



## Simulation and education

Performance and skill retention of intubation by paramedics using seven different airway devices—A manikin study<sup>☆</sup>

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## ABSTRACT

**Introduction:** Endotracheal intubation (ETI) is the most widespread method for emergency airway management. Several studies reported that ETI requires considerable skill and experience and if performed incorrectly, may result in serious adverse events. Unrecognized tube misplacement or oesophageal intubation is associated with high prehospital morbidity. This study investigates the usability of supraglottic airway devices compared to ETI and the skill retention of 41 previously inexperienced paramedics following training using a manikin model.

**Methods:** 41 paramedics participated in this study. None had prior experience in airway management, apart from bag-valve ventilation. After a standardised audio-visual lecture lasting 45 min, the paramedics participated in a practical demonstration using the advanced patient simulator SimMan® (Laerdal Medical, Stavanger, Norway). Afterwards, paramedics were instructed to perform airway-management using seven different techniques to secure the airway (ETI, Laryngeal mask unique [LMA], Proseal, Laryngeal tube disposable [LT-D®], I-Gel®, Combitube®, and EasyTube®) following a randomized sequence. Participants underwent reassessment after 3 months without any further training or practice in airway-management.

**Results:** During the initial training session, ETI was successfully performed in 78% of cases, while 3 months later the success rate was 58%. For the supraglottic airway devices, five out of six were successfully used by all paramedics at both time points, the exception being Proseal®. Our data show successful skill retention (success rate: 100%) after 3 months for five out of six supraglottic airway devices. Time to ventilation (T3) was significantly less for LMA, LT-D® and I-Gel® at all time points compared to ETI.

**Conclusion:** ETI performed by inexperienced paramedics is associated with a low success rate. In contrast, supraglottic airway devices like LMA, LT-D®, I-Gel®, Combitube® and EasyTube® are fast, safe and easy-to-use. Within the limitations of a manikin-study, this study suggests that inexperienced medical staff might benefit from using supraglottic airway devices for emergency airway management.

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## 1. Introduction

In emergency situations like cardiopulmonary resuscitation (CPR), ventilation and oxygenation of patients is a potentially lifesaving procedure.<sup>1–3</sup> Main indications for immediate airway interventions are severe trauma, cardiac arrest and other causes of

coma.<sup>4</sup> In this context, endotracheal intubation (ETI) is perceived as the optimal method for providing and maintaining a patent and secure airway.<sup>5–7</sup> However, ETI may lead to prolonged interruptions of CPR and in some cases laryngoscopy and intubation may prove impossible or cause a life threatening deterioration in the patient's condition.<sup>8,9</sup> In contrast, use of supraglottic airway devices may help to reduce time to ventilation, especially in patients with a difficult airway.<sup>10–12</sup>

ETI requires highly skilled and experienced personnel, who receive regular training and practice.<sup>13–18</sup> Especially in prehospital emergency situations, it is mandatory to secure the airway as safely and quickly as possible. Persistent and prolonged attempts at intubation may cause catastrophic respiratory events.<sup>19</sup>

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Difficulties with ETI as well as airway-associated adverse outcomes led to the concept of “difficult airway management”, where supraglottic airway devices provided valuable alternatives.<sup>20–22</sup> Supraglottic airway devices are less invasive and technically easier to use than ETI.<sup>7</sup>

In Europe, prehospital ETI is performed by physicians and paramedics. However, endotracheal intubations by paramedics are performed infrequently.<sup>18</sup>

In consequence, we performed this manikin study in order to evaluate time to ventilation, usability and skill retention of alternate supraglottic airway devices in comparison to ETI. This evaluation was repeated after 3 months. Our aim was to assess the performance of paramedics with respect to success rate and time of insertion of the alternate airway devices as compared to ETI.

## 2. Methods

Following approval by ethical committee of the Medical University Vienna, 41 active voluntary paramedics of the Red Cross Vorarlberg, Austria, participated after informed consent. All of them had already completed their training within the past 5 years. In Austria, training schedules for paramedics differ from other curricula, such as in Germany or the U.S.A.: basic airway management is limited to bag-valve ventilation and advanced airway management, which includes intubation, requires further training.

