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The EasyTube during general anesthesia for minor surgery

A randomized, controlled trial

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Abstract

Background: The EasyTube (EzT) is a supraglottic airway device that is used for emergency airway situations. Ventilation during general anesthesia should also be feasible, but literature on the EzT is scarce. We evaluated the EzT in comparison with the endotracheal tube (ETT) in its use during general anesthesia in a comparative study.

Methods: A total of 400 patients with American Society of Anesthesiologists (ASA) physical status I to II scheduled for minor surgery in 4 centers were randomized for ventilation via the ETT or EzT.

Results: In all patients, the EzT and the ETT could be inserted within 3 attempts. In all EzT patients, the inspiratory and expiratory minute volumes (6.64 ± 0.71 and 6.34 ± 0.69 L/min) were sufficient to reach target oxygenation values, similar to ETT patients ($P = .59$). Mean peak pressure, mean plateau pressure, and mean dynamic compliance did not differ between the groups. Sore throat and blood on the cuff after removal were the most frequent complications in both groups.

Conclusion: Ventilation for up to 1 hour during general anesthesia in patients with ASA physical status I to II with the EzT is feasible and safe.

Abbreviations: ASA = American Society of Anesthesiologists, $EtCO_2$ = end-tidal CO_2, ETT = endotracheal tube, EzT = EasyTube, OLP = oropharyngeal leak pressure, SAD = supraglottic airway device, SpO_2 = oxygen saturation.

Keywords: airway management, EasyTube, endotracheal tube, general anesthesia

1. Introduction

The EasyTube (EzT, Well Lead Medical Co., Guangzhou, Panyu, China) is a supraglottic airway device (SAD) that enables effective ventilation irrespective of its placement in the trachea or esophagus[1,2] and is basically a further developed and enhanced version of the Combitube (Medtronic, Vienna, Austria).[3,4] Its 2-lumen design allows ventilation via the proximal lumen and simultaneous placement of a gastric tube via the distal lumen. The EzT has been designed for the "cannot intubate, cannot ventilate" scenario in prehospital as well as intrahospital settings and is utilized in medical emergency services and emergency departments all over the world,[5,6] not only for anticipated and unanticipated difficult airway situations but also as an airway device used by nonanesthesiologists or situations where only limited practice is possible.[7–9] In the majority of cases, the EzT will be exchanged for an endotracheal tube (ETT) once the difficult airway situation has been resolved or the patient has reached the hospital. This is possibly because the ETT is the gold standard for securing an airway and because anesthesiologists are by the nature of their profession most experienced with the ETT.[10,11] However, a study suggests that general anesthesia with the EzT is indeed feasible and by no means worse than anesthesia with a conventional ETT,[12] indicating that general anesthesia can be continued with this SAD in situ.[13,14] This would present several advantages: the larger balloons of the EzT are less traumatic to the mucosal tissue compared to a conventional ETT or to a laryngeal mask,[15] as the insertion of the EzT can be performed without using a laryngoscope; this also reduces tissue damage and tooth injuries caused by a laryngoscope;[16] it has been demonstrated that a similar SAD—the predecessor of the EzT, the Combitube—can be placed by anesthesiologists with relatively little formal training,[17] and that ventilation during elective surgery is feasible in principle.[18] The EzT itself has been further enhanced to facilitate insertion, minimize trauma, and maximize usability. But most importantly, avoiding a tube-exchange procedure in an emergency situation may help avoid upper airway bleeding, laryngeal edema, mechanical trauma, stress, and hypoxygenation[19,20] and might therefore impact outcome. However, such detailed data are missing for the EzT, with only smaller, single-center studies

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available. Furthermore, literature on the EzT is scarce; there are only few papers discussing important topics like ventilatory and hemodynamic parameters, as well as oxygenation during ventilation with the EzT, all of them being pivotal for the clinician.[2]

The aim of the study was to systematically investigate the EzT beyond its purpose as a rescue device in a prospective, multicenter cohort study to evaluate the EzT in comparison with the ETT for minor surgery with regard to ventilatory and hemodynamic parameters, oxygenation, and rate of complications. We chose to evaluate the EzT in comparison with the ETT as gold standard of airway management.

