

Original Article

A comparison of Disposcope endoscope and Fiberoptic bronchoscope during awake orotracheal intubation in obese patients with anticipated difficult airway: a prospective, randomized and controlled clinical trial

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Abstract: Fiberoptic bronchoscope (FOB) has been the preferred instrument for many years in the management of difficult airway. Disposcope endoscope (DE) is a new medical device for tracheal intubation. This study intended to compare the feasibility and safety issues of FOB and DE during awake orotracheal intubation. Forty obese patients with anticipated difficult airway undergoing awake orotracheal intubation were included in this study. All the patients were randomly allocated to awake orotracheal intubation using FOB (FOB group) or DE (DE group) after conscious sedation. The time was required to view the vocal cords and to complete the intubation, the conditions of intubation, the hemodynamic changes during intubation and the adverse events after surgery were recorded. The visual analog scale (VAS) scores of the easy experiences for viewing the vocal cords and passing the tracheal tube through the glottis evaluated by the operator were also recorded. The time of viewing the vocal cords was shorter in the DE group (32.3±13.3 s) than that in the FOB group (46.5±22.3 s) (P = 0.03). The time of successful tracheal intubation was shorter in the DE group (37.0±14.0 s) when compared with that in the FOB group (66.3±28.4 s) (P < 0.01). The coughing scores were higher in the DE group (2.9±1.1) than that in the FOB group (2.7±0.9) (P = 0.04). The limb movement scores were higher in the DE group (3.9±0.3) when compared with that in the FOB group (3.4±1.1) (P = 0.04). The tolerance scores during intubation were higher in the DE group (3.6±0.6) than that in the FOB group (3.0±0.9) (P = 0.04). The VAS scores of the easy experiences for viewing the vocal cords and passing the tracheal tube through the glottis were higher in the DE group than that in the FOB group (P < 0.05); The incidence of throat pain after surgery was lower in the DE group when compared with that in the FOB group (P < 0.05). The results showed that Disposcope endoscope provided shorter intubation time, better intubation conditions and lower incidence of throat pain compared with Fiberoptic bronchoscope during awake orotracheal intubation in obese patients with anticipated difficult airway.

Keywords: Disposcope endoscope, Fiberoptic bronchoscope, awake orotracheal intubation, anticipated difficult airway

Introduction

Failure to maintain patient's airway during anesthesia can be fatal. Adverse complications associated with inability to maintain patient's airway involve aspiration, hypoventilation, hypoxemia, brain damage or even death [1-3]. Most importantly, almost 30% of all deaths related to anesthesia were attributed to difficult airways [4] and in up to 40% of the difficult airways were associated with obesity [1]. Awake tracheal intubation assisted by Fiberoptic bron-

choscope (FOB) is regarded as the gold standard for the management of difficult airway [5]. However FOB is costly and the performance of FOB intubation often requires a considerable amount of training and experiences, so it is imperative to search for a reliable, simple and safe intubation equipment to deal with difficult airway.

Disposcope endoscope (DE) is a new medical device used for tracheal intubation [6]. It is consisted of three parts. The first part is a 14.2

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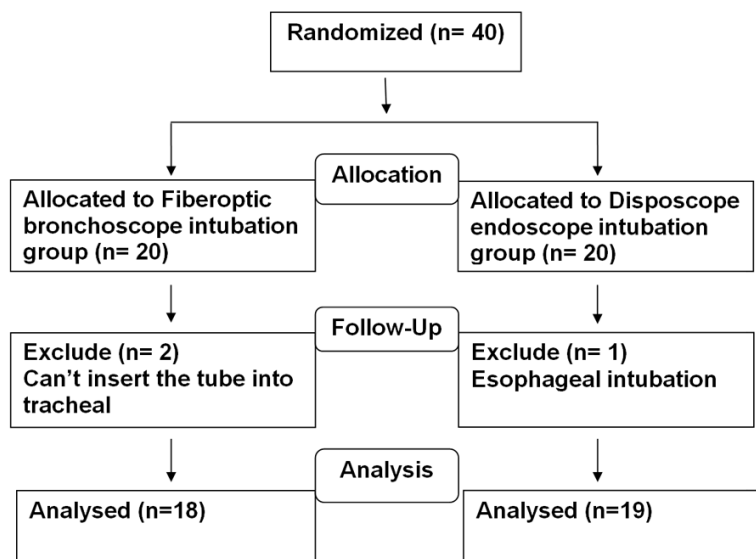


