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Original Article

Safe Easy Endotracheal Kit-flexible-guided endotracheal intubation reduces stress response under general anesthesia: a randomized controlled trial

Hao Yang[1*], Wenyun Xu[2,3*], Bin Zhao[1], Cunhao Duan[1], Shaochuang Zheng[1], Yun Pan[1], Li Tan[4], Yang Liu[3], Zui Zou[3], Jianhua Xia[1]

[1]Department of Anesthesiology, Shanghai Pudong New Area People's Hospital, Shanghai, China; [2]Department of Anesthesiology, Second Affiliated Hospital of Naval Medical University, Shanghai, China; [3]School of Anesthesiology, Naval Medical University, Shanghai, China; [4]Department of Anesthesiology, Chongqing University Cancer Hospital, Chongqing, China. [*]Equal contributors and co-first authors.

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Abstract: Objective: To evaluate the stress response during general anesthesia intubation using the Safe Easy Endotracheal Kit-flexible (SEEKflex) with a video laryngoscope. Methods: From January to May 2023, 95 patients scheduled for elective surgery under general anesthesia were randomly assigned to either the traditional tube core group (n = 48) or the SEEKflex-guided group (n = 47). Vital signs and the first intubation success rate were recorded from pre-intubation to 2 minutes post-intubation. The trial was registered with the Chinese Clinical Trial Registry (ChiCTR2200066808). Results: The incidence of elevated blood pressure was significantly lower in the SEEKflex-guided group compared to the traditional tube core group (27.66% vs. 56.25%, P<0.05). Although the overall intubation success rate was 100% in both groups, the first intubation success rate was significantly higher in the SEEKflex-guided group (100% vs. 91.67%, P<0.05). Conclusion: SEEKflex-guided intubation, compared to the traditional tube core method, resulted in more stable hemodynamic responses and a higher first intubation success rate.

Keywords: Blood pressure, intubation, Safe Easy Endotracheal Kit-flexible, first intubation success rate, general anesthesia

Introduction

Endotracheal intubation is a standard procedure for anesthesiologists to secure the airway in patients undergoing general anesthesia during surgery. However, in certain patients, the stimulation caused by intubation can lead to significant risks, such as hypoxemia and cardiac arrest due to cardiovascular instability [1-6]. These adverse events are particularly common in patients with shock or respiratory failure, where the incidence increases substantially [7-12].

In clinical practice, endotracheal intubation typically involves inserting a metal tube core into the endotracheal tube and shaping them together prior to the procedure. In cases of difficult airways, a Bougie is often used. This longer device is first placed in the trachea to guide the tube insertion [13].

However, in cases of incomplete glottic exposure, the use of a tube core may require forceful elevation of the laryngoscope for improved visualization, often resulting in multiple attempts. As a result, the first intubation success rate ranges from 85-93% [14]. Repeated attempts not only increase the risk of pharyngeal injury but also cause significant hemodynamic fluctuations, compromising the safety and comfort of anesthesia.

The Safe Easy Endotracheal Kit-Flexible (SEEKflex), an adjustable catheter introducer, offers a potential solution to these challenges (**Figure 1A**, **1B**). SEEKflex features a medical-grade stainless steel wire core encased in polyvinyl chloride plastic (Model: JD-B, Wenzhou Jiate Medical Equipment Co., Ltd.). It is available in two versions: a standard 45 cm version (**Figure 1A**) and an extended 80 cm version (**Figure 1B**). To facilitate intubation, the tip of the