2. Methods

The study was approved by the Ethical Committees of the 4 centers and abided by the Ethical Principles for Medical Research Involving Human Subjects outlined in the Declaration of Helsinki. A total of 400 patients in 4 distinct centers (Department of Anaesthesiology, Bnai Zion Medical Centre, Haifa, Israel; Department of Anaesthesia, Intensive Care Medicine, Emergency Medicine and Pain Therapy, University of Mainz, Germany; Department of Anaesthesia and Intensive Care, Mutual de Seguridad Hospital C. CH.C., Santiago, Chile; and Department of Anaesthesiology and General Intensive Care, Medical University of Vienna, Vienna, Austria; Supplemetary table S1, http://links.lww.com/MD/B754) were included in the study. All patients had an American Society of Anesthesiologists (ASA) physical status 1 or 2 and were scheduled to undergo extraperitoneal, non-laparoscopic, elective surgery requiring general anesthesia. Exclusion criteria included: age <18 years, acute or chronic lung disease, patients presenting with sore throat, known esophageal disease, oropharyngeal abnormalities, and patients with a cervical spine disease. All participants gave written informed consent before the study. Patients were randomized to receive ventilation with either the EzT or the ETT using a computer-generated randomization list. Fifty patients were included in each center. In all 200 cases, the EzT size 41 French was used. The EzT size 41 F is designed for use in patients with a height from 130 to 200 cm; therefore, only 1 size was used in these adult patients. In 200 patients, conventional endotracheal intubation was performed using standard ETT (7.0 ID mm in women, 8.0 ID mm in men; Tyco Healthcare Mallinckrodt, Athlone, Ireland) under direct laryngoscopy (MacIntosh blade).

Preoperatively, the patients' airways were classified according to the Mallampati test.[21] Routine noninvasive monitoring was used, including electrocardiogram, pulse oxymetry, noninvasive blood pressure measurement, and capnography. Following anesthesia, the patient's mouth was opened with one hand and the EzT was inserted in parallel to the patient's chest, so as to facilitate insertion, until the black ring on the EzT was positioned between the patient's maxillary teeth. The EzT was inserted blindly and thereby expected to enter the esophagus.

The ETT was inserted with the help of a laryngoscope. The tongue was held aside while inserting the tube into the trachea. Prior, the head was positioned in the facilitated Jackson position.

The oropharyngeal and tracheoesophageal cuffs of the EzT were inflated successively with 80 and 5 to 10 mL, respectively, as recommended by the manufacturer (supplementary figure S1, http://links.lww.com/MD/B754). Correct placement of the device was confirmed by auscultation, pulse oxymetry, and end-tidal CO_2 ($EtCO_2$)-concentration measurements. In case of failure to ventilate effectively or place the EzT within 3 attempts, a conventional endotracheal intubation with an ETT was planned to be used as rescue device. Time of insertion to final placement and first ventilation was measured in seconds using a stopwatch. Simultaneously, insertion difficulty as graded by the anesthesiologist (1–5; 1: very easy, 5: impossible) was documented.

After insertion of the EzT or the ETT, anesthesia was maintained with inhaled sevoflurane and fentanyl. Patients' lungs were ventilated with positive pressure ventilation. Pressure controlled modes were used, and a level of 5 cmH_2O positive end-expiratory pressure (PEEP) was applied. Ventilatory settings remained unchanged throughout the procedure, with an inspiratory/expiratory time of 1:2 and an average tidal volume of 12 mL/kg. Dynamic compliance and resistance were checked. Oropharyngeal leak pressure (OLP) measurement was performed by closure of the expiratory valve of the circle system with a flow of 3 L/min and observation when the airway pressure reached equilibrium. Significant leakage was defined as a difference of the inspiratory and the expiratory minute volume of >0.5 L/min for more than 1 minute. Data collection was truncated after 1 hour for the statistical analysis, as there was significant attrition of data due to the short duration of the procedures. At that time, a substantial number of surgeries were completed. The EzT was removed at the end of the procedure and inspected for traces of blood. When responsive, the patient was questioned for sore throat or dysphagia during postoperative rounds 24 hours after general anesthesia. The patient received analgesics if required for postoperative pain management on request; this was documented and considered in the documentation of sore throat and dysphagia.