All participants received a standardised audio-visual lecture lasting 45 min covering relevant aspects of anatomy and different techniques for securing an airway. Following the lecture, paramedics participated in a practical demonstration, where intubations with the respective devices were demonstrated by an independent physician.

Airway-management was performed with the following seven airway devices:

1. Laryngeal mask unique (LMA Company North America, San Diego, CA, U.S.A.), size 4.
2. Proseal® (LMA Company North America, San Diego, CA, U.S.A.), size 4.
3. Laryngeal tube disposable (King-LT-D, VBM, Sulz, Germany), size 4.
4. I-Gel® (Intersurgical Ltd., Wokingham, England), size 4.
5. Combitube® (Covidien, Mansfield, MA, U.S.A.), SA 37 F.
6. EasyTube® (Teleflexmedical Ruesch, Research Triangle Park, NC, U.S.A.), Ch 41.
7. Laryngoscopic guided ETI (7.5 mm I.D., Mallinckrodt, Athlone, Ireland), reinforced with a rigid bougie.

Each paramedic performed airway management with the seven devices in a computer-generated randomized sequence using advanced patient simulator SimMan® (Laerdal Medical, Stavanger, Norway).<sup>23,24</sup> The paramedics were not allowed to watch each other.

The primary outcome parameter was the duration of intubation (T3), beginning with picking up a airway device or laryngoscope and ending with the first visible ventilation of the lungs in absence of gastric inflation. If incorrect positioning of the device was recognized by paramedics, reposition was allowed. For insertion attempts (T1) lasting longer than 30 s, paramedics were instructed to stop airway-management and start interposed bag-mask ventilation.<sup>7</sup> After a maximum of three attempts or unrecognized oesophageal tube misplacement or intubation, airway-management was defined as a failure.

- T1 (“time to intubation”) was defined as the time from picking up the device or laryngoscope, to its successful insertion into the manikin.

- T2 (“time to inflation”) was defined as the time from picking up the device or laryngoscope, to the inflation of cuffs (where applicable).

The success rates for all seven devices was recorded and provided an additional secondary parameter for analysis.

Three months later, all 41 paramedics participated in a second evaluation. No further training or demonstration of the airway-devices had been given in the mean time. The primary (T3) and the secondary parameters (T1, T2 and success rate) were measured again.

### 2.1. Statistical analysis

For descriptive statistics we used Sigmaplot, Version 11.0 (Systat Software Inc., Chicago, IL, USA).

We analysed the anonymised data for T1 and T3 using the Mann–Whitney–Rank Sum-Test, searching for differences between the data sets obtained at the two time points (first and second turn). Mann–Whitney–Rank Sum-Test was also used search for difference of time to ventilation (T3) between ETI and supraglottic airway devices. Exact Fisher test was used to compare success rates of ETI between first and second evaluation. For analyzing success rate of Proseal® during second evaluation we used Likelihood Quotation Chi-Square.

Based on expected average variance of T3 of approximately 30% and a standard deviation of 30%, 41 volunteers were included to achieve a power of 90% for detecting a significant difference.

Results are reported as the mean value and standard deviation ( $\pm$ SD) in seconds (s). A *p*-value of less than 0.05 was considered as statistically significant.

## 3. Results

This study was conducted between September 2009 and January 2010. Forty-one paramedics (8 female and 33 male, age  $30 \pm 13$ ) participated in this study.

### 3.1. Time to ventilation (T3)

Successful intubation and start of ventilation using ETI ( $n = 32$ ) took  $36.9 \pm 10.8$  s during initial session [Table 1], and  $29.8 \pm 6.1$  s ( $n = 24$ ) in the 3-month reevaluation [Table 2].

Of the supraglottic devices tested, the quickest technique was I-Gel® ( $14.9 \pm 5.3$  s for first and  $13.9 \pm 4.7$  s for second assessment). T3 was slowest using Proseal®, with averages of  $43.9 \pm 11.9$  s initially and  $60.9 \pm 35.3$  s during reevaluation.