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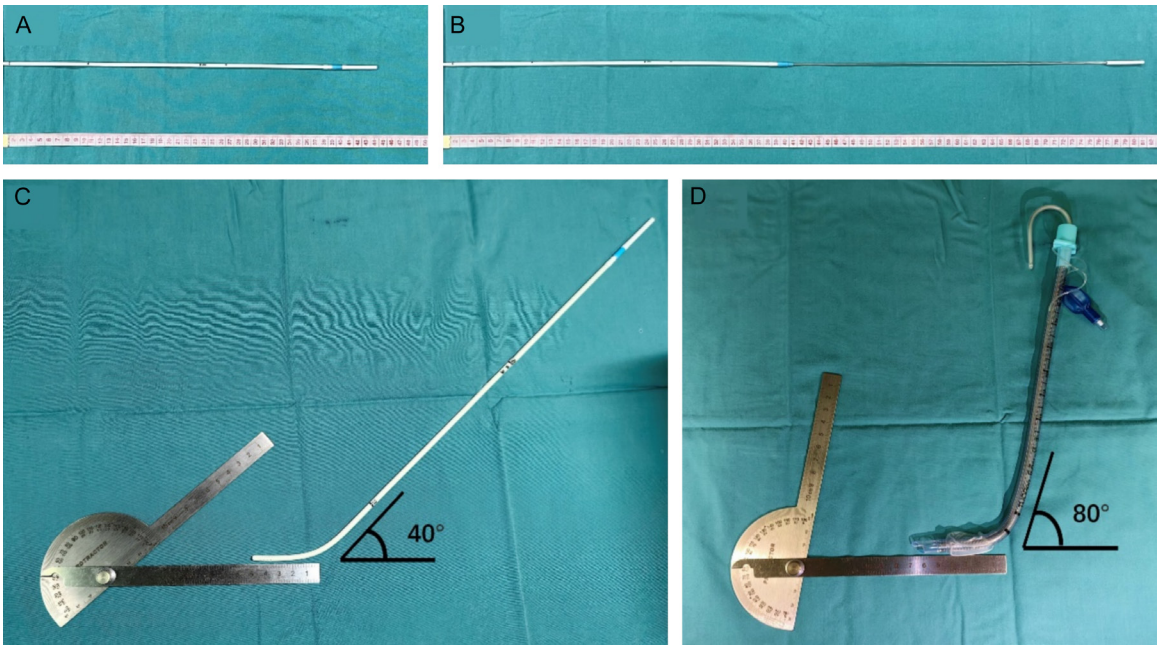

Figure 1. Schematic diagram of SEEK under different states and shaping diagram of two sets of tube cores before intubation. (A) (a standard 45 cm version) and (B) (an extended 80 cm version) show an adjustable core called Safe Easy Endotracheal Kit-flexible (SEEKflex). The interior of SEEKflex is made of medical grade stainless steel reinforced steel wire, and the exterior is wrapped in plastic made of polyvinyl chloride. Before intubation, the adjustable core end of the SEEKflex-guide group is bent approximately 40° at a position 5 cm from the tip (C), while the tube core and endotracheal tube were bent together at an angle of about 80° (D).

SEEKflex is shaped and lubricated, with the angle adjusted based on user expertise.

In our preliminary clinical trials, SEEKflex successfully guided tracheal intubation under video laryngoscopy during general anesthesia, without severe adverse events. However, further evaluation is needed to determine its effectiveness in reducing the stress response during intubation and minimizing postoperative airway complications.

To address these gaps, we conducted a randomized controlled trial to compare the incidence of blood pressure elevation during intubation between SEEKflex-guided and traditional tube core endotracheal intubation, which served as the primary endpoint. Secondary outcomes included the first intubation success rate, intubation duration, and incidence of postoperative airway complications.

Materials and methods

Ethical approval

The study was approved by the Ethics Committee of Pudong New Area People's Hospital in Shanghai. Prior to commencement, the trial was registered in the Chinese Clinical Trial Registry (ChiCTR2200066808). Experimental research was conducted at Pudong New Area People's Hospital and the Second Affiliated Hospital of Naval Medical University. The study adhered to the principles of the Declaration of Helsinki, and all participants provided written informed consent prior to enrollment.

All procedures were performed by the same attending anesthesiologist and assistant, both with extensive experience in SEEKflex-guided endotracheal intubation (having performed the technique more than 50 times on both models and humans) at the same hospital. Intubation was assisted by a video laryngoscope (Model: TD-C-IV, Zhejiang Youyi Medical Instrument Co., Ltd.), and the disposable intubation kit used was an enhanced general anesthesia kit produced by Tuoren Medical Instruments Co., Ltd.