3. Statistical analysis

The primary outcome measure was success of insertion. Secondary outcomes were duration of ventilation, inspiratory and expiratory minute volumes, OLP, rate of complications, and rating of insertion difficulty by anesthesiologists.

We calculated the necessary sample size with at least 94 participants using G*Power 3.1 (2-tailed t test; Cohen d: 0.8, alpha error: 0.05, power: 0.95; Heinrich-Heine-University, Duesseldorf, Germany). Effect size was determined based on the differences detected in own utilizations published thereafter due to lack of data at the time of the study design.[1] Data were tested for normal distribution, and analysis was performed by Chi-squared statistics and unpaired t tests, respectively. Insertion difficulty as graded by the anesthesiologist, ASA physical status, and Mallampati class were compared using the Kruskal–Wallis test. Bonferroni correction for multiple testing was used. For the primary end point, we used the 2 one-sided test procedure.[22] The intention-to-treat approach was used for data analysis.[23] Results were presented as mean and standard deviation or median and range; a $P<.05$ was considered statistically significant. Log-rank test was used for curve comparison. Analysis was done with GraphPad Prism 5 (GraphPad Software Inc., San Diego, CA).

4. Results

A total of 200 patients were included into the study (EzT group), 82 (41%) female. A total of 200 endotracheal intubated patients served as controls (ETT group), 98 (49%) female. No significant differences were found with regard to patients' demographic data between the groups. Detailed demographic data and data on surgical procedures are depicted in Table 1.

Table 1

Demographic data of patients with use of EzT or ETT (A) and data on surgical procedures (B).

A

	EzT (n = 200)		ETT (n = 200)		
	Mean	**Std. deviation**	**Mean**	**Std. deviation**	***P***
Age, y	53.8	16.5	60.1	19.8	n.s.
Height, cm	172.2	7.4	170.1	10.1	n.s.
Weight, kg	71.8	10.6	77.4	21.2	n.s.
BMI, kg/m^2	24.1	3.1	27.1	7.0	n.s.
	N	**%**	**N**	**%**	
Female	82	41.0	98.0	49	n.s.
Male	118	59.0	102.0	51	
ASA physical status					
1	132	66.0	36.0	18	n.s.
2	68	34.0	164.0	82	n.s.
Mallampati class					
1	162	81.0	148.0	74	n.s.
2	38	19.0	36.0	18	n.s.
3	0	0.0	16.0	8	n.s.

B

	EzT	
	N	**%**
Cystoscopy	41	20.5
TUR	34	17.0
Hernia	23	11.5
Arthroscopy	22	11.0
Hysteroscopy	20	10.0
Stent insertion	13	6.5
Uretheroscopy	12	6.0
Hand surgery	11	5.5
Ankle surgery	8	4.0
Brest biopsy	8	4.0
Bone biopsy	4	2.0
Orchiectomy	2	1.0
Varicocelectomy	2	1.0
	ETT	
	N	**%**
Hernia	60	30.0
Appendectomy	58	29.0
Hysterectomy	36	18.0
Urogenital surgery	20	10.0
Arthroscopy	16	8.0
Ankle surgery	4	2.0
Brest surgery	2	1.0
Hand surgery	2	1.0
Orchiectomy	2	1.0

Values have been corrected for multiple testing. ETT = endotracheal tube, EzT = EasyTub, TUR = transurethral resectione.

4.1. Insertion

In all patients, the EzT could be inserted within 3 attempts, with a success rate of 82.0% at the first attempt, 17.5% at the second attempt, and 0.5% at the third attempt. In 19 out of 236 (8.1%) attempts, the anesthesiologist decided to use a laryngoscope for insertion; these included 18 (7.6%) second attempts and 1/3 attempt (Table 2). Time to successful placement was 22.4 seconds (±4.5 seconds, Table 2). Anesthesiologists rated insertion difficulty with a median of 1 (range 1–3). In all cases, the EzT was placed in the esophagus.

