered as one of optional safe choices for difficult airway in patients with cervical spinal tumor.

Keywords: Cervical spinal tumor, difficult airway, awake tracheal intubation, introducer, fiberoptic bronchoscope, SEEK^{flex}

Introduction

Cervical spinal tumors often develop in/beside vertebral body first, and the treatment strategy in clinic is based on biology, location and extent of the lesion, including surgery or others. Patients with cervical spinal tumor who need treatments always suffer from anticipated or unpredictable difficult airway owing to limited neck flexion or extension, impaired vertebral stability, even obstructed upper airway [1]. These airways are very intractable and with high-risk of acute airway accidents "Can't Intubation, Can't Oxygenation" during the perioperation. It was reported that unexpected difficult airways could account for 25% of anesthesia-related deaths [2]. So, comprehensive preoperative airway assessment is necessary [1-3], meanwhile, it is of great significance to establish specific strategies to reduce related airway complications.

Given the safety and maneuverability of difficult airway management, awake tracheal intubation (ATI) under topical anesthesia and sedation which has a high success rate and a low-risk profile, is usually the primary accepted preference in intensive care unit (ICU), emergency ward, pre-hospital rescue room and operating room [3]. There have been lots of tools to perform ATI, including direct laryngoscope, various video laryngoscope, flexible fiberoptic bronchoscope, supraglottic airway devices, assistant introducers, etc. Anesthesiologists always choose the optimal equipment according to different extent of airway difficulties and individual familiarity of the equipment. Flexible fiberoptic bronchoscope guided intubation is accepted as the gold standard in these patients [4].

However, disadvantages of fiberoptic bronchoscope guided intubation, including high requirements of operation skill, indistinctness of visu-

alization due to secretions or blood, a prolonged process with several attempts, patient intolerance, and hemodynamic instability, limit its broad application by clinician [5-7]. Video laryngoscope appeared as the first substitute in ATI [8, 9], having solved part of drawbacks, but under video laryngoscope, if epiglottis could be seen but glottis not, or glottis could be seen little due to glottis stenosis and tiny inlet of trachea, tracheal tube would be hardly inserted into after several attempts. Then, introducers appeared as an assistant tool, such as Frova intubating introducer with a high first attempt intubation success rate while combined with video laryngoscope because of bougies' rigid material [10], but there is no relevant document found in ATI. Therefore, how to improve the success rate of ATI remains challenging.

Methods

Study design/population

Based on an upgraded malleable tracheal introducer (Safe Easy Endotracheal Kit-flexible, SEEK^{flex}), which was previously developed by our team for extubation of critically ill COVID-19 patients [11], we successfully developed a novel "twelve-step" technique and aimed to make ATI safer, easier and faster in difficult airway management.

This study presents the first 5 patients of an ongoing prospective randomized controlled study of ATI in adults who are assessed as difficult airway before intubation and also suitable for video-laryngoscopy-assisted intubation. Exclusion criteria included that percutaneous thyrocricocentesis is contraindicated, ASA grade > III or patients refuse to join in this study. This study was approved by local ethical review committee and then registered at Chinese Clinical Trial Registry (ChiCTR2200060783). The informed consents were all obtained.

Structure and characteristics of SEEK^{flex}

SEEK^{flex} is a new single-use tracheal introducer (**Figure 1A**) with an OD of 4.0 mm, ID of 2.4 mm, which is suitable for tracheal tube size ID > 4.5 mm and contains maximum ventilation capacity of 1.85 ml. It has a main body (**Figure 1Ab-g**) and an accessory (**Figure 1Aa**). The main body can be separated into two parts (inner stiffening stylet and outer polyvinyl chloride catheter) and spirally locked back again by a connector (**Figure 1Ad**). The inner stiffening stylet is malleable. In a word, it is characteristically malleable, stretchable, detachable, and lockable. Characteristics and advantages of SEEK^{flex} are listed in **Table 1**.

