A RANDOMIZED CLINICAL TRIAL OF ENDOTRACHEAL INTUBATION FOLLOWING THIOPENTAL-SUCCINYLCHOLINE OR SEVOFLURANE-NITROUS OXIDE ANESTHESIA FOR GENERAL ANESTHESIA IN ELECTIVE SURGERIES IN ADULTS

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ABSTRACT: We performed a double-blinded, prospective, randomized controlled trial to compare intubating conditions facilitated by succinylcholine or sevoflurane. One hundred twenty patients were randomized to receive either succinylcholine or sevoflurane for tracheal intubation. For the Succinylcholine group, patients were induced with thiopental 5 mg · kg⁻¹ and tracheally intubated after administration of succinylcholine 1.5 mg · kg⁻¹ IV. Patients receiving sevoflurane took three vital capacity breaths of 8% sevoflurane and 66% N₂O in O₂. At the loss of eyelash reflex, ventilation was assisted to establish end-tidal CO₂ between 25–30 mm Hg, and intubation was performed. Criteria of jaw relaxation, vocal cords position and intubating response were used to assess intubation condition. If the intubation score was ≤6 of 12, it was described as acceptable; otherwise it was described as an unacceptable intubation condition. Tracheal intubation was successful in all patients. The study was intubator and observer blinded with reference to patient group and they judged that four patients (6.7%) in the Sevoflurane group and only one patient (1.7%) in the Succinylcholine group had an unacceptable intubation condition. However, there was no significant difference between groups (P > 0.05). Therefore, the three vital capacity breaths inhalation technique with sevoflurane may be an alternative for endotracheal intubation in adults.

Implications: The three vital capacity inhaled anesthetic techniques with 8% sevoflurane and 66% N₂O in O₂ may be an alternative for endotracheal intubation in adults who are at high risk from succinylcholine.

INTRODUCTION: Succinylcholine is commonly used to facilitate rapid tracheal intubation. However, it is associated with side effects¹ and may be contraindicated in some patients. Non depolarizing muscle relaxants with a rapid onset of action are an alternative to succinylcholine, but these drugs may also be associated with undesirable effects such as prolonged neuromuscular blockade, or an inability to rapidly reverse the paralysis if airway management via mask or tracheal intubation is not possible. For these reasons, a method of providing adequate intubating conditions without using muscle relaxants has been sought². In adults, an inhaled induction of anesthesia with a volatile anesthetic such as Sevoflurane is one possibility³⁻⁵. The induction of anesthesia with three vital capacity breaths of Sevoflurane in young, non premedicated adults approaches the speed of IV induction of anesthesia⁴⁻⁹. An anesthetic adjuvant significantly decreased the time to acceptable tracheal intubating conditions with anesthetic induction via face mask with sevoflurane^{5, 10-13}. A small dose of sedatives and fentanyl were therefore given to all patients. However, very few have compared tracheal intubation induced by sevoflurane versus succinylcholine in healthy adults.

The aim of this study was to compare intubation conditions, hemodynamic responses and adverse events in normal patients given either sevoflurane or a standard thiopental-succinylcholine induction of anesthesia sequence for tracheal intubation. Patients' satisfaction was also compared.

MATERIAL AND METHODS: After approval by the Institutional Ethics Committee, written informed consent was obtained from 120 ASA physical status I-II patients aged between 20 and 60 yr. who were scheduled to undergo elective non cardiothoracic surgery and required endotracheal intubation. Patients had no risk factors for an inhaled induction technique such as obesity (body mass index $>30 \text{ kg} \cdot \text{m}^{-2}$), pregnancy, small bowel obstruction, history of esophageal reflux or hiatal hernia. The study excluded patients with difficult airway problems and those with hyperkalemia, suspected malignant hyperthermia, cardiac, pulmonary or renal diseases. Using Mallampati classification, each patient's airway was evaluated. Also, thyromental distance and inter incisor gap were measured.