In all patients, the ETT could be inserted within 3 attempts, with a success rate of 88.0% at the first attempt, 11.0% at the second attempt, and 1.0% at the third attempt (Table 2). In all attempts, the anesthesiologist used a MacIntosh laryngoscope size 3 or 4 for insertion. Time to achieve an effective airway was 32.8 seconds (±17.9 seconds, Table 2). Anesthesiologists rated insertion difficulty with a median of 1 (range 1–3). Except for duration of ventilation and insertion time, no significant difference was detected with regard to insertion attempts and difficulty (Table 2). Mean insertion time for successful intubation with the ETT was significantly longer than intubation with the EzT.

4.2. Ventilation

In all EzT patients, the achieved inspiratory and expiratory minute volumes (6.64 ± 0.71 and 6.34 ± 0.69 L/min) were

Table 2

Insertion and ventilation during general anesthesia with the EzT and ETT.

	EzT (n = 200)		ETT (n = 200)		
	Mean	**Std. deviation**	**Mean**	**Std. deviation**	***P***
Duration of ventilation, min	25.4	14.1	40.7	26.1	.01*
Insertion time, s	22.3	4.5	32.8	17.9	.01*
	N	**%**	**N**	**%**	
Nr. of insertion attempts					
1	164	82.0	176	88.0	n.s.
2	35	17.5	22	11.0	n.s.
3	1	0.5	2	1.0	n.s.
Insertion difficulty					
1	158	79.0	170	85.0	n.s.
2	38	19.0	28	14.0	n.s.
3	1	0.5	2	1.0	n.s.

ETT = endotracheal tube, EzT = EasyTube.
* Values have been corrected for multiple testing.

sufficient to reach target oxygenation values, similar to ETT patients (6.46 ± 0.81 and 6.23 ± 0.59 L/min, $P = .59$; Fig. 1). No significant leakage was detected in the EzT group or the ETT group (Fig. 2A). Overall mean leakage was 0.30 L/min (±0.29) in the EzT group and 0.23 L/min (±0.19) in the ETT group. Mean OLP for the EzT was 32.10 cmH_2O (±5.70) and thereby above the ventilatory peak pressure most of the time. Mean peak pressure (23.16 ± 3.21 vs 22.92 ± 4.42 cmH_2O) and mean plateau pressure (14.62 ± 3.19 vs 14.03 ± 2.79 cmH_2O) did not differ between the groups. When calculating the difference between the OLP and the peak pressure at a given time, the OLP exceeded the peak pressure 65 times during the investigated time span in all patients (Fig. 2B). Peak and plateau pressure as well as PEEP also did not change significantly over time (Fig. 3). Dynamic compliance and resistance did not change significantly during the procedure in both groups. In the EzT group, mean compliance was 48.53 ± 12 mL/cmH_2O compared to 43.15 ± 8 mL/cmH_2O in the ETT group ($P = .76$). Mean resistance was 65.78 ± 37.19 cmH_2O/L/s in the EzT group and 61.22 ± 31.89 cmH_2O/L/s in the ETT group ($P = .49$).