Figure 1. Flow diagram of patient distribution.

cm sized display screen. The second part is a 'wire transmitter' used for connection to display screen. The third part is the 'wire transfer' including a wire transfer tube and a micro-camera which is located at the tip of the wire enables operator to view the glottis more clearly. The tracheal tube is placed over the wire transfer tube. Under the guidance of DE, the tracheal tube can be placed more easily. Whether DE can serve as a replacement for FOB during awake orotracheal intubation is unknown. Thus, we hypothesized that DE would be more effective and safe than FOB during awake orotracheal intubation.

Materials and methods

Study participants

This study was approved by the Ethics Review Committee of the first hospital of Qinhuangdao, China and written informed consent was obtained from all patients. Forty obese patients with anticipated difficult airway were screened by a senior anesthesiologist preoperatively and randomly assigned into FOB group or DE group. Randomization (1:1) was based on codes generated using the SAS 9.2 software. These codes were kept in sequentially numbered opaque envelopes and stored at the site of investigation until the end of the study (Figure 1).

Inclusion criteria: Patients with anticipated difficult airway, body mass index (BMI) ≥ 30 kg/

m², modified Mallampati classification 3 or 4, requiring general anesthesia for surgery were enrolled in this study.

Exclusion criteria: Patient's age > 70 or < 18 years, ASA class IV or V, abnormalities of heart, brain, liver, lung, kidney and coagulation functions.

Anesthesia methods

All the patients in two groups without premedication received standard monitoring systems in the operating room, including heart rate (HR), non-invasive blood pressure (NIBP), electrocardio-

gram (ECG), pulse oximetry (SpO₂). All the patients were intravenously injected with midazolam 0.03 mg/kg and received remifentanyl (Yichang Humanwell Pharmaceutical, Yichang, China; no: 2408026) at a loading dose of 0.5 μ g/kg (1 mg of remifentanyl was diluted into 20 μ g/mL with 50 mL of 0.9% saline) followed by a continuous infusion at a speed of 0.1-0.15 μ g·kg⁻¹·min⁻¹.

After received the loading dose of remifentanyl, all the patients were suggested to open mouth as large as possible then the oral cavity, tongue and hypopharynx mucosa were sprayed with 2% lidocaine (3 ml). In addition, a transtracheal injection of 2% lidocaine (2-3 ml) was administered. The dose of lidocaine was less than 2 mg/kg to avoid toxic reactions. All the patients were administered with oxygen by mask at a rate of 3 L/min.

Awake orotracheal intubation

After conscious sedation and sufficient analgesia of the pharyngeal and laryngeal, a bite block was placed between the teeth of patients to prevent damage to FOB or DE. FOB (Fiberoptic bronchoscope, external diameter 3.8 mm, MDHAO Medical Technology Co, Ltd, Zhuhai China) and DE (Disposcope endoscope, Taiwan) were loaded with a 6.5 mm tracheal tube for women and a 7.0 mm tracheal tube for men (Figure 2A and 2B). In the FOB group, the epiglottis and glottis were identified by the FOB (Figure 2D). The FOB was inserted deep into