The study was conducted in a randomized double-blinded controlled trial. Second and third year anesthetic residents blindly participated as the intubators and the anesthesiologists blindly participated as the observers. Both intubator and observer were not in the operating room during the induction to avoid witnessing the fasciculations from succinylcholine and unaware of the induction sequence or technique. Patients were randomly allocated to receive either thiopental/succinylcholine or Sevoflurane. A three vital capacity technique (taking a forced exhalation to residual volume followed by three maximum breaths) and the procedures were explained to the patients during the preoperative visit. Patients fasted for at least 6 h before anesthetic induction. All patients were given diazepam 5 or 10 mg orally 1–2 h before induction.

Once venous access was established, all patients received lactated Ringer's solution at the amount of $5 \text{ mL} \cdot \text{kg}^{-1}$ within 10 min. Patients received fentanyl $1.5 \mu\text{g} \cdot \text{kg}^{-1}$ IV and breathed with 100% oxygen and fresh gas flow (FGF) 6 L/min via a face mask connected to a circle breathing circuit for 3 min before induction of anesthesia.

For the Succinylcholine group, patients were induced with thiopental $5 \text{ mg} \cdot \text{kg}^{-1}$ IV and asked to take three vital capacity breaths (4 L/min nitrous oxide [N_2O] and 2 L/min O_2), as previously instructed. At the loss of eyelash reflex, succinylcholine $1.5 \text{ mg} \cdot \text{kg}^{-1}$ was injected IV, and an oral airway was inserted. The FGF was decreased from 6 to 3 L/min (2 L/min N_2O and 1 L/min O_2), and ventilation was assisted. At 60 s after receiving succinylcholine, the intubator and the observer were called to enter the operating room. The intubator performed a direct laryngoscopy and visualized the vocal cords. Later, the observer visualized the vocal cords while the intubator applied the laryngoscope. Finally, the intubator inserted the tracheal tube. After that both intubator and observer observed the response to laryngoscopy and scored the intubation conditions independently.

For the Sevoflurane group, after a forced exhalation, patients took three vital capacity breaths via the face mask connected to the breathing circuit. At the loss of eyelash reflex, an oral airway was inserted, the FGF was decreased from 6 to 3 L/min, and ventilation was assisted. The intubator and the observer were called to enter the operating room. The intubator performed a direct laryngoscopy and visualized the vocal cords. Later, the observer visualized the vocal cords while the

ORIGINAL ARTICLE

intubator applied the laryngoscope. Finally, the intubator inserted the tracheal tube. Like the Succinylcholine group, the intubation condition was assessed independently.

Patients in both groups were intubated by direct laryngoscopy with a Macintosh 3 blade. Size 7.5 or 8.0 endotracheal tubes were used in female and male patients respectively. After successful intubation, ventilation was assisted to establish ETCO_2 levels between 35–40 mm Hg until the patients resumed their spontaneous ventilation or 5 min passed. At that point, the patients received routine muscle relaxants and anesthetics.

Demographic data and hemodynamic and intubation conditions were recorded. Degree of jaw relaxation, vocal cord position, and intubating responses were used for assessment of intubating conditions (Table 1). Jaw relaxation was described as fully relaxed (score = 1), mildly resistant (score = 2), tight but open (score = 3), and impossible (score = 4). Vocal cord position was described as widely open (score = 1), mid position (score = 2), moving but open (score = 3), and closed (score = 4). Intubating responses were described as none (score = 1), diaphragmatic movement (score = 2), mild/moderate coughing (score = 3), and severe coughing (score = 4). Intubating conditions were graded as excellent (total score [TS] = 3), good (TS = 4–6), poor (TS = 7–9), or impossible (TS = 10–12). The total score of 6 or less was classified as an acceptable intubation condition otherwise as unacceptable condition. Heart rate (HR) and blood pressure were recorded before induction (baseline), at the time of premedication, immediately before intubation, and at 1, 3, and 5 min after intubation. Additionally, time to loss of eyelash reflex, time to tracheal intubation, and time to return of spontaneous ventilation were also recorded. Time to loss of eyelash reflex was defined as the time between induction of anesthesia (placement of mask over the patient's face) and loss of eyelash reflex. Time to tracheal intubation was defined as the time between induction of anesthesia and successful intubation. Time to return of spontaneous ventilation was defined as the time between successful intubation and return of spontaneous ventilation. The occurrence of breath holding for longer than 15 s at any time during induction, inspiratory or expiratory stridor, laryngospasm, excessive salivation, cough, hiccough, or excitement were noted. During the postoperative visit, the investigator, who was blinded as to the technique, asked the patients to complete a questionnaire related to satisfaction with their anesthetic and any untoward symptoms. Continuous variables were analyzed using independent sample t-tests. Discrete variables were analyzed using χ^2 test and Fisher's exact test. Repeated-measures analysis of variance was used for analysis of hemodynamic changes in each group. Kappa statistics were used to measure the agreement between intubators and observers. Also, inter observer reliability was tested. P values < 0.05 were considered statistically significant.

