

Comparison of Tritube™ tube and Evone® ventilator use with traditional narrow-lumen tube use in microlaryngeal surgery cases

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Cite this article as: Sayın Kart J, Dalkılıç Hökenek U. Comparison of Tritube™ tube and Evone® ventilator use with traditional narrow-lumen tube use in microlaryngeal surgery cases. J Health Sci Med 2023; 6(1): 190-194.

ABSTRACT

Aim: To evaluate the feasibility and safety of the Tritube™ tube and Evone® ventilator and compare patients intubated using Tritube™ and ventilated with flow-controlled ventilation (FCV) using Evone® (TT-FCV group) to those intubated using a traditional microlaryngeal intubation tube and ventilated with volume-controlled ventilation (MLT-VCV group) in terms of perioperative parameters and outcomes during microlaryngeal surgery (MLS).

Material and Method: A prospective observational design was conducted. This study was carried out in 6 (six) months between February 2022 and September 2022. After receiving their informed consent, 18 patients were randomly assigned to two groups. Patients older than 18 years, who were scheduled for elective MLS were included in the study. The closed opaque envelope method was used for randomization. The same standard anesthesia protocol was applied to all patients. The patients' demographic parameters, American Society of Anesthesiology physical status (ASA), Mallampati and Cormack-Lehane scores, duration of ventilation, duration of surgery, hemodynamic parameters, ventilation parameters, and complications were recorded.

Results: Twenty-one patients recruited for the study. Three of them regretted to participate to study. At the end 18 patients were analyzed. The mean age of population was 53(43-62). When the intraoperative respiratory and hemodynamic parameters of the patients were compared between the two groups, the regional cerebral oxygen saturation (rScO₂) (p=0.020), tidal volume (p=0.005), compliance of the respiratory system (p=0.001), and post-extubation rScO₂ (p=0.001) values were statistically significantly higher in the TT-FVC group compared to the MLT-VCV group. Right rScO₂ (p=0.038), left rScO₂ (p=0.047), and time to extubation (p=0.021) were statistically significantly lower in the TT-FVC group compared to the MLT-VCV group.

Conclusion: According to the findings we obtained, utilizing Tritube™ and Evone® during MLS surgeries appears to be effective in terms of achieving safe airway management.

Keywords: Microlaryngeal surgery, ventilation, hemodynamics

Our research's data was presented in 6th European Airway Management Congress as 'Oral Presentation' on September 2022.

INTRODUCTION

Head and neck surgery is usually challenging due to its anatomical nature for both anesthesiologist and surgeon (1,2). Therefore, perioperative management of it is difficult and open to complications. The restricted tracheal lumen produced by any mass, the wide area covered by difficult airway devices, the need to utilize a small-diameter tube to expose the surgical field, and the resulting continual increase in pressure are potential hurdles during these procedures. (3). Tritube™ is an ultra-thin tracheal tube with an outer diameter of 4.4 mm and an inner diameter of 2.4 mm, designed for adult patient ventilation (4). It consists of three lumens: a ventilation lumen, a cuff

lumen, and an intratracheal pressure measurement lumen (5). The ventilation lumen has a cross-sectional area equal to that of a tube with an internal diameter of 2.4 mm and is designed to be connected to devices using EVA technology (such as Ventrain) through a Luer connector. The ventilation lumen has an eye of Murphy. The lumen for measuring intratracheal pressure can be attached to a manometer for continuous monitoring of intratracheal pressure. With Ventrain, inflation of the cuff will both protect the airway and optimize ventilation. The ventilation lumen of the tube contains a pliable stylet with centimeter markings.

