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 controlledtrial to compare intubating conditions facilitated by succinylcholineor sevoflurane. One hundred twenty patients were randomizedto receive either succinylcholine or sevoflurane for trachealintubation. For the Succinylcholine group, patients were inducedwith thiopental 5 mg · kg^{-1} and tracheally intubatedafter administration of succinylcholine 1.5 mg · kg^{-1} IV. Patients receiving sevoflurane took three vital capacitybreaths of 8% sevoflurane and 66% N_2O in O_2. At the loss ofeyelash reflex, ventilation was assisted to establish end-tidalCO_2 between 25–30 mm Hg, and intubation was performed. Criteria ofjaw relaxation, vocal cords positionand intubating responsewere used to assess intubation condition. If the intubationscore was ≤6 of 12, it was described as acceptable; otherwiseit was described as an unacceptable intubation condition. Trachealintubation was successful in all patients. The study was intubator and observerblinded with reference to patient group and they judged that four patients (6.7%)in the Sevoflurane group and only one patient (1.7%) in theSuccinylcholine group had an unacceptable intubation condition.However, there was no significant difference between groups($P > 0.05$). Therefore, the three vital capacity breaths inhalationtechnique with sevoflurane may be an alternative for endotrachealintubation in adults.
Implications: The three vital capacity inhaled anesthetic techniqueswith 8% sevoflurane and 66% N_2O in O_2 may be an alternative for endotracheal intubationin adults who are at high risk from succinylcholine.

INTRODUCTION: Succinylcholine is commonly used to facilitate rapid trachealintubation. However, it is associated with side effects[1]and may be contraindicated in some patients. Non depolarizingmuscle relaxants with a rapid onset of action are an alternativeto succinylcholine, but these drugs may also be associated withundesirable effects such as prolonged neuromuscular blockade, or an inability to rapidly reverse the paralysis if airway managementvia mask or tracheal intubation is not possible. For these reasons, a method of providing adequate intubating conditions withoutusing muscle relaxants has been sought[2]. In adults, an inhaledinduction of anesthesia with a volatile anesthetic such as Sevofluraneis one possibility[3-5]. The induction of anesthesiawith three vital capacity breaths of Sevoflurane in young, non premedicatedadults approaches the speed of IV induction of anesthesia [4–9].An anesthetic adjuvant significantly decreased the time to acceptabletracheal intubating conditions with anesthetic induction viaface mask with sevoflurane [5, 10–13]. A small dose ofsedatives and fentanyl were therefore given to all patients.However, very few have compared tracheal intubation induced bysevoflurane versus succinylcholine in healthy adults.

The aim of this study was to compare intubation conditions, hemodynamic responsesand adverse events in normal patientsgiven either sevoflurane or a standard thiopental-succinylcholineinduction of anesthesia sequence for tracheal intubation. Patientsatisfaction was also compared.

MATERIAL AND METHODS: After approval by the Institutional Ethics Committee, writteninformed consent was obtained from 120 ASA physical status I-IIpatients aged between 20 and 60 yr. who were scheduled to undergoelective non cardiothoracic surgery and required endotrachealintubation. Patients had no risk factors for an inhaled inductiontechnique such as obesity (body mass index >30 kg $\cdot m^{-2}$), pregnancy, small bowel obstruction, history of esophagealrefluxor hiatal hernia. The study excluded patients with difficultairway problems and those with hyperkalemia, suspected malignanthyperthermia, cardiac, pulmonaryor renal diseases. UsingMallampati 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 controlledtrial. Second and third year anesthetic residents blindly participatedas the intubators and the anesthetists blindly participatedas the observers. Both intubator and observer were not in the operating room during theinduction to avoid witnessing the fasciculations from succinylcholineand unaware of the induction sequence or technique. Patients were randomlyallocated to receive either thiopental/succinylcholine or Sevoflurane.A three vital capacity technique (taking a forced exhalationto residual volume followed by three maximum breaths) and theprocedures were explained to the patients during the preoperativevisit. Patients fasted for at least 6 h before anesthetic induction.All patients were given diazepam 5 or 10 mg orally 1–2h before induction.