SEEK^{flex} is quite different from airway exchange catheter and Frova intubating introducer regarding their applications, structures, materials, and characteristics. Compared with Airway Exchange Catheter (AEC), SEEK^{flex} can be used to assist endotracheal intubation for securing the airway besides exchanging tracheal tubes. Especially, compared with Frova introducer, SEEK^{flex} is simplified and even can be operated accessibly by just one inexperienced clinician, while Frova introducer needs two and more operators' cooperation.

Procedures of SEEK^{flex} operation in ATI

We summarized a "twelve-step" approach for ATI (**Figure 1B**) which was practiced in model by our team and verified to be feasible, then designed to make this approach applied in clinical cases in a randomized controlled trial to verify more. A remedy for unexpected events or unsuccessful tracheal intubation with this technique also should be necessary to be designed, that fiberoptic-bronchoscope should be chosen as a backup tool available beside. So we strongly suggest that those who are not familiar with this technique should have practiced in model before applying in patients. The detailed intubation procedure of one case for an example is elaborated to be seen at **Appendix S1**.

Serious adverse event

The serious adverse event was considered as one of the following changes: (I) decrease in oxygen level (SpO_2) of 10% from baseline; (II) change in mean arterial pressure (MAP) or heart rate (HR) of ± 20%. If serious adverse event happens, the study will stop, and switch to fiberoptic bronchoscope after full oxygenation.

Outcomes

Primary outcomes were safety and feasibility, defined as completion of ATI without serious adverse events, and secondary outcome was the first intubation attempt rate, total intuba-

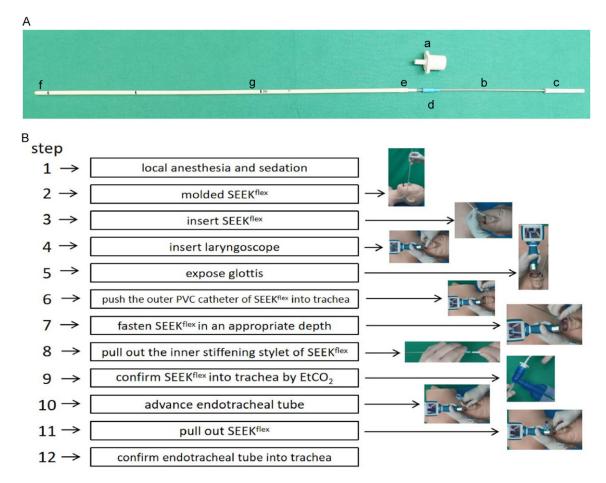


Figure 1. A. Structure of SEEK^{flex} (Status of stretching for a little): Accessory: (a) Adapter; Main body: (b) Inner stiffening stylet, about 45 cm in length, (c) Handle, (d) Transition Connector, (e) Lock Connector, (f) Vents, (g) Outer PVC* catheter, about 38 cm in length. PVC*: polyvinyl chloride. B. "Twelve-step" approach to operate ATI with SEEK^{flex}.

	SEEK ^{flex}	Frova intubating introducer	Airway Exchange Catheter			
Application	Assist endotracheal intubation; Exchange tracheal tube	Assist endotracheal intubation	Exchange tracheal tube			
With stiffening stylet or not?	Yes	Yes	No			
Can be molded or not?	Yes (Type 1) pre-molded 39° (Type 2) not pre-molded	Yes pre-molded 65°	No			
Length	43-81 cm	35 cm/70 cm	45 cm/83 cm			
Scale Mark	Yes	Yes	Yes			
Vent	3 small vents at the tip Multiple side vents	Two side vents	Single vent at the tip Small vents on the side			
For placement of ETT ¹	ID > 4.5 mm	$ID \ge 3.0 \text{ mm}$ $ID \ge 6.0 \text{ mm}$	$ID \ge 3.0 \text{ mm}$			
Connection mode of connector	Spirally lock	Buckle	Buckle			
Characteristics	Stretchable; Detachable; Lockable	Detachable	/			
Material	Catheter: PVC ² ; Stiffening stylet: steel	Catheter: Polyethylene; Stiffening stylet: steel	Catheter: Polyethylene			
Operation	Single or two operators	Two operators cooperate	Two operators cooperate			

Table 1. Comparison of SEEK^{flex}, frova intubating introducer, and airway exchange catheter

 $\mathsf{ETT^1:}\ \mathsf{Endotrachealtube;}\ \mathsf{PVC^2:}\ \mathsf{PolyvinylChloride.}$

tion time, satisfaction of patients in the whole process and relevant complications.