Patient selection

A total of 100 patients scheduled for elective surgery requiring endotracheal intubation and general anesthesia were enrolled between

January and May 2023, with 50 patients from Pudong New Area People's Hospital and 50 from the Second Affiliated Hospital of Naval Medical University.

Inclusion Criteria: (1) Age between 18 and 65 years. (2) American Society of Anesthesiologists (ASA) physical status class I or II. (3) Body Mass Index (BMI) between 18 and 30 kg/m^2. (4) Stable vital signs within the specified ranges: Respiratory rate: 10-24 breaths/min. Pulse oxygen saturation (SpO_2): ≥95%. Systolic blood pressure (SBP): 90-140 mmHg. Diastolic blood pressure (DBP): 60-90 mmHg. Heart rate (HR): 60-100 beats/min. Surgical position: supine or lithotomy. Surgical site: abdomen or lower limb. Operating time: ≤3 hours.

Exclusion Criteria: (1) Inability to expose the epiglottis under laryngoscopy (Cormack-Lehane Scale class IV). (2) Mouth opening <3 cm or a history of difficult intubation.

Anesthetic management

Before surgery, patients were randomly assigned to either Group a (SEEKflex-guided group) or Group b (traditional tube core group) using a computer-generated randomization list. Group assignments were sealed in envelopes and provided to the anesthesiologist prior to anesthesia.

In the operating room, all patients received peripheral venous access, and lactated Ringer's solution was administered at 10 mL/kg/h. Heart rate (HR), oxygen saturation (SpO2), electrocardiogram (ECG), and bispectral index (BIS) were routinely monitored. Invasive blood pressure was continuously measured using a 22G arterial puncture needle (0.7 mm outer diameter) inserted into the radial artery of the right arm.

The observer recorded the patient's baseline vital signs (HR, SpO_2, SBP, DBP, and mean arterial pressure [MAP]) after the patient rested for 5 minutes (T0: pre-anesthesia induction). Patients then received 3 minutes of oxygen inhalation via a mask, followed by intravenous administration of the following induction agents: midazolam 0.03 mg/kg, sufentanil 0.03 μg/kg, propofol 1.5 mg/kg, and rocuronium 0.6 mg/kg. Once sufficient muscle relaxation was achieved, the patient's head was positioned in the sniffing position. Vital signs were recorded again before intubation (T1).

When BIS ≤60, endotracheal tubes of appropriate inner diameters were selected based on gender (6.5 mm for females, 7.0 mm for males). The intubation technique followed the method assigned in the envelope. Before intubation, the front end of the SEEKflex or traditional stylet was lubricated. In Group a, the SEEKflex was bent approximately 40° at a position 5 cm from the tip (**Figure 1C**). In Group b, the tube core and endotracheal tube were bent together at an angle of about 80° (**Figure 1D**).

For both groups, the anesthesiologist used a video laryngoscope to expose the glottis by lifting the epiglottis with the left hand. In Group a, the SEEKflex was used to guide intubation. The anesthesiologist inserted the SEEKflex into the glottis and advanced the outer plastic sleeve approximately 10 cm beyond the glottis. The assistant removed the inner steel core to a vertical position, after which the tracheal tube was advanced along the SEEKflex to the appropriate depth.

In Group b, the anesthesiologist directly inserted the curved endotracheal tube into the glottis with the right hand. After the assistant removed the core, the tube was advanced to the appropriate depth. For both groups, the insertion depth was standardized to 23 cm for males and 22 cm for females. If resistance was encountered during insertion, the tube was gently rotated clockwise and advanced in the direction of least resistance.

For patients with a visible epiglottis but an obscured glottis, the SEEKflex in Group a was used to gently lift the epiglottis and expose the glottis before advancing the tube. In contrast, the Group b performed a blind insertion below the epiglottis.

If the first intubation attempt failed, the anesthesiologist could adjust the bend of the stylet or SEEKflex and attempt again. Intubation was limited to a maximum of three attempts; failure to intubate within three attempts triggered emergency airway management.