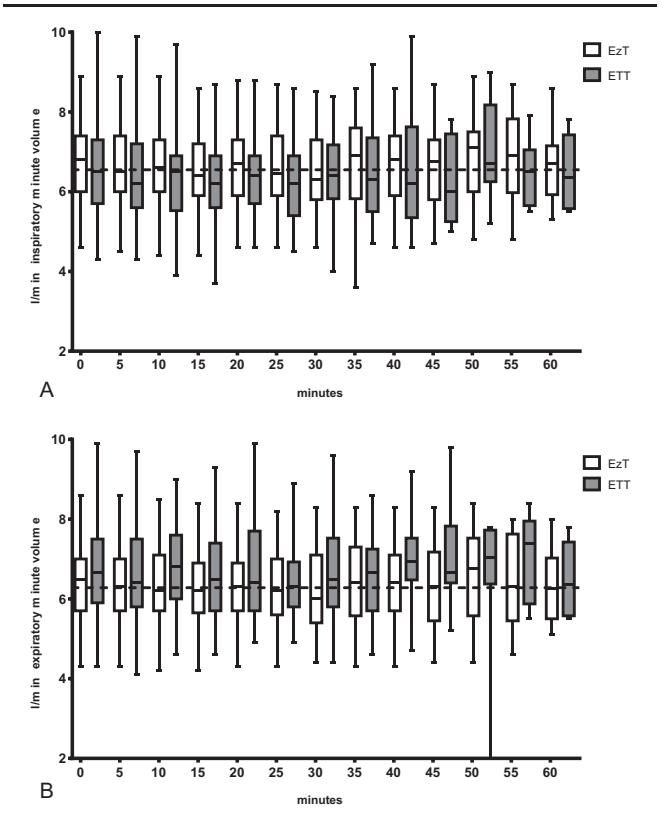

Figure 1. Inspiratory (A) and expiratory minute volume (B) during general anesthesia with the EasyTube (white) and the endotracheal tube (gray). Dashed line represents overall mean.

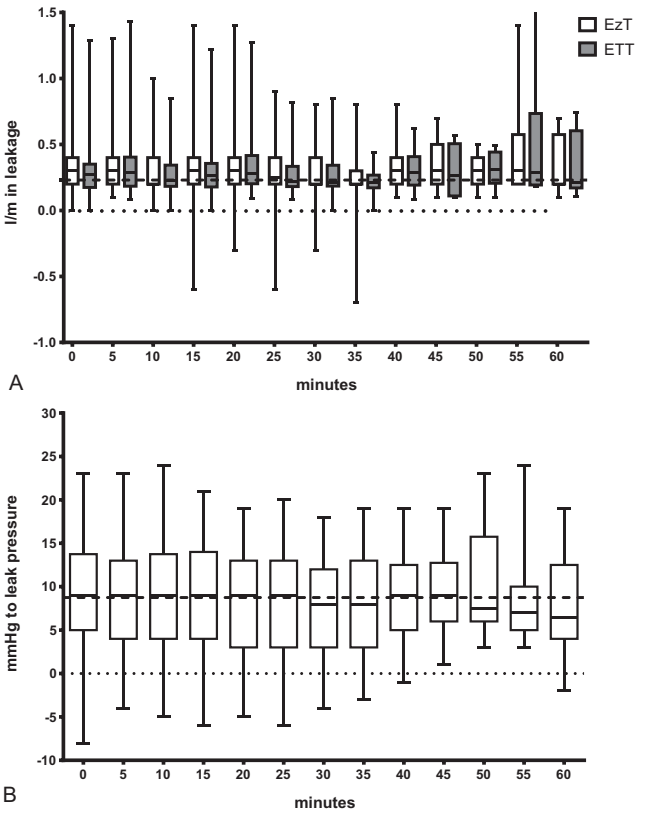

Figure 2. Ventilation leakage of the EasyTube (EzT) (white) and the endotracheal tube (gray) (A) and difference between oropharyngeal leak pressure and peak pressure of the EzT (B) during general anesthesia. Dashed line represents overall mean, dotted line represents zero.