Evone® (Ventinova Medical, Eindhoven, the Netherlands) is a ventilator designed for use with the Tritube™ intubation tube and offers two different ventilation modes: jet ventilation and flow-controlled ventilation (FCV) (6-8). When in the FCV mode, Evone® creates negative suction pressure during the expiratory phase to actively remove air from the lungs. In volume-controlled ventilation (VCV), there is passive air outflow during the expiratory phase, and an exponential decrease occurs in the airway pressure (Paw) graph, which appears as a curved curve. In contrast, in the FCV mode, since there is an active expiratory phase, Paw decreases linearly, which indicates that the outflow of gas from the alveoli is constant throughout the expiratory phase (6). This new ventilation strategy has been used in many experimental animal studies, and it has been shown to improve lung recruitment and oxygenation (5, 9, 10). Difficult airway management has been successfully performed in patients intubated with Tritube™ tube and ventilated with Evone® (Ventinova Medical, Eindhoven, the Netherlands) ventilator, and the benefits of these devices during laryngeal surgery have been reported (11-14). In this study, our primary aim was to compare microlaryngeal surgery patients intubated using a traditional narrow-lumen intubation tube and ventilated with VCV using a standard ventilator to those intubated using the Tritube™ tube and ventilated with FCV using the Evone® ventilator in terms of hemodynamics, perioperative respiratory parameters and complications. The secondary objectives of our study are the duration of anesthesia and surgery in minutes and the length of hospitalization in days.

MATERIAL AND METHOD

The study was carried out with the permission of University of Health Sciences, Kartal Dr. Lütfi Kırdar City Hospital Ethics Committee (Date: 28.01.2022, Decision No: 2022/514/218/26). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

This study had a prospective observational design. It was carried out in 6 (six) months between February 2022 and September 2022. Written informed consent from the participants, we randomly assigned the patients into two groups. The closed opaque envelope method was used for randomization. The first group was intubated using the Tritube™ tube and ventilated with FCV using the Evone® ventilator (TT-FVC group), and the second group was intubated using a traditional microlaryngeal tube and ventilated with VCV (Primus IE; Dräger Medical, Germany) (MLT-VCV group). Patients aged older than 18 years, who were scheduled for elective microlaryngeal surgery were included in

the study. The patients' demographical parameters, American Society of Anesthesiology physical status, Mallampati and Cormack-Lehane scores, duration of surgery, hemodynamic parameters (cardiac apex beat, mean arterial pressure, oxygen saturation, end tidal carbon dioxide pressure), ventilation parameters (end expiratory pressure, positive inspiratory pressure, compliance of the respiratory system) and complications were recorded. To standardize intubation conditions, 0.6 mg/kg rocuronium was administered. Total intravenous anesthesia was induced and maintained with 10 mg/kg/hour propofol and 0.5-1 mcg/kg/min remifentanyl. At the end of surgery, the cuff was deflated, high-frequency jet ventilation (HFJV) was applied, and the value of tidal volume after extubation was recorded.

Statistical Analysis

Statistical analyses were performed using SPSS version 26.0. Categorical groups were examined using the Pearson test and Fisher's exact test. The effect size was taken to be the same as the medium (medium=0.50), with a confidence interval (CI) level of 80% and alpha value of 5%, and the values showed the Laplace distribution. The total sample size was found to be 18 using the Mann-Whitney U test as a reference model (G Power 3.1.9.2, Windows 10). The averages of the values used in the perioperative patient follow-up were taken.

RESULTS

Twenty-one patients recruited for the study. Three of them regretted to participate to study. At the end 18 patients were analyzed. No unexpected intensive care stays or complications were observed in the patients. No significant difference was observed between the two groups in terms of demographic and clinical data (**Table 1**). The mean age for all study participants were 53 (43-62). Gender distribution of population was 16 (88.8%) male, 2 (11.2%) female. There was no statistical significance difference between the groups on age, gender, smoking status and Body Mass Index (BMI) (**Table 1**). ($p > 0.05$)

In the TT-FVC group, the regional cerebral oxygen saturation (rScO₂) ($p=0.020$), tidal volume ($p=0.005$), compliance of the respiratory system ($p=0.001$), and post-extubation rScO₂ ($p=0.001$) values were statistically significantly higher, and right rScO₂ ($p=0.038$), left rScO₂ ($p=0.047$), and time to extubation ($p=0.021$) were statistically significantly lower compared to the MLT-VCV group. Intraoperative respiratory and hemodynamic variables were summarized in **Table 2**.