Once venous access was established, all patients received lactatedRinger's solution at the amount of 5 mL $\cdot$ kg^{-1} within 10 min. Patients received fentanyl1.5 μg $\cdot$ kg^{-1} IV and breathed with 100% oxygenand fresh gas flow (FGF) 6 L/min via a face mask connected toa circle breathing circuit for 3 min before induction of anesthesia.

For the Succinylcholine group, patients were induced with thiopental5 mg $\cdot$ kg^{-1} IV and asked to take three vital capacitybreaths (4 L/min nitrous oxide [N_2O] and 2 L/min O_2), as previouslyinstructed. At the loss of eyelash reflex, succinylcholine 1.5mg $\cdot$ 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/minO_2), and ventilation was assisted. At 60 s after receiving succinylcholine, the intubator and the observer were called to enter the operatingroom. The intubator performed a direct laryngoscopy and visualizedthe vocal cords. Later, the observer visualized the vocal cordswhile the intubator applied the laryngoscope. Finally, the intubatorinserted the tracheal tube. After that both intubator and observerobserved the response to laryngoscopy and scored the intubationconditions independently.

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

intubatorapplied the laryngoscope. Finally, the intubator inserted thetracheal tube. Like the Succinylcholine group, the intubationcondition was assessed independently.

Patients in both groups were intubated by direct laryngoscopywith a Macintosh 3 blade. Size 7.5 or 8.0 endotracheal tubeswere used in female and male patients respectively. After successfulintubation, ventilation was assisted to establish $ETCO_2$ levelsbetween 35–40 mm Hg until the patients resumed their spontaneousventilation or 5 min passed. At that point, the patients receivedroutine muscle relaxants and anesthetics.

Demographic data and hemodynamic and intubation conditions wererecorded. Degree of jaw relaxation, vocal cord position, andintubating responses were used for assessment of intubatingconditions (Table 1). Jaw relaxation was described as fullyrelaxed (score = 1), mildly resistant (score = 2), tight butopen (score = 3), and impossible (score = 4). Vocal cord positionwas described as widely open (score = 1), mid position (score= 2), moving but open (score = 3), and closed (score = 4). Intubatingresponses were described as none (score = 1), diaphragmaticmovement (score = 2), mild/moderate coughing (score = 3), andsevere coughing (score = 4). Intubating conditions were gradedas excellent (total score [TS] = 3), good (TS = 4–6), poor (TS = 7–9), or impossible (TS = 10–12). Thetotal score of 6 or less was classified as an acceptable intubationcondition 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, timeto loss of eyelash reflex, time to tracheal intubation, andtime to return of spontaneous ventilation were also recorded.Time to loss of eyelash reflex was defined as the time betweeninduction of anesthesia (placement of mask over the patient'sface) and loss of eyelash reflex. Time to tracheal intubationwas defined as the time between induction of anesthesia andsuccessful intubation. Time to return of spontaneous ventilationwas defined as the time between successful intubation and returnof spontaneous ventilation. The occurrence of breath holdingfor longer than 15 s at any time during induction, inspiratoryor expiratory stridor, laryngospasm, excessive salivation, cough, hiccough, or excitement were noted. During the postoperativevisit, the investigator, who was blinded as to the technique, asked the patients to complete a questionnaire related to satisfactionwith their anesthetic and any untoward symptoms.Continuous variables were analyzed using independent samplet-tests. Discrete variables were analyzed using χ^2 test and Fisher'sexact test. Repeated-measures analysis of variance was usedfor analysis of hemodynamic changes in each group. Kappa statisticswere used to measure the agreement between intubators and observers.Also, inter observer reliability was tested. P values < 0.05were considered statistically significant.

Airway conditions and intubating responses	Score	Intubator		P value	Observer		P value
		Succinyl-choline	Sevoflurane		Succinyl-choline	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)	

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 of60 patients. There were no significant differences between groupsin terms of gender, age, ASA physical status, weight, height, thyromental distance, inter incisor gap, or Mallampati'smodified classification (Table 2).