Vital signs (HR, SpO_2, SBP, DBP, MAP) were recorded immediately after intubation (T2) and at specific time points: 15 seconds (T3), 30 sec-

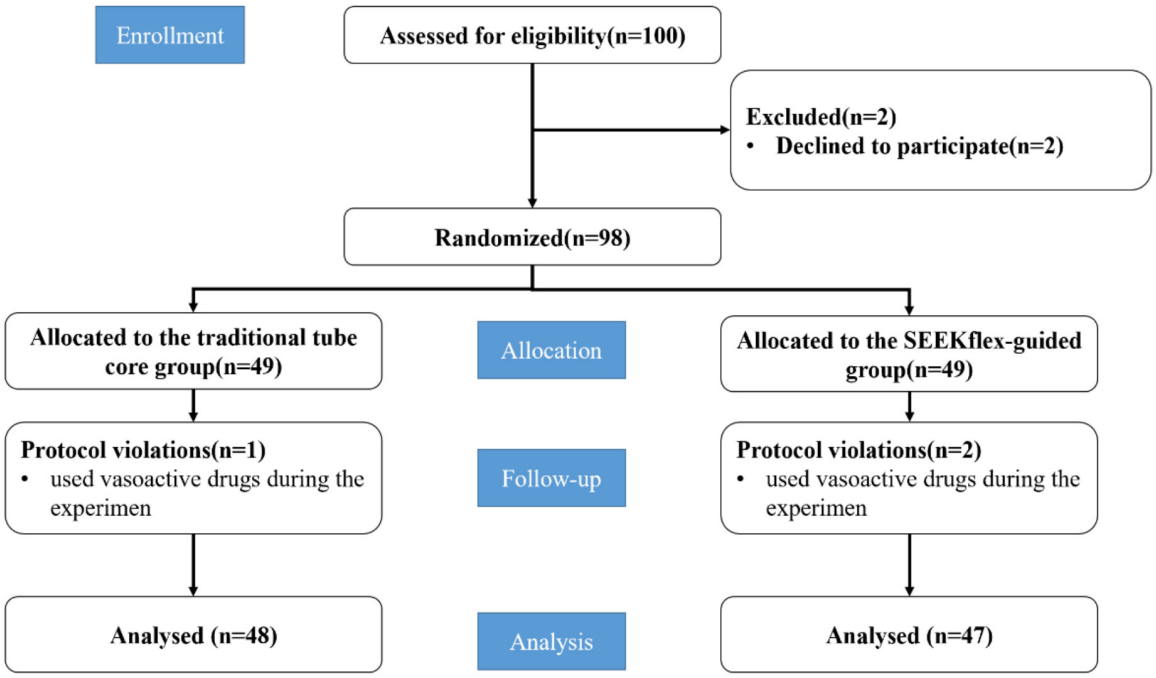

Figure 2. Flow diagram.

onds (T4), 60 seconds (T5), 90 seconds (T6), and 120 seconds (T7). The duration of tracheal intubation was measured from mask removal to successful tube placement. Additional recorded data included the incidence of elevated blood pressure, first-attempt success rate, and overall intubation success rate. Elevated blood pressure was defined as a ≥30% increase in SBP at any time point post-intubation compared to T1.

Within 24 hours post-intubation, an anesthesiology nurse, blinded to group assignments, assessed occurrences of tooth damage, sore throat, and hoarseness. The primary outcome was the incidence of elevated blood pressure.

Sample size calculation

The sample size was based on the incidence of elevated blood pressure in previous studies. Assuming a 60% incidence in Group b and 30% in Group a, with $\alpha = 0.01$ (two-tailed) and $\beta = 0.1$, the required sample size was estimated to be 39 patients per group, totaling at least 78 patients.

Statistical analysis

Statistical analysis was conducted using SPSS 22. Intra-group differences were analyzed using Friedman's rank repeated measures, and differences at specific time points post-induction were assessed with the Wilcoxon Signed Rank Test. A two-way repeated-measures analysis was used to evaluate differences in cyclic variables between groups over time, with the independent factor being the group and the repeated factor being time.