Awake orotracheal intubation with Disposcope endoscope

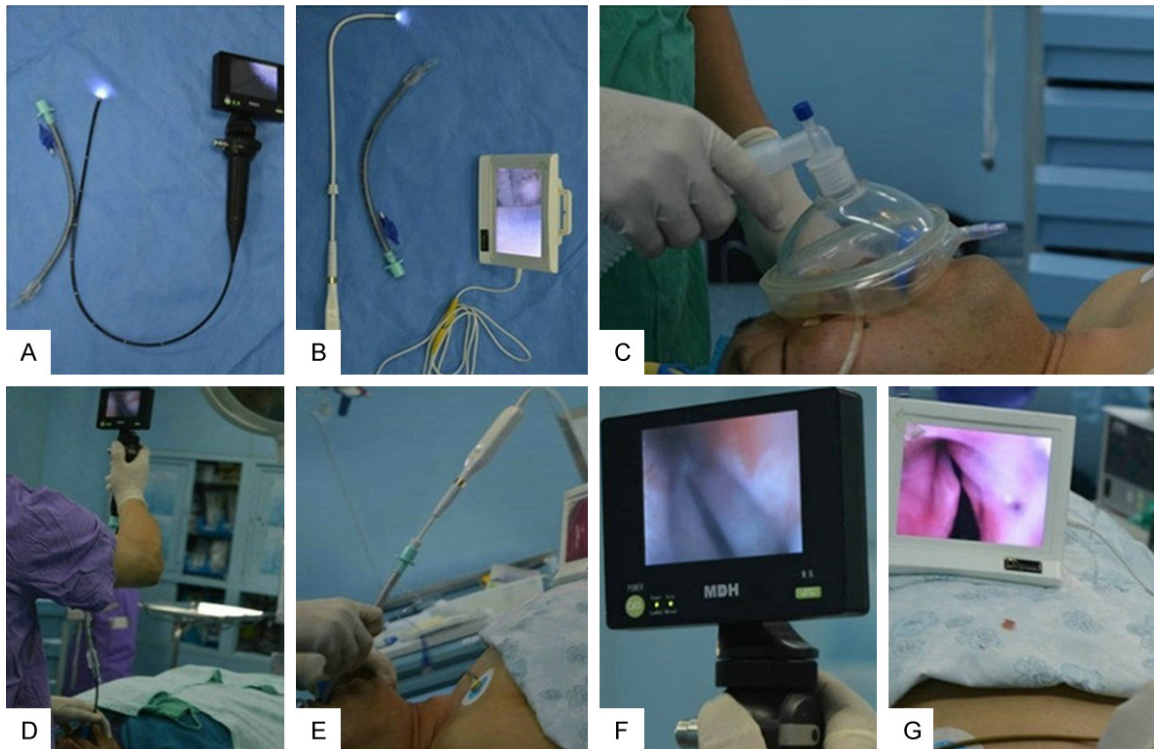


Figure 2. Procedure of awake orotracheal intubation. A. Fiberoptic bronchoscope and tracheal tube. B. Disposcope endoscope and tracheal tube. C. Mask oxygen supply at a speed of 3 L/min after conscious sedation. D, E. FOB or DE loaded with a 6.5 mm tracheal tube for females and a 7.0 mm tracheal tube for males was inserted into oral cavity. F, G. Epiglottis and glottis were identified by FOB or DE and the tracheal tube was pushed into the trachea via FOB or DE.

the tracheal after the anterior of FOB was passed the glottis and then the tracheal tube was pushed into the tracheal via the FOB (**Figure 2F**). In the DE group, the operator gripped the chin and lower incisors of patient with the left hand to open mouth adequately wide and inserted the wire body enclosed within a tracheal tube into oral cavity by the other hand (**Figure 2E**). The operator inserted the wire body downward along the oropharyngeal curve and advanced it to the vocal cords. After the wire body was passed the glottis, the operator pulled out the wire body at the same time advanced the tracheal tube into the tracheal. This procedure was under the direct vision of video screen (**Figure 2G**). The placement of tracheal tube was confirmed by bilateral auscultation and capnography. All the patients were intubated by the same anesthesiologist who was experienced with the management of difficult airway.

During intubation urapidil 25 mg was intravenously injected if MAP \geq 120% of the baseline level and 6 mg ephedrine was given when

MAP \leq 80% of the baseline level; 25 mg esmolol was intravenously injected if HR $>$ 100 beats/min and 0.5 mg atropine was given when HR $<$ 50 beats/min [7]. Orotracheal intubation was suspended and oxygen was supplied by mask when SpO₂ $<$ 90%. The coughing scores, vocal cord movement scores and limb movement scores during intubation were recorded to assess orotracheal intubation conditions (**Appendix 1** [8]).