T3 was significantly faster for ETI, LMA, LT-D® and EasyTube® during the second evaluation [Table 3].

**Table 1**

Performance of airway devices during first evaluation (in s).

	Time 1 ( $\pm$ SD)	Time 2 ( $\pm$ SD)	Time 3 ( $\pm$ SD)	<i>n</i>	Success rate
ETI	24.43 ( $\pm 8.78$ )	31.61 ( $\pm 9.76$ )	36.88 ( $\pm 10.75$ )	32	78%
LMA Unique	10.80 ( $\pm 3.21$ )	16.37 ( $\pm 3.89$ )	21.87 ( $\pm 4.94$ )	41	100%
Proseal®	25.47 ( $\pm 10.28$ )	36.94 ( $\pm 11.26$ )	43.85 ( $\pm 11.85$ )	41	100%
LT-D®	7.61 ( $\pm 2.70$ )	21.58 ( $\pm 4.45$ )	26.40 ( $\pm 4.85$ )	41	100%
I-Gel®	9.39 ( $\pm 4.08$ )	NA	14.95 ( $\pm 5.29$ )	41	100%
Combitube®	12.79 ( $\pm 8.70$ )	31.69 ( $\pm 9.60$ )	36.21 ( $\pm 9.15$ )	41	100%
EasyTube®	10.44 ( $\pm 5.61$ )	28.31 ( $\pm 8.51$ )	34.95 ( $\pm 9.14$ )	41	100%

All times are presented as mean ( $\pm$ SD) in s. NA: not applicable.

T1 (“time to intubation”).

T2 (“time to inflation”).

T3 (“time to ventilation”).

**Table 2**

Performance of airway devices during second evaluation (in s).

	Time 1 (±SD)	Time 2 (±SD)	Time 3 (±SD)	n	Success rate
ETI	18.46 (±5.76)	24.60 (±5.27)	29.75 (±6.13)	24	58%
Proseal®	33.44 (±18.88)	41.01 (±20.75)	46.64 (±21.89)	33	80%
LMA Unique	7.83 (±3.0)	12.74 (±4.45)	18.26 (±5.55)	41	100%
LT-D®	9.58 (±5.05)	17.77 (±6.19)	22.61 (±6.56)	41	100%
I-Gel®	8.38 (±3.41)	NA	13.99 (±4.67)	41	100%
Combitube®	12.06 (±5.11)	26.93 (±9.08)	33.67 (±9.17)	41	100%
EasyTube®	8.51 (±3.08)	22.93 (±7.24)	29.01 (±7.72)	41	100%

All times are presented as mean (±SD) in s. NA: not applicable.

T1 ("time to intubation").

T2 ("time to inflation").

T3 ("time to ventilation").

**Table 3**

Level of significance between first and second evaluation for each device.

Mann–Whitney–Rank Sum-Test	Time 1	Time 3
ETI	0.012	0.004
LMA Unique	<0.001	<0.001
Proseal®	0.045	0.625
LT-D®	0.08	0.003
I-Gel®	0.125	0.417
Combitube®	0.897	0.182
EasyTube®	0.053	0.001

T1 ("time to intubation").

T3 ("time to ventilation").

During both evaluations, T3 for LMA, LT-D® and I-Gel® were significantly shorter than for ETI ( $p < 0.05$ ). In contrast, Combitube® and EasyTube® did not differ significantly from ETI at either evaluation [Tables 4 and 5]. T3 for Proseal® was significantly slower during first ( $p = 0.013$ ) and second evaluation ( $p < 0.001$ ) than ETI.

### 3.2. Time to insertion (T1)

T1 for ETI during first evaluation was  $24.4 \pm 8.8$  s and  $18.5 \pm 5.8$  s during second evaluation, and was significantly faster at the second assessment than at the first ( $p = 0.012$ ).

**Table 4**

Level of significance of T1 and T3 using the respective device comparing to ETI during first evaluation.