Tracheal intubation was successful in all patients. Jaw relaxationwas similar in both groups (Table 1). There were significantdifferences between groups with respect to vocal cord position($P < 0.05$) (Table 1). The position of the vocal cords wasmore 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 Sevofluranegroup (48.3%–65%) compared with the Succinylcholine group(30%–31.7%). The vocal cords in two patients receivingsevoflurane were closed, but the trachea was successfully intubatedat the first attempt. Concerning the intubating responses aftersuccessful intubation (Table 1), they were significantly lessin the Succinylcholine group than in the Sevoflurane group ($P< 0.001$). Only 8.3% of patients who received succinylcholinehad diaphragmatic movement, compared with 21.7%–48.3%of patients who received sevoflurane. Mild to moderate coughingwas less frequent in the Succinylcholine group (3.3%–6.7%)compared with the sevoflurane group (11.7%–21.7%). Onepatient in the Sevoflurane group exhibited severe coughing.

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

Details of the times to the various end points are shown inFigure 1. The report indicates that the majority of patientscan be successfully intubated with sevoflurane provided oneis willing to wait the extra 4 min to reach 6% end-tidal sevoflurane($P = 0.000$). The mean time from induction of anesthesia to lossof eyelash reflex was significantly shorter in the Succinylcholinegroup than the Sevoflurane group ($P = 0.001$). The mean timefrom intubation to return of spontaneous ventilation was significantlyfaster in the Sevoflurane group than the Succinylcholine group($P = 0.001$). One patient in the Sevoflurane group and 11 patientsin the Succinylcholine group had no return of spontaneous ventilationwithin 5 min after intubation.

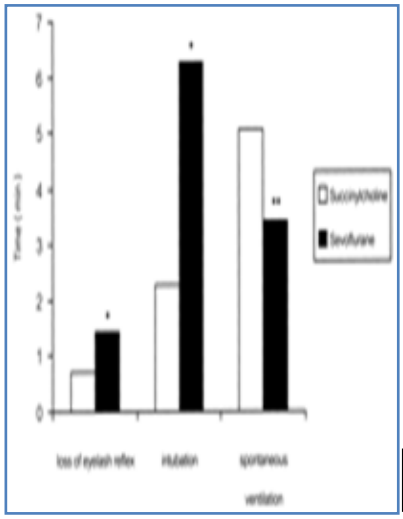

Figure 1: Mean time to various end-points. Significantly more time was taken from induction to loss of eyelash reflex and intubation in the Sevoflurane group than the Succinylcholine group (*P ≤0.001). Significantly less time from intubation to spontaneous ventilation in the Sevoflurane group than the Succinylcholine group (**P = 0.001). Loss of eyelash reflex denotes time between induction of anesthesia and loss of eyelash reflex. Intubation denotes time between induction of anesthesia and successful intubation. Spontaneous ventilation denotes time between successful intubation and return of spontaneous ventilation.

Figure 1

The baseline and premedication values of HR and arterial bloodpressure were similar in the two groups (Fig. 2). Systolicblood pressure, diastolic blood pressure, and mean arterialblood pressure (MAP) in the succinylcholine group were significantlyincreased than the sevoflurane group during intubationandat 1 and 3 min after intubation (P < 0.001). HR in the Succinylcholinegroup was more rapid than the Sevoflurane group during intubation(P < 0.05).