Descriptive statistics were used to present data as median with interquartile range, mean (SD), or frequency (%). The Mann-Whitney U-test, adjusted for stratified variables, was used to assess intergroup differences in continuous outcomes, represented as median differences with 95% CI. Significance was defined as $P< 0.05$ (two-tailed).

Results

Comparison of patient inclusion and clinical features

Of the 100 patients initially enrolled, five were excluded (two declined participation, and three required vasoactive drugs during the experiment). Thus, 95 patients were included in the final analysis: 47 in Group a and 48 in Group b (**Figure 2**).

Table 1. Demographic and clinical data of the patients in two groups

	Group a (n = 47)	Group b (n = 48)
Age (yr)	48 [35-58]	46 [37-57]
Sex		
Female	23 (49%)	25 (52%)
Male	24 (51%)	23 (48%)
BMI ($kg·m^{-2}$)	23 [22-25]	23 [21-24]
ASA physical Status		
I	20 (43%)	23 (48%)
II	27 (57%)	25 (52%)
Laryngoscopic View Grading System		
I	19 (40%)	23 (48%)
II	26 (55%)	23 (48%)
III	2 (4%)	2 (4%)

Demographic and clinical data of the patients in two groups. Data are n (%), or median (inter-quartile range). Percentages do not add up to 100% because of rounding. Group a: the SEEKflex-guided group. Group b: the traditional tube core group. ASA: American Society of Anesthesiologists; BMI: Body Mass Index.

Baseline clinical characteristics are summarized in **Table 1**. There were no significant differences in age (P = 0.4) or BMI (P = 0.667). Additionally, no significant differences were observed in SBP, DBP, MAP, or HR between the two groups, either pre-induction (T0) or post-induction (T1) (all P>0.05; see **Table 2** for details).

Comparison of stress response

Significant differences in hemodynamic measures (SBP, DBP, MAP, HR) were observed at each time point after intubation (T2, T3, T4, T5, T6, T7) compared to post-induction values (T1) in both groups (all P<0.05, **Table 2**; **Figure 3**). Significant differences in SBP, MAP, and HR were noted at T3, T4, T5, and T6 (all P<0.05, **Table 2**; **Figure 3A**, **3C**, **3D**). Interestingly, DBP showed significant differences only at T4 and T5 (both P<0.05, **Table 2**; **Figure 3B**). By 120 seconds post-intubation (T7), there were no significant differences in SBP, DBP, MAP, or HR between the two groups (all P>0.05, **Table 2**).

The incidence of elevated blood pressure differed significantly between the groups. In Group b, 56.25% (27/48) of patients experienced elevated blood pressure, compared to only 27.66% (13/47) in Group a (OR 0.3, 95% CI: 0.13-0.7, P = 0.007, **Table 3**). Thus, the incidence of elevated blood pressure was significantly lower in Group a.

Comparison of first intubation success rate

Although the overall intubation success rate was 100% in both groups, the first intubation success rate differed. Group b achieved a first-intubation success rate of 91.67% (44/48), while Group a achieved 100% (47/47) (OR 1.09, 95% CI: 1-1.19, P = 0.044).

The intubation time in Group a (25.43 [23.52-27.25] s) was significantly longer than in Group b (22.37 [20.6-24.42] s) (P<0.001, **Table 3**). Despite this, no significant hypoxia occurred in either group, with SpO_2 remaining above 95% in all patients throughout the observation period.

Comparison of postoperative airway complications

There were no significant differences in the incidence of postoperative airway complications between the two groups (all P>0.05). Pharyngeal pain occurred in 4.3% (2/47) of Group a and 10.42% (5/48) of Group b (OR 0.38, 95% CI: 0.07-2.08, P = 0.449). Similarly, the incidence of hoarseness was comparable between the groups: 2.13% (1/47) in Group a and 4.17% (2/48) in Group b (OR 0.5, 95% CI: 0.04-5.71, P = 1). No cases of tooth damage were reported in either group.