Study endpoints

The primary endpoints were the time to view the vocal cords (TVC) and the time to successful tracheal intubation (TSI). TVC was defined as the time from inserting the devices between the teeth until the operator indicated verbally that he view the vocal cords. TSI was defined as the time from inserting the devices between the teeth until the appearance of a capnography curve. TVC and TSI were assessed by an independent observer with a stopwatch. We also recorded the coughing scores, limb movement scores, tol-

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Table 1. Demographic characteristics of patients in two groups

	FOB group (n = 18)	DE group (n = 19)	P Value
Age (years)	44.8±12.5	48.3±13.6	0.40
ASA			
I (n, %)	8 (44)	9 (47)	1.00
II (n, %)	7 (39)	8 (42)	1.00
III (n, %)	3 (17)	2 (11)	0.66
Gender (M/F)			
Male (n, %)	8 (44)	11 (58)	0.52
Female (n, %)	10 (56)	8 (42)	
Height (cm)	170.3±7.1	167.2±6.4	0.17
Weight (kg)	95.1±10.0	90.3±8.3	0.13
BMI (kg/m ²)	31.8±2.0	32.7±1.7	0.54

Data are expressed as means ± SD or percentages. ASA, American Society of Anesthesiologists; SD, standard deviation; BMI, body mass index.

Table 2. Airway assessment of patients before intubation

	FOB group (n = 18)	DE group (n = 19)	P Value
Mouth opening (n, %)			
≥ 4 cm	14 (78)	16 (84)	0.69
< 4 cm	4 (22)	3 (16)	
Thyromental distance (n, %)			
≥ 6.5 cm	10 (56)	11 (58)	1.00
6-6.5 cm	5 (28)	4 (21)	0.71
< 6 cm	3 (17)	4 (21)	1.00
Mallampati class (n, %)			
3	13 (72)	15 (79)	0.71
4	5 (28)	4 (21)	0.71
Neck movement (n, %)			
≥ 90°	14 (78)	12 (63)	0.48
80-90°	2 (11)	4 (21)	0.66
< 80°	2 (11)	3 (16)	1.00

Data are expressed as means ± SD. SD, standard deviation.

erance scores during intubation, the number of failure intubations (intubation time requiring > 180 seconds was defined as failure intubation), the number of esophageal intubations and the occurrence of adverse events such as hypotension, hypertension, bradycardia, synchosphymia and respiratory depression. The operator was asked to indicate VAS scores of the easy experiences for viewing the vocal cords and passing the tracheal tube through the glottis immediately after the intubation (score range: 0-10, 0 = very difficult, 10 = very easy).

An interview was conducted one day after the procedure by another anesthesiologist to evaluate patient's recall (memory of pre-anesthetic

preparations, local anesthesia and intubation) and adverse complications (hoarseness and pain of throat).

Statistical analysis

In this study, the sample size was based on a pilot study, in which we measured the time to view the vocal cords and the time to successful tracheal intubation with FOB or DE (not included in the real study). With significance set at 0.05 and power set at 80%, the sample size required to detect differences was 36 patients. Thus, we recruited 40 patients to prevent unforeseen difficulties.

Analyses were performed using SPSS 21.0 statistical software. Continuous variables were presented as mean ± standard deviation (SD) and the differences between groups were compared using the independent-samples t-test. The differences of proportions were analyzed using the Chi-squared test. The differences of the incidence were analyzed using Fisher's exact test. The P value less than 0.05 was considered statistically significant.

Results

Forty patients were enrolled in this study. Two patients were excluded in the FOB group, because the operator was unable to pass the tracheal tube through the glottis via the FOB; one patient was excluded in the DE group for esophageal intubation.

Demographic characteristics and airway assessment

There were no significant differences in the baseline data between two groups, including age, height, weight, sex ratio, body mass index, ASA classification and modified Mallampati classification (**Tables 1, 2**).

The time of tracheal intubation, tracheal intubation condition and tolerance of patient during intubation

The time of viewing the vocal cords was shorter in the DE group (32.3±13.3 s) than that in the FOB group (46.5±22.3 s) (P = 0.03). The time of successful tracheal intubation was shorter in

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Table 3. Comparison of time of viewing the vocal cords, time of successful tracheal intubation, tracheal intubation conditions and tolerance of patients to intubation between two groups

	FOB group (n = 18)	DE group (n = 19)	P Value
TVC (s)	46.5±22.3	32.3±13.3	0.03*
TSI (s)	66.3±28.4	37.0±14.0	< 0.01*
Condition of orotracheal intubation (score)			
Vocal cord movement	2.9±0.9	3.0±0.9	0.87
Coughing	2.7±0.9	2.9±1.1	0.04*
Limb movement	3.4±1.1	3.9±0.3	0.04*
Tolerance of orotracheal intubation (score)			
During intubation	3.0±0.9	3.6±0.6	0.04*
After intubation	2.5±0.7	2.8±0.4	0.06

Data are expressed as means ± SD or percentages, *P < 0.05 statistically significant. TVC, time of viewing the vocal cords; TSI, time of successful tracheal intubation.