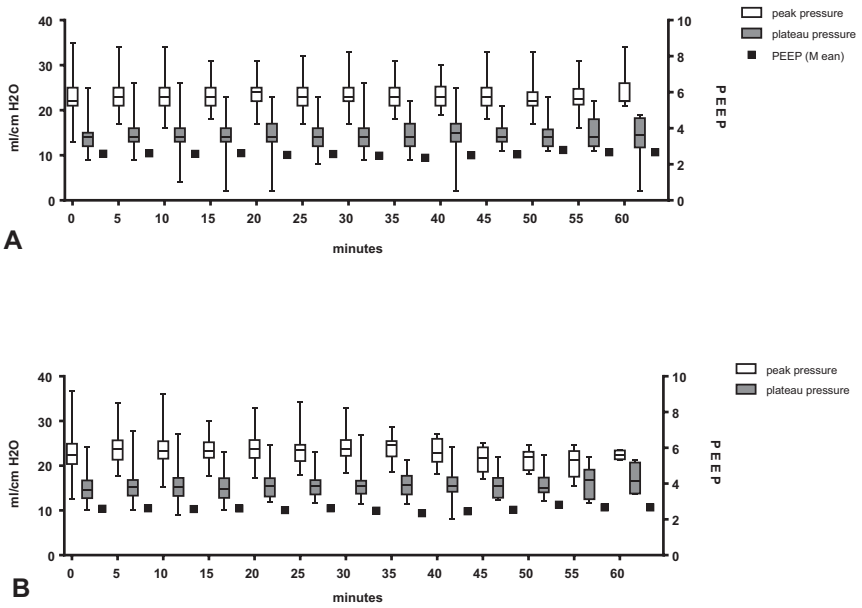

Figure 3. Peak pressure, plateau pressure, and PEEP during general anesthesia with the EasyTube (A) and the endotracheal tube (B). PEP = positive end-expiratory pressure.

4.3. Hemodynamics and oxygenation

No significant differences in heart rate (69.88 ± 9.66 vs 68.31 ± 9.91 bpm, $P = .078$), systolic (129.99 ± 2.48 vs 130.97 ± 3.04 mmHg, $P = .84$), and diastolic blood pressure (73.78 ± 1.67 vs 72.11 ± 1.55 mmHg, $P = .74$), were observed either in the EzT group or the ETT group; there were also no significant variations of heart rate of blood pressure in the course of anesthesia.

Mean oxygen saturation (SpO_2) values in the EzT group were 97.98% (±1.31) and 98.07% (±1.60) in the ETT patients ($P = .67$). Mean $EtCO_2$ values in the EzT group were 37.35 ± 3.00 mm Hg compared to 39.02 ± 3.80 mm Hg in the ETT patients ($P = .42$).

4.4. Complications

The most frequent complication was sore throat, followed by the presence of blood on the EzT after removal, and dysphagia (Table 3). In 4 patients, tongue edema was present after extubation, which had resolved by the next day. Three patients had visible, superficial, and mucosal lesions. No severe laceration or perforation of the oral, pharyngeal, or esophageal mucosa was detected.[24] In the ETT group, sore throat and blood on the cuff also were the most frequent complications, but to a lesser extent that in the EzT group (Table 3). Two patients in the ETT group presented a lost tooth during intubation with a MacIntosh laryngoscope. Regurgitation (at least during postoperative rounds at 24 hours after anesthesia) was not observed in both groups.

Table 3

Complications during general anesthesia with EzT and ETT.

	EzT (n = 200)		ETT (n = 200)		
	N	%	N	%	P
Sore throat	45	22.5	34	17.0	n.s.
Blood on balloon	44	22.0	32	16.0	n.s.
Dysphagia	22	11.0	6	3.0	n.s.
Tongue edema	4	2.0	2	1.0	n.s.
Mucosal lesions	3	1.5	4	2.0	n.s.
Tooth breakage	0	0.0	2	1.0	n.s.
Occlusion of the pharyngeal lumen	0	0.0	n/a	n/a	

ETT = endotracheal tube, EzT = EasyTube.

5. Discussion

The most important finding of our study is that insertion of the EzT was comparable to the ETT in terms of success rate, that ventilation via the EzT provides sufficient SpO_2 while effectively eliminating CO_2 and does not cause significant leakage or complications, which makes the EzT a suitable device for general anesthesia. This is in accordance with previous results.[13,14,25,26] To our knowledge, this represents the biggest study population and the only multicenter-study with the utilization of the EzT during general anesthesia to date.