Discussion

In this study, we demonstrated the advantages of SEEKflex-guided intubation (Group a) over traditional stylet-guided intubation. Group a exhibited a significantly lower incidence of elevated blood pressure during intubation. Additionally, the first intubation success rate was 100% in Group a, a marked improvement compared to Group b. However, no significant differences were observed in postoperative airway complications, such as pharyngeal pain, hoarseness, or dental injury, between the two groups. He-

Table 2. Blood pressure and heart rate at each time point in the two groups

Variables	T0	T1	T2	P_{t2t1}	T3	P_{t3t1}	T4	P_{t4t1}	T5	P_{t5t1}	T6	P_{t6t1}	T7	P_{t7t1}
SBP (mmHg)														
Group a (n = 47)	123.57 (9.26)	100.17 (8.01)	104.87 (9.88)	<0.001	118.28 (9.36)	<0.001	124 (12.05)	<0.001	115.13 (9.48)	<0.001	109.85 (8.85)	<0.001	105.64 (7.71)	<0.001
Group b (n = 48)	124.88 (9.56)	99.46 (6.12)	105.63 (7.57)	<0.001	124.67 (9.22)	<0.001	132.69 (10.89)	<0.001	122.52 (8.78)	<0.001	115.88 (7.97)	<0.001	108.33 (6.1)	<0.001
P_{ab}	0.461	0.421	0.78	-	0.003	-	0.001	-	<0.001	-	<0.001	-	0.078	-
DBP (mmHg)														
Group a (n = 47)	72.02 (7.69)	59.85 (6.25)	63.68 (7.36)	<0.001	70.79 (7.69)	<0.001	73.43 (8.35)	<0.001	69.51 (7.08)	<0.001	65.38 (6.5)	<0.001	63.17 (6.91)	0.002
Group b (n = 48)	72.4 (6.6)	58.96 (5.8)	63.75 (5.07)	<0.001	73.54 (5.6)	<0.001	78.27 (6.23)	<0.001	72.08 (5.56)	<0.001	67.65 (5.48)	<0.001	63.92 (4.73)	<0.001
P_{ab}	0.718	0.357	0.693	-	0.089	-	0.001	-	0.04	-	0.108	-	0.385	-
MAP (mmHg)														
Group a (n = 47)	90.28 (7.62)	74.62 (6.51)	78.94 (8.33)	<0.001	88.38 (9.16)	<0.001	92.02 (9.19)	<0.001	85.17 (7.55)	<0.001	80.53 (6.68)	<0.001	77.85 (6.93)	<0.001
Group b (n = 48)	91.85 (8.05)	73.25 (6.77)	79.52 (5.95)	<0.001	94.75 (6.72)	<0.001	101.54 (8.39)	<0.001	91.96 (6.3)	<0.001	85.33 (5.81)	<0.001	80.15 (6.21)	<0.001
P_{ab}	0.34	0.381	0.935	-	0.001	-	<0.001	-	<0.001	-	0.001	-	0.117	-
HR (bpm)														
Group a (n = 47)	76 (9.34)	62.53 (6.01)	65.87 (6.56)	<0.001	75.49 (6.82)	<0.001	79.23 (7.35)	<0.001	73.32 (6.91)	<0.001	69.3 (6.15)	<0.001	64.4 (3.91)	<0.001
Group b (n = 48)	78.81 (9.25)	63.04 (5.39)	66.83 (6.29)	<0.001	82.04 (5.79)	<0.001	88.65 (7.91)	<0.001	80.75 (6.69)	<0.001	73.46 (5.13)	<0.001	65.19 (2.91)	<0.001
P_{ab}	0.127	0.846	0.444	-	<0.001	-	<0.001	-	<0.001	-	0.001	-	0.438	-

Blood pressure and heart rate of patients in two groups at each time point. Data are mean (standard error of the mean). P_{ab} means group b compared to group a. P_{t2t1}, P_{t3t1}, P_{t4t1}, P_{t5t1}, P_{t6t1} and P_{t7t1} means T2, T3, T4, T5, T6, T7 compared to post-induction values (T1). Group a: the SEEKflex-guided group. Group b: the traditional tube core group. SBP: systolic blood pressure; DBP: diastolic blood pressure; MAP: mean arterial pressure; HR: heart rate.