Mann–Whitney–Rank Sum-Test	Time 1	Time 3	n
ETI	24.43 (±8.78)	36.88 (±10.75)	32
LMA Unique	<0.001	<0.001	41
Proseal®	0.781	0.013	41
LT-D®	<0.001	<0.001	41
I-Gel®	<0.001	<0.001	41
Combitube®	<0.001	0.768	41
EasyTube®	<0.001	0.331	41

T1 ("time to intubation").

T3 ("time to ventilation").

**Table 5**

Level of significance of T1 and T3 using the respective device comparing to ETI during second evaluation.

Mann–Whitney–Rank Sum-Test	Time 1	Time 3	n
ETI	18.46 (±5.76)	29.75 (±6.13)	24
LMA Unique	<0.001	<0.001	41
Proseal®	<0.001	<0.001	33
LT-D®	<0.001	<0.001	41
I-Gel®	<0.001	<0.001	41
Combitube®	<0.001	0.142	41
EasyTube®	<0.001	0.403	41

T1 ("time to intubation").

T3 ("time to ventilation").

All supraglottic airway devices, except Proseal®, were significantly faster to insert [Tables 4 and 5] than ETI. During first evaluation, fastest T1 was achieved using LT-D® ( $7.6 \pm 2.7$  s). During second evaluation, fastest insertion was performed using LMA ( $7.8 \pm 3$  s).

LMA also was significantly faster during second evaluation than during first evaluation [ $p < 0.001$ ; Table 3]. Insertion of Proseal® was significantly slower ( $p = 0.045$ ) during second evaluation ( $33.4 \pm 18.9$  s) than during initial evaluation ( $25.5 \pm 10.3$  s). No statistically significant differences between first and second evaluations were found for LT-D® ( $p = 0.08$ ), I-Gel® ( $p = 0.125$ ), Combitube® ( $p = 0.897$ ) or EasyTube® ( $p = 0.053$ ).

### 3.3. Success rate

During initial evaluation, ETI was performed incorrectly 9-times, resulting in a success rate of 78%. The airway-management procedures using all supraglottic airway devices were successful. A significant difference in success rates between ETI and the other techniques was detected ( $p = 0.002$ ).

During second evaluation, success rate for ETI decreased to 58%. Success rate for ETI was significantly lower compared to LMA, LT-D®, I-Gel®, Combitube® or EasyTube® ( $p < 0.001$ ).

Proseal® success rates varied: During the first evaluation all paramedics were successful, however 3 months later the success rate was only 80% (8 out of 41 attempts failed due to timeout). Although 20% failed in using Proseal® at reevaluation, the risk of performing unsuccessful intubation using Proseal in comparison to ETI was significantly lower ( $p = 0.029$ ).

## 4. Discussion

Following a single training session, the 41 paramedics recruited for our study were more successful at performed intubations with five out of six supraglottic airway devices than with ETI.

Up until now, no study has compared the application of widely used supraglottic airway devices with ETI by paramedics. Studies have investigated various airway devices in different settings and in different populations, with varying results of success rates. Differences appear to correlate strongly with the degree of personal experience and training of the operator.<sup>16,17,25</sup>

The most important finding of our study was that T3 was significantly shorter for five out of six supraglottic airway devices than for ETI following an initial training session, but only for three out of six supraglottic airway devices after a 3-month period without practicing any of the intubation techniques. The devices LMA, LT-D® and I-Gel® performed significantly better on both occasions than ETI. No significant difference to ETI was found at second occasion for Combitube® and EasyTube®. The device Proseal® took longer than ETI on both occasions.