Results

SEEK^{fiex} and the twelve-step approach were totally applied in five patients with cervical spinal tumor in ATI. And pre-operatively, the airways of these patients were all assessed as difficult airway (**Table 2**).

The intubation courses went uneventfully and successfully at the first attempt in all five patients, the total intubation time was 58-86 seconds, without signifcant changes of intubation reaction in MAP, HR and SpO2, and the other relevant data are summarized in **Table 2**.

Post-operatively, the patients were satisfied and had no painful and fearful recall of awake intubation course and were discharged from hospital after recovery, without any relevant complications (including epistaxis, hoarseness, or sore throat).

Discussion

Our practice demonstrated a successful and feasible use of the novel intubation introducer. Fiberoptic-bronchoscope guided intubation was usually chosen in patients with awake difficult airway [7, 12-15]. Nevertheless, fiberoptic bronchoscope intubation has many limitations [7]. Firstly, its lens can easily be disturbed by secretions or blood [16, 17], which is one of the main reasons why intubation time is longer than other tools [12]. Secondly, it requires highlevel proficient skills of the operator, otherwise, flexible lens at the tip would repeatedly touch and stimulate vocal cords and tissues nearby while searching for glottis for intubation. As is reported, up to 20% of cases of critically ill adults undergoing emergency tracheal intubation failed on the first attempt, usually causing severe hypoxaemia and cardiac arrest [18]. So, it's necessary to increase the first attempt rate in ATI. Finally, owing to the bad experience of the stimulation, patients may have high hemodynamic variation and further suffer more cardiovascular complications, meanwhile, some will even develop serious psychological disease.

Compared with the fiberoptic bronchoscope, SEEK^{flex} is softer, more convenient, easier to

master, and even safer. Via the small multiple vents of the outer catheter, it can be used as a mini-type tracheal tube for ventilation in a short while to assure oxygenation, though it was reported to cause barotrauma and fatalities by high pressure which we should pay close attention to [19]. With broad view of direct laryngoscope or video-laryngoscope, this approach won't be disturbed by secretions at peri-glottic area. Meanwhile, compared with fiberoptic bronchoscope, SEEK^{flex} seems to greatly simplify the insertion of tracheal tube and reduce harm to the patients according to our cases, especially with less uncomfortable sensation and more stable hemodynamics.

Nowadays, video laryngoscope combined with introducer-guided intubation has been reported that it could increase the success rate of intubation at first attempt because of bougies' rigid material [20]. But there is no relevant document found in ATI, maybe because Frova introducer is inconvenient in operation and hard to popularize. SEEK^{flex} seems to solve part of these drawbacks. Compared with Frova introducer, SEEK^{flex} is simplified and can be operated easily by the clinician who even have less experience. This study of five intubation courses went uneventfully and successfully at the first attempt, without signifcant changes of intubation reaction.

SEEK^{flex} is a modified Frova intubating introducer with unique structure and characteristics, meanwhile, it is simplified and can be operated easily. However, when visual tool is not beside, it can not be used alone, furthermore, we only studied five cases and these outcomes couldn't represent for a generalized conclusion, and we also didn't compare with another bougies like frova introducer, so we still need to design further study to confirm its "safety and feasibility" and to find more effective evidence.

Conclusions

This novel "twelve-step" approach based on SEEK^{flex} for ATI can be considered as one of optional choices for difficult airway in patients with cervical spinal tumor.