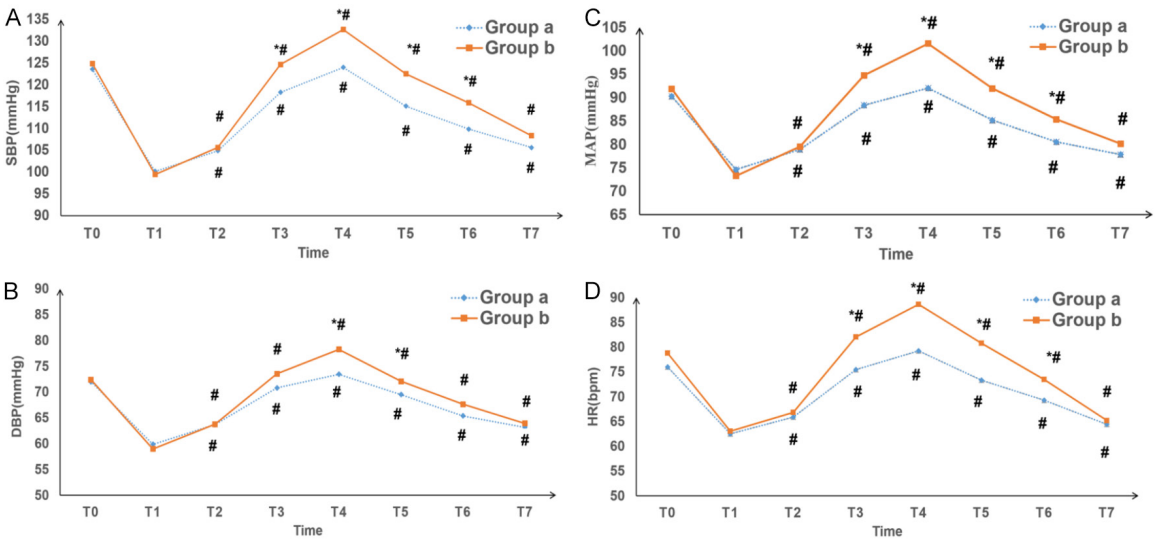

Figure 3. Comparison of hemodynamics between the two groups at different time points. (A-D) The images depict the systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and heart rate (HR) values between the groups at different time points, respectively. Compared to the moment after induction (T1), there were significant differences in hemodynamic measures (SBP, DBP, MAP, and HR) at each time point (T2, T3, T4, T5, T6, T7) after intubation in both Group a and Group b. At time points T3, T4, T5, and T6, there were significant differences in SBP, MAP, and HR among the groups (all $P<0.05$) (A, C, D). However, the significant difference in DBP between groups only occurred at T4 and T5 (both $P<0.05$) (B). There were no significant differences in SBP, DBP, MAP, or HR between the two groups at T0 and T1 (all $P>0.05$). Points represent mean (SD). Group a: the SEEKflex-guided group. Group b: the traditional tube core group. *: $P<0.05$ compared to group a. #: $P<0.05$ compared to post-induction values (T1).

Table 3. Stress response and incidence of postoperative airway complications in the two groups

	Group a (n = 47)	Group b (n = 48)	Odds ratio (95% CI)	*P* value
Rate of elevated blood pressure	13/47 (27.66%)	27/48 (56.25%)	0.3 (0.13-0.7)	P = 0.007
First intubation success rate	47/47 (100%)	44/48 (91.67%)	1.09 (1-1.19)	P = 0.044
Intubation time(s)	25.43 [23.52-27.25]	22.37 [20.6-24.42]	-	P <0.001
Rate of dental injury	0	0	-	-
Rate of pharyngalgia	2/47 (4.3%)	5/48 (10.42%)	0.38 (0.07-2.08)	P = 0.449
Rate of hoarseness of voice	1/47 (2.13%)	2/48 (4.17%)	0.5 (0.04-5.71)	P = 1

Stress response and incidence of postoperative airway complications in two groups. Group a: the SEEKflex-guided group. Group b: the traditional tube core group. Data are n (%) or median (inter-quartile range).

modynamic differences between the two intubation methods were observed predominantly at 15, 30, 60, and 90 seconds post-intubation, with no significant differences at other time points.