Variables	All patients n=18	TT-FCV n=9	MLT-VCV n=9	p value
Age (year)	53 (43-62)	45 (41-59)	56 (51-63)	0.122
Gender (male)	16 (88.8)	8 (44.4)	8 (44.4)	1.000
Smoking status (smoker)	13 (72.2)	7 (38.9)	6 (33.3)	1.000
BMI (kg/cm ²)	22.7 (22.4-25)	25 (21.1-27.9)	22.7 (22.4-23)	0.170
Comorbidity (present)	8 (44.4)	4 (22.2)	4 (22.2)	1.000
ASA score				
1	3 (16.7)	2 (11.1)	1 (5.6)	0.812
2	13 (72.2)	6 (33.3)	7 (38.9)	
3	2 (11.1)	1 (5.6)	1 (5.6)	
Cormack score				
1	9 (50)	3 (16.7)	6 (33.3)	0.347
2	9 (50)	6 (33.3)	3 (16.7)	
Mallampati score				
1	7 (38.9)	3 (16.7)	4 (22.2)	1.000
2	11 (61.1)	6 (33.3)	5 (27.8)	
Duration of surgery (minute)	35 (30-46)	33 (25-45)	40 (32-47)	0.425
Duration of anesthesia (minute)	45 (40-60)	41 (32-53)	50 (40-61)	0.268
Length of hospital stay (day)	1 (1)	1 (1)	1 (1-1.5)	0.539

Values given as frequency (percentage) and median (interquartile range). TT-FCV: Tritube™ tube intubation and flow-controlled ventilation with Evone®, MLT-VCV: traditional microlaryngeal tube intubation and volume-controlled ventilation, ASA: American Society of Anesthesiology, BMI: body mass index

Variables	All patients n=18	TT-FCV n=9	MLT-VCV n=9	p
Post-intubation rScO ₂ (%)	99 (99-100)	99 (99-100)	99 (98-100)	0.416
CAB (1/minute)	71 (63-86)	63 (57-81)	83 (70-86)	0.063
OAB (mmHg)	91 (89-100)	94 (88-103)	90 (89-95)	0.330
rScO ₂ (%)	99 (99-100)	100 (99-100)	99 (99-100)	0.020
EtCO ₂ (kPa)	37 (36-38)	36 (36-40)	37 (37-38)	0.893
Tidal volume (ml)	499 (467-547)	546 (520-623)	484 (456-494)	0.005
EPP (cmH ₂ O)	5 (5)	5 (5)	5 (5)	0.317
Respiratory rate (1/minute)	12 (11-13)	11 (9-13)	12 (12-14)	0.170
PIP (cmH ₂ O)	18 (16-20)	16 (14-20)	19.4 (18-20)	0.085
CRS (ml/cmH ₂ O)	39 (33-56)	55 (47-63)	33 (32-37)	0.001
Right rScO ₂ (%)	75 (72-77)	72 (70-76)	76 (74-77)	0.038
Left rScO ₂ (%)	75 (72-76)	74 (71-75)	76 (73-77)	0.047
Time to extubation (minute)	6.5 (5.75-7.25)	6 (4-7)	7 (6-8.5)	0.021
Post-extubation rScO ₂ (%)	99 (98-100)	100 (99-100)	98 (97-98)	0.001

Values given as median (interquartile range). TT-FCV: Tritube™ tube intubation and flow-controlled ventilation with Evone®, MLT-VCV: traditional microlaryngeal tube intubation and volume-controlled ventilation, CAB: cardiac apex beat, MAP: mean arterial pressure, rScO₂: regional cerebral oxygen saturation, ETCO₂: end tidal carbon dioxide pressure, EPP: end expiratory pressure, PIP: positive inspiratory pressure, CRS: compliance of the respiratory system

DISCUSSION

Microlaryngeal surgical operations involve a number of challenges for both anesthesiologists and surgeons. The aim should be to ensure adequate ventilation throughout the operation and provide optimal surgical conditions while maintaining a safe and secure airway (15, 16).