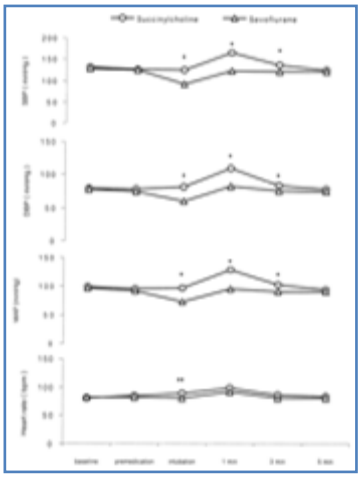

Figure 2: Hemodynamic response. There were significant differences of heart rate (**P < 0.05) during intubation and blood pressure (*P < 0.001) during intubation, at 1, 3 min after intubation in the two groups. (MAP = mean arterial blood pressure; SBP = systolic blood pressure; DBP = diastolic blood 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 intubationbut increased at 1 min (P < 0.001), as compared with baselinelevel (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 suchas breath holding, laryngospasm, cough, hiccough, excessivesalivation, or excitement. No patient had oxygen desaturation(defined as O_2 saturation < 95%) that necessitated any promptcorrection during the study. Some patients had subjective symptomsduring the postoperative period (Table 4) but there were nostatistically 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 Sevofluranegroup) (P = 0.843). Two patients in the Succinylcholine groupwere not satisfied with the technique because of nausea andvomiting. One patient in the Sevoflurane group was not satisfiedwith the technique because of the odor of sevoflurane. However, most patients in the Succinylcholine group (91.7%) and in theSevoflurane group (93.3%) indicated that they would be willingto use the same anesthetic technique again (P = 0.729). Theodor of sevoflurane was described as pleasant, unpleasant, andno smell by 38.3%, 18.3%, and 43.3% of patients in the Sevofluranegroup as compared with 28.3%, 3.3%, and 68.3% of patients inthe Succinylcholine group, respectively (P = 0.005). Patientsreceiving succinylcholine (31.6%) also reported an odor duringinduction. This may be the result of a residual odor from previoususe of the anesthetic system or patient bias that inclined themto guess that they had received an inhaled induction irrespectiveof the technique used [14, 15].

DISCUSSION: The major findings of this study are that 6% of ET-sevofluranein 66% nitrous oxide provided good (76.6%) or excellent (16.7%)conditions for tracheal intubation in healthy, premedicatedpatients with normal airway anatomy. Even though a wide openingof vocal cords and providing better intubating conditions arethe advantages of succinylcholine compared with sevoflurane, sevoflurane may be useful whenever succinylcholine is absolutelycontraindicated. For example, after major denervation injuries, spinal cord transection, peripheral denervation, stroke, andextensive burns patients should avoid succinylcholine becausesevere hyperkalemia after succinylcholine occasionally leadsto cardiac arrest[6]. Moreover, sevoflurane administered byface mask at a concentration of 8% was not associated with anyadverse airway events. A frequent incidence of coughing anddiaphragmatic movement after intubation in the Sevoflurane groupmay be explained by the fact that we needed adequate time forboth intubator and observer to visualize the vocal cords beforeintubation. During that time, the patients did not receive sevofluraneand the reduction of sevoflurane concentration may have putthem into the situation of "light anesthesia"

The mean time to loss of eyelash reflex and tracheal intubationwas longer in the patients receiving sevoflurane than in thepatients receiving succinylcholine. These data suggest thatsuccinylcholine should remain the drug of choice for rapid trachealintubation. The mean time to return of spontaneous ventilationafter tracheal intubation was less in the patients receivingsevoflurane than in the patients receiving succinylcholine, which may be an advantage in patients with an unexpected airwaydifficulty.

A potential limitation of the inhaled induction technique fortracheal intubation is hypotension associated with deliveringa large concentration of sevoflurane[4]. There were significantdecreases in MAP (73.2 ± 18.9 mm Hg) during intubation.However, in all cases, good peripheral perfusion was thoughtto exist based on observation of skin color and pulse oximeter[4].

Moreover, MAP after intubation was quickly restored toa level near baseline. This technique cannot be recommendedfor hypovolemic or debilitated patients, the elderly, or thosewith clinically significant cardiovascular disease. In the viewof hemodynamic responses to intubation, the HR and blood pressurechanges were more in the Succinylcholine group.

We used the primary outcome of our study, the acceptable intubationcondition, to calculate the power of the study (1 - ß).We found that the power of this study = 0.9, which meant thatour sample size was adequate.

In conclusion, endotracheal intubation during sevoflurane vitalcapacity rapid inhaled anesthetic technique has a high successrate and is comparable with succinylcholine but has less favorableintubation conditions. Therefore, inhalation with sevofluranemay be an alternative technique for endotracheal intubationin adult patients who are at high risk with succinylcholine.

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