The SEEKflex-guided intubation technique represents a novel advancement in endotracheal intubation. Our findings confirm that this method significantly reduces the incidence of elevated blood pressure compared to the traditional tube core technique. Direct stimulation of the vocal cords or trachea is a major cause of cardiovascular responses, including hypertension and tachycardia [15-17]. Traditional intubation often involves forceful lifting of the laryngoscope to maximize glottic exposure, leading to intense throat irritation [18, 19]. While healthy and young patients may tolerate these reflex increases in sympathetic activity, such responses pose risks for patients with ischemic heart disease [20]. In contrast, SEEKflex-guided intubation minimizes direct stimulation of the vocal cords and trachea, reducing hemodynamic fluctuations.

The slightly longer intubation time in the SEEKflex-guided group (approximately 3 seconds) is

expected due to additional steps, such as removing the SEEKflex core before inserting the endotracheal tube. However, this minor delay did not result in hypoxemia, as SpO_2 levels remained above 95% throughout the procedure. The improved first intubation success rate is a critical advantage, as repeated intubation attempts increase the risk of postoperative complications and stress for anesthesiologists [21]. This is especially important considering the estimated incidence of difficult airway intubation ranges from 3% to 10% [22]. Challenges such as poor glottic visibility, pharyngeal obstruction, obesity, and limited cervical mobility often contribute to failed intubations [23, 24]. The novel SEEKflex-guided intubation approach facilitates the insertion of a glottic-guided catheter, thereby enhancing the likelihood of successful first intubation, comparable to the use of a Bougie [25]. However, conventional probes face challenges when inserted into the glottis due to their rigid material [26]. Moreover, prior research has indicated that the intubation success rate among patients with cervical spine injury varies widely, ranging from 74% to 99% [27-29]. Consequently, a rigid core alone is insufficient to resolve all intubation difficulties [30]. Under the guidance of SEEKflex, the first intubation success rate reached 100%, possibly holding significant value for difficult intubation scenarios.

This study observed no cases of dental damage, likely attributable to the unique design of SEEKflex. Dental injury is a significant concern, sometimes accounting for up to 42% of anesthesia-related claims [31-33]. Previous research has shown that devices such as the Lightwand reduce the risk of dental damage in elderly patients [34]. SEEKflex's enhanced visibility and reduced force requirements during intubation likely contribute to the absence of dental injuries in this study.

However, this study has several limitations. First, the study population consisted of young adults with ASA I or II classifications. Older patients and those with ASA III or IV classifications are more vulnerable to hemodynamic fluctuations and require a smoother intubation process. Future studies should include these populations to validate the findings. Second, the outcome measures were broad and did not include detailed indicators of myocardial ischemia, such as ST-segment changes. Larger studies with comprehensive monitoring are necessary to evaluate fully the clinical benefits of SEEKflex-guided intubation.

In conclusion, our study highlights the significant advantages of SEEKflex-guided intubation in adult patients with normal blood pressure. This technique reduces the incidence of elevated blood pressure during intubation, enhances the first intubation success rate, and minimizes hemodynamic responses compared to traditional stylet-guided intubation. SEEKflex-guided intubation is a safe, effective, and innovative method that improves the safety and efficiency of endotracheal intubation.

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Disclosure of conflict of interest

None.

Address correspondence to: Jianhua Xia, Department of Anesthesiology, Shanghai Pudong New Area People's Hospital, Shanghai, China. E-mail: jianhuaxia2000@sina.com; Zui Zou, School of Anesthesiology, Naval Medical University, Shanghai, China. E-mail: zouzui@smmu.edu.cn

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