The Tritube™ intubation tube was designed to be used with the Evone® ventilator, and it has been reported that it may be a good alternative to traditional small-diameter tubes since it provides adequate gas exchange, and its outer diameter of 4.4 mm allows for a sufficient working space for the surgeon (17, 18). In this study, we compared the respiratory and hemodynamic parameters of the patients intubated using Tritube™

and ventilated using Evone® (TT-FCV group) to those intubated using a traditional small-diameter intubation tube and ventilated using VCV (MLT-VCV group). We obtained a lower airway peak pressure and more stable hemodynamic data from the TT-FCV group and did not observe any complication in the perioperative period. Similarly, Meulemans et al. (19), reported that the FCV mode provided adequate oxygenation, with the end-tidal CO₂ values being within the normal range and no complications being observed related to the ventilation mode. In another study using Tritube™, Schmidt et al. (11) found that this tube could be clogged with secretions and stated that tube dislocation could occur due to coughing and retching. We encountered no such complication in any of our patients.

Mora et al. (20), referred to the risk of blood aspiration following the switch to HFJV due this ventilation mode requiring the lowering of the cuff of the intubation tube. In the current study, after the surgical bleeding control of the patients, intravenous sugammadex was administered to eliminate neuromuscular blockade, and we observed that the patients were hemodynamically stable and softly spontaneously breathing, and we extubated them by lowering the cuffs of the Tritube™ intubation tube and switching them to the HFJV mode. We did not encounter any complications related to blood aspiration in any of our patients.

As stated in many studies, in upper airway operations, especially in microlaryngeal surgery, the use of an ultra-thin Tritube™ tube offers a great advantage by creating sufficient working space for the surgeon (3, 5, 19).

Throughout our study, we observed that this tube provided sufficient working space in the surgical field, and there was no airway pressure or ventilation problem during the operation, resulting in high surgical team satisfaction and even shortening the operation time relatively. The Evone® ventilator takes time to set up and calibrate, and its use requires experience, which are factors limiting its use in emergency operations (11, 19).

Although we had some reservations concerning the use of a ventilator and ventilation mode that we were not accustomed to when we first started the study, we did not encounter any ventilation problems in the patients. For the Tritube™ intubation tube, the higher cost compared to standard intubation tubes can be considered as a drawback (3, 21).

Tritubes' advantages in terms of airway management and surgical settings are combined with its ventilation advantages. FCV mode can result in more homogeneous lung aeration, higher ventilation efficiency, and enhanced gas exchange compared to VCV and PCV modes (22-25). Recently a crossover research comparing FCV and VCV found that FCV provides superior ventilation efficiency (26). In addition, compared to HFJV, FCV minimizes the risk of air entrapment, hyperinflation and barotrauma (27,28). Similarly, we did not observe any complications in any of the trial participants. In accordance with the literature, this supports the safety of Tritube and FCV.

This study does have some limitations. First, our research was limited to a specific patient group. Second, our study was conducted on a small number of patients in a single-center, highly specialized surgical procedure. Future multicenter, multiple-method surgical trials will aid in determining the efficacy of Tritube™ intubation tube and Evone® ventilator use.

CONCLUSION

Although the literature on the Tritube™ intubation tube and Evone® ventilator is still limited, safe airway management in microlaryngeal surgery seems to be advantageous in terms of ventilation and extubation, and we consider that the data obtained from the current study will be supported by future studies.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of University of Health Sciences, Kartal Dr. Lütfi Kırdar City Hospital Ethics Committee (Date: 28.01.2022, Decision No: 2022/514/218/26).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The author has no conflicts of interest to declare.

Financial Disclosure: The author declares that this study has received no financial support.

Author Contributions: The author declares that he has participated in the design, execution, and analysis of the paper, and he has approved the final version.

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