ETI is dangerous in inexperienced hands and is associated with a high rate of failed intubation. Immediately after a lecture and a practical training session, the relatively inexperienced paramedics reached a success rate of 78% for ETI. After a 3-month period without training, the volunteers were successful at ETI in only 58% of cases. Consequently paramedics, who have only recently completed their training or have experienced a period of less frequent practicing, may prove to be a risk to patients in an emergency situation requiring airway management. This is especially so, if an endotracheal tube is misplaced unrecognized into the oesophagus, potentially causing high prehospital mortality. Some studies have reported that up to 25% of ETI were misplaced by paramedics and up to 15% of paramedics failed to successfully intubation in a pre-hospital setting.<sup>19,26</sup> Mortality of children with misplaced tracheal tubes (in oesophagus) reached 95%, and 80% in adult patients.<sup>27,28</sup>

Deakin et al. reported that paramedics perform ETI infrequently.<sup>18</sup> Similarly, a recent study by Fullerton et al. found no significantly higher failure rate of intubation in experienced paramedics compared to physicians.<sup>29</sup> Therefore the risk factor for ETIs performed by paramedics appears to lie in the degree of training and practice of the paramedic. We agree with Paal et al., that less experienced medical staff should refrain completely from performing ETI and alternative airway devices, such as supraglottic, should be sought.<sup>20</sup> However, the definition of who counts as “less experienced” remains vague.

#### 4.1. LMA and I-Gel®

LMA is an accepted alternative to ETI, especially in situations when ETI has failed.<sup>7</sup> The results of our study showed, intubation using LMA was faster and more easily performed (success rate of 100% in all attempts) than ETI, even by inexperienced paramedics. However, a known disadvantage of LMA is the increased risk of aspiration in comparison to ETI, based the supraglottic device failing to protect the airway from aspiration of gastric contents.<sup>30</sup> Aspiration, although an important consideration, is not universally fatal and therefore the avoidance of aspiration is of a lesser priority than establishing a clear airway.<sup>31</sup>

In a recent study, Castle et al. reported T3 using LMA was 33.8 s.<sup>32</sup> The mean duration of T3 in our study using LMA was faster, ranging from approximately 18 to 22 s. This may be due to the standardised lecture beforehand or a bias being introduced through the use of the manikin.

In a manikin study, Wiese et al. reported a success rate of 96% and a time to intubation of 9.3 s of I-Gel® during first attempt.<sup>33,34</sup> Wharton et al. reported success rates of 82.5% during first and 15% during second attempts, and a median T1 of 17.5 s in 40 healthy anaesthetised patients.<sup>33,34</sup> In our study T1 was similar at both assessments (mean of 9.39 s, and 8.38 s respectively), and all paramedics were able to perform ventilation at both occasions. These results suggest that I-Gel® could be a useful and safe alternative to ETI. However, as with LMA, the risk of aspiration remains and more clinical experience should be gathered before this method can be safely recommended as a primary alternative device.<sup>34</sup>

#### 4.2. Proseal®

Performing intubation using Proseal® was ambivalent. All volunteers succeeded in performing intubation using this device during first evaluation. However, during second evaluation 8 out of 41 paramedics were not able to perform ventilation using Proseal® (success rate 80%). T3 was significantly longer for Proseal® than for ETI in both assessments ( $p = 0.013$  for first and  $p < 0.001$  for second evaluation). The explanation for the prolonged duration may be the gum-elastic introducer required for the Proseal® device: several of our volunteers appeared to have difficulties connecting the introducer to the device during our study. On the other hand, the risk of aspiration with a correctly placed Proseal® is less than for other supraglottic devices, but not as low as for ETI.<sup>35</sup> In summary, Proseal® performed the least well out of all the devices tested for T3 and the success rate declined after a period of 3 months.

#### 4.3. LT-D®

Heuer et al. recommended the use of LT-D® for airway management by paramedics in out-of-hospital CPR.<sup>36</sup> Russi et al.<sup>37,38</sup> and Tumpach et al.<sup>39</sup> also reported high success rates and fast insertion times for the LT-D®. Data from our study also show good performance and high success rates, and skill retention was promising. LT-D® could be a useful airway device, but clinical evidence is still limited and studies in patients in an emergency setting are not yet available.