Airway conditions and intubating responses	Score	Intubator		P value	Observer		P value
		Succinylcholine	Sevoflurane		Succinylcholine	Sevoflurane	
Jaw relaxation				0.514			0.921
Fully relaxed	1	47 (78.3)	43 (71.7)		41 (68.3)	43 (71.7)	
Mild resistance	2	12 (20.0)	14 (23.3)		18 (30.0)	16 (26.6)	
Tight, but opens	3	1 (1.7)	3 (5.0)		1 (1.7)	1 (1.7)	

ORIGINAL ARTICLE

Impossible	4	0	0		0	0	
Vocal cord position				0.000*			0.015†
Widely open	1	41 (68.3)	17 (28.4)		41 (68.3)	26 (43.4)	
Mid-position	2	18 (30.0)	39 (65.0)		19 (31.7)	29 (48.3)	
Moving, but open	3	1 (1.7)	2 (3.3)		0	3 (5.0)	
Closed	4	0	2 (3.3)		0	2 (3.3)	
Intubating responses				0.000*			0.000*
None	1	53 (88.4)	34 (56.6)		51 (85.0)	23 (38.3)	
Diaphragmatic movement	2	5 (8.3)	13 (21.7)		5 (8.3)	29 (48.3)	
Mild/moderate coughing	3	2 (3.3)	13 (21.7)		4 (6.7)	7 (11.7)	
Severe coughing	4	0	0		0	1 (1.7)	

Table 1: Intubation Conditions and Responses

Data expressed as number of patients (percentage).

* P < 0.001 and †P < 0.05 considered significant.

Patient characteristics	Group		P value
	Succinylcholine (n = 60)	Sevoflurane (n = 60)	
Gender (male/female)	6 /54	6 /54	1.000
ASA class (I/II)	49 /11	52 /8	0.617
Mallampati grade (1/2/3)	28 /23/9	25 /24/11	0.822
Age (yr.)	40.55 ± 9.14	39.70 ± 9.20	0.613
Weight (kg)	55.75 ± 10.84	55.13 ± 9.10	0.733
Height (cm)	156.33 ± 7.19	156.30 ± 6.46	0.979
TM distance (cm)	7.13 ± 1.04	7.01 ± 1.07	0.570
Inter-incisor gap (cm)	4.31 ± 0.53	4.24 ± 0.53	0.482

Table 2: Demographic Data

Values are mean ± SD except gender, ASA class, and Mallampati grade, which are expressed as number of patients. There were no differences between groups.

TM = Thyro-mental.

	Intubator			Observer		
	Succinylcholine	Sevoflurane	p-value	Succinylcholine	Sevoflurane	p-value
			0.001*			0.002+
Excellent (3)	33 (55.0)	10 (16.7)		27 (45.0)	10 (16.7)	
Good (4-6)	27 (45.0)	46 (76.6)		32 (53.3)	46 (76.6)	
Poor (7-9)	0	4 (6.7)		1 (1.7)	4 (6.7)	
Impossible (10-12)	0	0		0	0	
			0.119			0.364
Acceptable	60 (100%)	56 (93.3)		59 (98.3)	56 (93.3)	
Unacceptable	0	4 (6.7)		1 (1.7)	4 (6.7)	

Table 3: Intubation scores

Data expressed as Patients (percentage)

P – Value 0.001* and 0.002+ considered significant

RESULTS: A total of 120 patients were studied. Each group consisted of 60 patients. There were no significant differences between groups in terms of gender, age, ASA physical status, weight, height, thyromental distance, inter incisor gap, or Mallampati's modified classification (Table 2).