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Case number	Diagnosis			BMI (kg/cm²)	Assessment of airway				Relevant data around awake intubation				Hemodynamic/respiratory parameter (Max-Min*)				
		Gender (F/M*)	Age (years old)		Inter- incisor gap (cm)	Range of cervical flexion- extension (°)	Thyromental distance (cm)	Mallampati grade	SARI*	Numbers of intubation attempts	Total intubation time (s)	Numbers of esophageal insertions	Change intubation technique or not	VAS* of patients' satisfaction	Δof (mmHg)	Δmm (bpm)	Δbpm (%)
1	Recurrent fibroma	F	28	22.3	2.3	42	4	IV	8	1	86	0	no	3	111-103	104-94	96-92
2	Recurrent GCT*	F	36	23.6	5	85	6.2	IV	6	1	58	0	no	1	109-95	101-88	99-98
3	Metastatic carcinoma	М	57	19.3	4.5	35	5.5	IV	6	1	74	0	no	2	116-100	95-77	94-90
4	Recurrent chordoma	М	74	23.3	5	45	5	Ш	6	1	81	0	no	1	106-92	92-83	98-96
5	Postoperative hemorrhage	М	56	20.7	3.5	50	4.8	IV	7	1	78	0	no	3	125-113	87-69	95-92

Table 2. Patients' data during pre-operative assessment and intubation period

*F/M: Female/Male; *SARI: Simplified Airway Risk Index; *GCT: Giant Cell Tumor; *VAS: Visual Analogue Scale/Score; *Max-Min: Value From Maximum To Minimum. Total intubation time: From inserting SEEK¹⁰⁰ to endotracheal tube into trachea.

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Chinese Clinical Trial Registry approved this study (ChiCTR2200060783). All procedures and research activities performed in the study were in accordance with the ethical standards of the institutional research committee. Consent was obtained from a legally authorized representative.

The patients provided their written informed consents for reporting this article.

Disclosure of conflict of interest

None.

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A 28-year-old female (164 cm, 60 kg, BMI 22.3) with a recurrent huge fibroma (5 cm×4 cm) in the cervical tendon sheath after a decompression laminectomy two years ago was scheduled to undergo a posterior cervical tumor resection. Pre-operative airway assessment showed a limitation of mouth opening <2.5 cm, a thyromental distance of 4 cm, range of cervical flexion-extension <45° and Mallampati Class IV (Figure S1A).

After satisfactory local anesthesia for larynx and trachea (percutaneous thyrocricocentesis administrated with lidocaine), the rest part (nasopharynx, pharynx and sublingual space) was sprayed anesthetic via the vents of SEEK^{flex} (**Figure 1Af**). Afterwards, SEEK^{flex} was bent at about 10 cm from the distal end to form individual angle (most about 90°) (Figure S2) and inserted from the nostril into oropharynx along nasal meatus. Subsequently, the blade of Glide-scope was inserted into the mouth to expose the glottis, and a Cormack-Lehane view of Grade III was obtained. The tip of SEEK^{flex} was inserted under the epiglottis to lift it, then the outer PVC catheter was directed across the glottis and slid into the trachea for about 5 cm. Later, the inner stiffening stylet was pulled out and the outer catheter was locked by the adapter to assure the right position of the tip of PVC catheter by end-tidal carbon dioxide (EtCO₂). After the inner stiffening stylet being reconnected to the outer PVC catheter and locked with connector simultaneously, the endotracheal tube (ETT, ID=6.5) was advanced successfully into the trachea with the guidance of SEEK^{flex} (Figure S1B). Finally, anesthesia was induced by using sufentanil, cisatracurium and propofol. No desaturation or obvious hemodynamic instability was observed during the whole procedure.



Figure S1. A. The giant mass was located at the left back neck in lateral view; B. Intubation was performed by SEEK^{flex} via nostril.

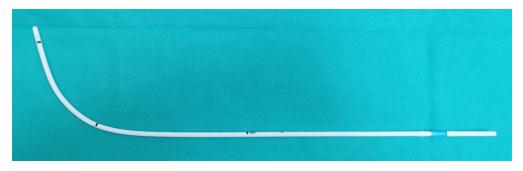


Figure S2. SEEK^{flex} was bent with an individual angle.