#### 4.4. Combitube® and EasyTube®

Lefrançois investigated the feasibility, safety and effectiveness of the Combitube® used by paramedics in 760 prehospital patients and reported a high success rate with low rate of side-effects.<sup>40</sup> Bollig et al. reported, that success rates were higher and intubation was significantly faster with Combitube® than with ETI.<sup>11</sup> In our study, T1 of Combitube® and EasyTube® was significantly faster than ETI. However, blocking two cuffs (measured as T2) with Combitube® and EasyTube® is more time-consuming than blocking the single cuff on a conventional endotracheal tube, as already published by Trabold et al.<sup>41</sup>

Combitube® and EasyTube® had 100% success rates in both evaluations, compared to 78% and 58% for ETI. Hoyle et al. also reported high success rates using Combitube® in patients with restricted airway access.<sup>42</sup>

In our study, we noted fewer failed intubation attempts for Combitube® and EasyTube® than for ETI. Our data also suggest, that intubation with Combitube® and EasyTube® can still be safely performed after a period of time, in which the technique is not practiced.

A recent paper by Chenaitia et al. described how physicians safely and effectively used EasyTube® in cases with difficult airway management in a pre-hospital setting, even with minimal training.<sup>43</sup> We also agree with Davis et al. that Combitube®, and in extension EasyTube®, are useful emergency airways, especially for paramedics.<sup>44,45</sup> In summary, the use of Combitube® and EasyTube® may be recommended especially in pre-hospital emergency situations, should an inexperienced operator be attending or repeated attempts of ETI fail.

A limitation of our study was the use of a manikin model, instead of patients. On the other hand, the advanced patient simulator SimMan® allows for realistic demonstration of the “normal” anatomical airway and provides good standardisation of the study conditions.<sup>23,24</sup> Therefore, these data need to be confirmed in a real-life scenario.

The skill retention data from the second evaluation were surprising to us.

ETI and insertion of LMA, LT-D and EasyTube® were carried out faster in the second than in the first evaluation. This was not demonstrated for I-Gel®, Combitube® and Proseal®, but does not appear to be clinically relevant. However, the insertion of the I-Gel® took 20 s less compared to the Combitube®/EasyTube®, which might be beneficial.

The reasons might be for I-Gel® that after insertion no further measures, such as blocking cuffs, have to be performed.

Proseal® performance was relatively poor in comparison to all other devices, including ETI. Combitube® took on average 36 s or 34 s. The longer average duration (however, clinically not relevant) can be explained by the two cuffs which need to be inflated.

In his paper, Konrad outlined that insufficient level of skill acquisition and retention may be the centre of poor anaesthesia and airway management.<sup>16</sup> Securing a difficult airway depends more on the experience of a rescuer than on a given airway device.<sup>46</sup> Consequently, performing successful airway management requires numerous training sessions, frequent retraining and regular clinic use and experience.

## 5. Conclusion

Within the limitations of this manikin setting, it might be suggested that in emergency situations safe and effective alternatives to ETI are available. ETI should preferably only be performed by trained and experienced paramedics or physicians. In inexperienced hands and used irregularly, ETI is difficult to perform



and can cause substantial morbidity and mortality if positioned incorrectly. Inexperienced medical staff including paramedics may therefore benefit from airway management using supraglottic airway devices.

The data obtained in our manikin study show that LMA, LT-D®, I-Gel®, Combitube® and EasyTube® are easy to use and effective alternatives to ETI. LMA, LT-D®, I-Gel®, Combitube® and EasyTube® are fast techniques and even in the relatively inexperienced hands of our volunteers high success rates in applying the devices were achieved. The use of the ProSeal appears to be questionable.

Further studies, ascertaining the risk of aspiration, feasibility and effectivity for various supraglottic airway devices in prehospital environment, such as during cardiopulmonary resuscitation, would provide an additional context in which medical staff could evaluate the risks and benefits of to the varying approaches for securing an airway in emergency situations.

### Conflict of interest statement

Supported by a grant of the Government of Vorarlberg/Austria.

The sponsor was not involved in data collection, analysis or interpretation; the manuscript was written by the investigators.

Michael Frass is the inventor of the Combitube® and has received royalties from Covidien. This study was not influenced in any way.

None of the other authors has a personal or financial interest in this research.

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