5.1. Insertion

The insertion success rates for both devices were comparable, with a higher success rate at the first attempt with the ETT. This might be owed to the fact that anesthesiologists participating in the study were more experienced with endotracheal intubation using a laryngoscope. The insertion success rates were comparable to other studies (Sethi et al[13] 87%, Gaitini et al[26] 92.5%, Lorenz et al[14] 95%, and Cavus et al[12] 64%). On the other hand, mean insertion time with the ETT was significantly longer despite the need to separately inflate 2 balloons of the EzT.[6,14] However, the observed time difference is clinically irrelevant during elective procedures. In 8.1% of the attempts, the anesthesiologist decided to use a laryngoscope for insertion of the EzT, all of them were second or third insertion attempts. Cavus et al[12] reported significantly longer times to ventilation with the EzT; we could not confirm this observation with our data.

5.2. Ventilation

The inspiratory and expiratory minute volumes were comparable to the results obtained by Gaitini et al.[26] We detected a mean gas

leakage of 0.30 L/min, whereas Gaitini et al[26] reported a mean leakage of 0.38 L/min, and recommended overinflating the oropharyngeal balloon with 15 to 20 mL of additional air in case of a leakage. As also the mean OLP was above the ventilatory peak pressure most of the time (Fig. 3B), it can be assumed that ventilation with the EzT is feasible.

The Combitube has significant airflow resistance that should be considered when patients are mechanically ventilated.[27] As the EzT is a very similar device, we also expected higher ventilatory pressures in the EzT group. Peak and mean airway pressures were in accordance to previously reported values,[13,26] but lower than reported for the Combitube.[27] Although we did not directly compare the devices, this might pose one of the advantages of the EzT over the Combitube. In addition, we did not observe a significant change in peak or mean airway pressure compared to baseline as reported by Sethi et al.[13] Mean OLP was comparable to values obtained by Lorenz et al.[14] However, the delivered oropharyngeal pressure was significantly lower than the pressure measured at the anesthesia breathing system, and therefore the applied ventilatory pressures should not cause barotrauma.[27]

5.3. Hemodynamics and oxygenation

Unlike Sethi et al[13], we did not observe tachycardia or elevated blood pressures in our patients during the course of anesthesia. It is also questionable whether these hemodynamic changes can be attributed to a specific airway device or rather to insufficient anesthesia or analgesia. Oxygenation was sufficient in both groups with no significant difference as described before.

5.4. Complications

No major complications were observed. The overall incidence of dental injury in the literature is reported between 0.06% and 12% with the ETT, which is in accordance with our data.[28–32] The risk of dental injury is practically nonexisting with EzT insertion, as it is usually inserted without utilizing a laryngoscope. All other complications were not significantly different between the EzT and the ETT (Table 3). While complications were more frequent in the EzT group, broken teeth in the ETT group might cause more severe problems. The biggest difference was found in dysphagia (11% vs 3%), which resolved spontaneously after 24 hours. This might be explained by the placement of the distal balloon in the esophagus and a by a relatively large balloon sitting in the oropharynx which might cause pharyngeal discomfort.[33]

5.5. Cost-effective ratio

The price of a standard ETT ranges from 1 to 3$, the EzT costs around 55$. However, the EzT may be sterilized and reused.

A limitation of our study is that we included only patients with an ASA physical status 1 to 2, which hinders generalization of the results to critically ill patients. Also, the participants underwent minor surgical procedures only. Furthermore, the investigated time period was 1 hour, so no conclusions for longer-lasting ventilation can be drawn from our data. We therefore cannot recommend using the EzT for surgeries lasting longer than 60 minutes or with for patients with ASA status higher than 2. Another limitation of this study is that only patients with anticipated normal airways were included, and thus, the performance of the EzT as a definitive airway in patients with expected difficult intubation remains unclear. There is currently only 1 randomized, clinical study on intubation with the EzT that reported 14 patients with a difficult airway,[5] and 1 manikin study of our own group addressing this important topic.[34] Therefore, further in vivo research on the use of the EzT in difficult airway situations is warranted.[35] Finally, the study has not been registered at a clinical trial registry, as this was not common practice at the time when the study was designed.

Conclusively, this study showed that the EzT is suitable for ventilation during general anesthesia in patients with ASA physical status 1 and 2 during minor elective short-term surgical cases.

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