Table 4. Comparison of VAS scores of the easy experiences for viewing the vocal cords and passing the tracheal tube through the glottis, number of attempts, patients' desaturation and adverse events during tracheal intubation

	FOB group (n = 18)	DE group (n = 19)	P Value
VV (score)	8.5±0.9	9.1±0.7	0.02*
VPT (score)	8.5±0.5	9.6±0.5	< 0.01*
Number of attempts (n, %)			
1	14 (78)	16 (84)	0.69
2	3 (17)	3 (16)	1.00
3	1 (6)	0 (0)	0.49
Desaturation < 90% (n, %)	4 (22)	2 (11)	0.41
Throat pain (n, %)	6 (33)	1 (5)	0.04*
Hoarseness (n, %)	4 (22)	3 (16)	1.00

Data are expressed as means ± SD or percentages, *P < 0.05 statistically significant. VV, VAS scores of the easy experiences for viewing the vocal cords; VPT, VAS scores of the easy experiences for passing the tube through glottis; VAS, Visual analog scale (score range, 0-10, score 0 = very difficult, 10 = very easy).

the DE group (37.0±14.0 s) when compared with that in the FOB group (66.3±28.4 s) (P < 0.01). The coughing scores were higher in the DE group (2.9±1.1) than that in FOB group (2.7±0.9) (P = 0.04). The limb movement scores were higher in the DE group (3.9±0.3) when compared with that in the FOB group (3.4±1.1) (P = 0.04). The tolerance scores during intubation were higher in the DE group (3.6±0.6) than that in the FOB group (3.0±0.9) (P = 0.04) (**Table 3**).

The intubation experiences of operator and adverse events

The VAS scores of the easy experiences for viewing the vocal cords were higher in the DE

group (9.1±0.7) when compared with that in the FOB group (8.5±0.9) (P = 0.02). The VAS scores of the easy experiences for passing the tracheal tube through the glottis were higher in the DE group (9.6±0.5) when compared with that in the FOB group (8.5±0.5) (P < 0.01).

The incidence of throat pain after surgery was lower in the DE group (1 of 19) than that in the FOB group (6 of 18) (P = 0.04) (**Table 4**).

Hemodynamic changes

There was no statistic difference in the hemodynamic changes between two groups (**Table 5**) (P > 0.05).

Discussion

Awake tracheal intubation is considered as a gold standard for the management of anticipated difficult airway [9, 10]. However the procedure of awake intubation is high-risk and associated with aspiration, hypoxemia, hypoventilation, brain damage or even death. Thus it is urgent need to analyze which device is the most appropriate for awake tracheal intubation [11].

In this study, we compared awake FOB orotracheal intubation with awake DE orotracheal intubation in obese patients with anticipated difficult airway. The results indicated that awake orotracheal intubation with DE was associated with shorter intubation time (successful tracheal intubation time was 37.0±14.0 s in the DE group vs 66.3±28.4 s in the FOB group), better intubation conditions (The coughing scores, limb movement scores and tolerance scores during intubation were 2.9±1.1, 3.9±0.3 and 3.6±0.6 in the DE group vs 2.7±0.9, 3.4±1.1 and 3.0±0.9 in the FOB group).

The incidence of throat pain after surgery was lower in the DE group (1 of 19) than that in the FOB group (6 of 18) (P = 0.04) (**Table 4**). There was no statistic difference in the hemodynamic changes between two groups (**Table 5**) (P > 0.05).