Tracheal intubation was successful in all patients. Jaw relaxation was similar in both groups (Table 1). There were significant differences between groups with respect to vocal cord position ($P < 0.05$) (Table 1). The position of the vocal cords was more often judged to be widely open in the Succinylcholine group (68.3%) compared with the Sevoflurane group (28.4%–43.4%). The vocal cords were likely to be mid position in the Sevoflurane group (48.3%–65%) compared with the Succinylcholine group (30%–31.7%). The vocal cords in two patients receiving sevoflurane were closed, but the trachea was successfully intubated at the first attempt. Concerning the intubating responses after successful intubation (Table 1), they were significantly less in the Succinylcholine group than in the Sevoflurane group ($P < 0.001$). Only 8.3% of patients who received succinylcholine had diaphragmatic movement, compared with 21.7%–48.3% of patients who received sevoflurane. Mild to moderate coughing was less frequent in the Succinylcholine group (3.3%–6.7%) compared with the sevoflurane group (11.7%–21.7%). One patient in the Sevoflurane group exhibited severe coughing.

Intubation scores differed significantly between the two groups ($P < 0.05$) (Table 3). Approximately half the patients in the Succinylcholine group (45%–55%) had excellent intubating conditions as compared with 16.7% in the Sevoflurane group. Most patients in the Sevoflurane group (76.6%) had good intubating conditions as compared with 45%–53.3% in the Succinylcholine group. Nearly all the Succinylcholine group (98.3%–100%) and most patients in the Sevoflurane group (93.3%) had acceptable intubation conditions (Table 3). According to an intubator and observer's opinion, four patients in the Sevoflurane group (6.7%) had unacceptable intubation conditions. One patient in the Succinylcholine group (1.7%) had an unacceptable intubation condition. However, there were no statistically significant differences between groups (for the intubator's opinion, $P = 0.119$ and the observer's opinion, $P = 0.364$). Using Kappa statistics to measure the agreement between intubators and observers, there was moderate strength of agreement between them ($K = 0.464$). Also, inter observer reliability was tested. As a result, interclass correlation coefficient (0.8562) and intraclass correlation coefficient (0.7486) indicated that the opinions of intubators and observers were reliable.

Details of the times to the various end points are shown in Figure 1. The report indicates that the majority of patients can be successfully intubated with sevoflurane provided one is willing to wait the extra 4 min to reach 6% end-tidal sevoflurane ($P = 0.000$). The mean time from induction of anesthesia to loss of eyelash reflex was significantly shorter in the Succinylcholine group than the Sevoflurane group ($P = 0.001$). The mean time from intubation to return of spontaneous ventilation was significantly faster in the Sevoflurane group than the Succinylcholine group ($P = 0.001$). One patient in the Sevoflurane group and 11 patients in the Succinylcholine group had no return of spontaneous ventilation within 5 min after intubation.

Figure 1

The baseline and premedication values of HR and arterial blood pressure were similar in the two groups (Fig. 2). Systolic blood pressure, diastolic blood pressure, and mean arterial blood pressure (MAP) in the succinylcholine group were significantly increased than the sevoflurane group during intubation and at 1 and 3 min after intubation ($P < 0.001$). HR in the Succinylcholine group was more rapid than the Sevoflurane group during intubation ($P < 0.05$).

Figure 2: Hemodynamic response. There were significant differences of heart rate (** $P < 0.05$) during intubation and blood pressure (* $P < 0.001$) during intubation, at 1, 3 min after intubation in the two groups. (MAP = mean arterial blood pressure; SBP = systolic blood pressure; DBP = diastolic blood pressure).

In the Succinylcholine group, MAP ($P < 0.001$) and HR ($P < 0.05$) were significantly increased at 1 min after intubation, whereas in the sevoflurane group, MAP ($P < 0.001$) and HR ($P < 0.05$) were significantly decreased during intubation but increased at 1 min ($P < 0.001$), as compared with baseline level (Fig. 2).

Figure 2

Symptoms	Group		P value
	Succinylcholine (n = 60)	Sevoflurane (n = 60)	
Sore throat	22	26	0.576
Cough	18	24	0.339
Hoarseness of voice	32	35	0.713
Difficulty in swallowing	4	5	0.729
Bleeding by mouth	0	0	
Myalgia	10	10	1.000
Awareness	0	0	

Table 4: Subjective Symptoms during Postoperative Period

Values are number of patients having symptoms. There were no significant differences between groups.

During induction, no patient demonstrated adverse events such as breath holding, laryngospasm, cough, hiccup, excessive salivation, or excitement. No patient had oxygen desaturation (defined as O_2 saturation < 95%) that necessitated any prompt correction during the study. Some patients had subjective symptoms during the postoperative period (Table 4) but there were no statistically significant differences between groups ($P > 0.05$).

Patient satisfaction with induction was good in both groups (95% in the Succinylcholine group and 96.7% in the Sevoflurane group) ($P = 0.843$). Two patients in the Succinylcholine group were not satisfied with the technique because of nausea and vomiting. One patient in the Sevoflurane group was not satisfied with the technique because of the odor of sevoflurane. However, most patients in the Succinylcholine group (91.7%) and in the Sevoflurane group (93.3%) indicated that they would be willing to use the same anesthetic technique again ($P = 0.729$). The odor of sevoflurane was described as pleasant, unpleasant, and no smell by 38.3%, 18.3%, and 43.3% of patients in the Sevoflurane group as compared with 28.3%, 3.3%, and 68.3% of patients in the Succinylcholine group, respectively ($P = 0.005$). Patients receiving succinylcholine (31.6%) also reported an odor during induction. This may be the result of a residual odor from previous use of the anesthetic system or patient bias that inclined them to guess that they had received an inhaled induction irrespective of the technique used^{14,15}.

DISCUSSION: The major findings of this study are that 6% of ET-sevoflurane in 66% nitrous oxide provided good (76.6%) or excellent (16.7%) conditions for tracheal intubation in healthy, premedicated patients with normal airway anatomy. Even though a wide opening of vocal cords and providing better intubating conditions are the advantages of succinylcholine compared with sevoflurane, sevoflurane may be useful whenever succinylcholine is absolutely contraindicated. For example, after major denervation injuries, spinal cord transection, peripheral denervation, stroke, and extensive burns patients should avoid succinylcholine because severe hyperkalemia after succinylcholine occasionally leads to cardiac arrest⁶. Moreover, sevoflurane administered by face mask at a concentration of 8% was not associated with any adverse airway events. A frequent incidence of coughing and diaphragmatic movement after intubation in the Sevoflurane group may be explained by the fact that we needed adequate time for both intubator and observer to visualize the vocal cords before intubation. During that time, the patients did not receive sevoflurane and the reduction of sevoflurane concentration may have put them into the situation of "light anesthesia".

The mean time to loss of eyelash reflex and tracheal intubation was longer in the patients receiving sevoflurane than in the patients receiving succinylcholine. These data suggest that succinylcholine should remain the drug of choice for rapid tracheal intubation. The mean time to return of spontaneous ventilation after tracheal intubation was less in the patients receiving sevoflurane than in the patients receiving succinylcholine, which may be an advantage in patients with an unexpected airway difficulty.

A potential limitation of the inhaled induction technique for tracheal intubation is hypotension associated with delivering a large concentration of sevoflurane⁴. There were significant decreases in MAP (73.2 ± 18.9 mm Hg) during intubation. However, in all cases, good peripheral perfusion was thought to exist based on observation of skin color and pulse oximeter⁴.

Moreover, MAP after intubation was quickly restored to a level near baseline. This technique cannot be recommended for hypovolemic or debilitated patients, the elderly, or those with clinically significant cardiovascular disease. In the view of hemodynamic responses to intubation, the HR and blood pressure changes were more in the Succinylcholine group.

We used the primary outcome of our study, the acceptable intubation condition, to calculate the power of the study ($1 - \beta$). We found that the power of this study = 0.9, which meant that our sample size was adequate.

In conclusion, endotracheal intubation during sevoflurane vital capacity rapid inhaled anesthetic technique has a high success rate and is comparable with succinylcholine but has less favorable intubation conditions. Therefore, inhalation with sevoflurane may be an alternative technique for endotracheal intubation in adult patients who are at high risk with succinylcholine.

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