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Table 5. The hemodynamic changes of patients during intubation

	FOB group (n = 18)	DE group (n = 19)	P Value
MAP (mmHg)			
T0	103.4±15.0	104.8±13.0	0.77
T1	84.4±10.9	91.5±13.6	0.08
T2	100.7±17.3	104.3±19.0	0.54
T3	90.2±17.1	85.6±25.8	0.48
HR (bpm)			
T0	80.6±15.4	83.7±10.3	0.40
T1	75.7±17.9	80.5±13.3	0.35
T2	92.4±20.6	91.5±16.7	0.88
T3	82.7±20.1	81.9±13.1	0.86
Hypertension (n, %)	3 (17)	5 (26)	0.69
Hypotension (n, %)	3 (17)	2 (11)	0.66
Sychnosphygmia (n, %)	5 (28)	4 (21)	0.71
Bradycardia (n, %)	1 (6)	0 (0)	0.49

Data are expressed as means ± SD or percentages. MAP, Mean arterial pressure; HR, Heart rate; SD, standard deviation.

up) and lower incidence of throat pain after surgery (1 of 19 patients in the DE group vs 6 of 18 patients in the FOB group) when compare with FOB. A possible explanation for these findings may be that when using the FOB for awake intubation, the operator needed to insert the anterior of FOB deep into the tracheal where local analgesia was insufficient. Therefore this stimulus could induce a cough reflex and limb movement which increased the difficulty of intubation. Additionally, this technique occasionally failed because the tip of the tracheal tube sometimes impinged on the laryngeal structures during passing the tracheal tube through the glottis [12, 13]. So this procedure usually accompanied with unexpected airway injuries [14]. In contrast, when using the DE for awake intubation, the operator gripped the chin and lower incisors of patients to open the mouth adequately wide, thus exposed the vocal cords more easily. Furthermore the micro-camera of the DE is located at the tip of the stylet-form body and the tip of wire body is enclosed within the tracheal tube. All the procedure of intubation can be observed on the display screen. So the tracheal tube was advanced into the glottis under direct vision [6]. Moreover, the wire body of DE is semirigid and flexible. The operator can adjust it to optimum angles according to the patient's situation. The railroading of the tracheal tube over the DE is more straight-forward. So the tracheal tube was advanced into the glottis more quickly on seeing the vocal cords. Therefore, awake

oro-tracheal intubation using DE was faster, easier and less trauma than using FOB.

In our study, we found no statistical differences in the hemodynamic changes between two groups, the reasons may be that we recorded noninvasive blood pressure and the ages of patients in our study ranged from 18 to 70. Therefore, the results of hemodynamic changes in this study may be insufficient to reflect the real change of hemodynamic response to the intubation.

The study of Rosenstock found no difference in the time of awake tracheal intubation with McGrath video laryngoscope (MLV) or FOB in patient with difficult airway [5].

However, during awake MVL intubation, the blade of MVL may causes pressure on the laryngeal structures, thereby probably creating discomfort in patient compared with stylet type devices. Furthermore, it is difficult to pass the tracheal tube through glottis when the pharyngeal axis intersects with laryngeal axis at a big angle, whereas those problems with intubation can be easily overcome by intra-tubal visualization type.

The design of DE is similar to Bonfils and Trachway, but compare with Trachway [15, 16] and Bonfils [17, 18], DE has more advantages. First, the wire body of DE is made of flexible memory metal that can easily substantially bent, which enables operator to adjust it to optimum angles according to the patient's situation. Second, the DE has a clear video imaging which is very efficient and flexible to operate. So the DE may be more easy to use than the Bonfils and Trachway, especially for young anesthesiologists who have little experiences with these equipments.

Limitations

There were some limitations in our study. First it was impossible to blind operator to the technique. Consequently, we cannot eliminate the possibility of biases in operator in the comparisons of the two intubation techniques. Second, the overall sample size was small. Third, these

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results may not be applicable to novices who have little experiences in the management of difficult airway.

Conclusion

Disposcope endoscope provided shorter intubation time, better intubation conditions and lower incidence of throat pain compared with the Fiberoptic bronchoscope during awake orotracheal intubation in obese patient. Awake DE intubation seems as a potential alternative to awake FOB intubation.

Disclosure of conflict of interest

None.

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Appendix 1

Intubation conditions score

(i) vocal cord movement score

(4 = open, 3 = moving, 2 = closing, 1 = closed).

(ii) coughing score

(4 = none, 3 = slight, 2 = moderate, 1 = severe).

(iii) limb movement score

(4 = none, 3 = slight, 2 = moderate, 1 = severe).

Comfort score during intubation

(4 = no reaction, 3 = slight grimacing, 2 = heavy grimacing or verbal protest, 1 = defensive movement of head or hands).

Comfort score after intubation

(3 = cooperative immediately after orotracheal intubation, 2 = restless/minimal resistance, 1 = severe resistance/general anesthesia required immediately).