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Original Contribution

Tracheal intubation using intubating laryngeal tube iLTS-D™ and LMA Fastrach™ in 99 adult patients: A prospective multicentric randomised non-inferiority study

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ABSTRACT

Study objective: This study aimed to investigate the overall success of tracheal intubation using the intubating Laryngeal Tube Suction-Disposable (iLTS-D™, VBM, Sulz a. N., Germany) compared to the Laryngeal Mask Airway (LMA) Fastrach™ (Teleflex, Athlone, Ireland). We hypothesised that the iLTS-D™ would be non-inferior to the LMA Fastrach™ for tracheal intubation and ventilation.
Design: Multicentric, non-inferiority, randomised controlled study.
Setting: Operating rooms from two tertiary and one secondary centre in Switzerland from January 2017 to July 2019. The investigators were trained anaesthetists with extensive experience with laryngeal masks but limited to laryngeal tubes. The study was discontinued after the planned interim analysis.
Patients: Ninety-nine adult patients were included after randomisation. The inclusion criteria were American Society of Anesthesiologists physical status 1 to 3 in patients scheduled for elective surgery requiring tracheal intubation. Patients with a history of difficult intubation were excluded.
Intervention(s): After anaesthesia induction and once neuromuscular blockade was obtained, ventilation was initiated, and tracheal intubation was performed through the randomised device with the flexible endoscope tip placed proximally to the tip of the tracheal tube (visualised blind intubation).
Measurements: The primary outcome was the intubation success rate after two attempts. The secondary outcomes were time to intubation, successful ventilation rate, time to achieve ventilation, and gastric access success rate.
Main results: The overall intubation success rate was significantly higher in the Fastrach™ group than in the iLTS-D™ group (91.8% vs 70.0%, $p = 0.006$). No difference was found in the ventilation success rate (94% for iLTS-D™ and 100% for LMA Fastrach™ [$p = 0.829$]). The time to achieve ventilation and intubation were similar between the groups. No major airway complications were noted.
Conclusions: Although both supraglottic devices provided the same effective ventilation rate, the LMA Fastrach™ was superior to the iLTS-D™ as a conduit for intubation in 99 adult patients without a known difficult intubation. These preliminary results need to be confirmed in studies that include a larger population.
Trial registration: Clinicaltrials.gov, 21.09.2016, Identification Number NCT02922595.

1. Introduction

Supraglottic airway devices (SADs) have been increasingly used in airway management [1] and are some of the most difficult airway guidelines [2,3]. In specific settings, SADs are used as rescue devices in failed intubations [4,5] and specific models have been designed to facilitate tracheal tube (TT) placement through their ventilation channels. Even among experienced hands, tracheal intubation through an SAD has a widely variable success rate, ranging from 15% to 99% [6–9].

The intubating laryngeal mask LMA Fastrach™ (Teleflex, Athlone, Ireland) is a well-established first-generation laryngeal mask specifically designed for tracheal intubation and remains the gold standard for blind

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and flexible endoscope-guided intubation [10–13].

The intubating Laryngeal Tube Suction-Disposable (iLTS-D™, VBM, Sulz a. N., Germany) (Fig. 1) is a recent evolution of the laryngeal tube LTS-D™ (VBM, Sulz a. N., Germany), an established supraglottic device which has been identified as being quick and easy to insert, even by untrained personnel, with a high success rate and good airway sealing pressure for ventilation [14–16]. The iLTS-D™ has been specifically designed to allow tracheal intubation through its ventilation conduit. The first published studies on the new iLTS-D™ demonstrated it to be easy to insert, allowing quick access to oxygenation and ventilation [17–19], making this second generation SAD a potential reference for SAD-assisted intubation.

While many studies have compared the LMA Fastrach™ to other SADs for blind intubation [7,9,20], there is limited data about blind intubation for the general population using the iLTS-D™ [17,21].

This multicentre prospective randomised patient-blinded non-inferiority study aimed to investigate the overall success of visualised blind tracheal intubation using the iLTS-D™ compared to the LMA Fastrach™ in an adult population without known difficult intubation scheduled for elective surgery. We hypothesised that the iLTS-D™ would be non-inferior to the LMA Fastrach™ for tracheal intubation and ventilation while providing gastric access.

2. Materials and methods

After the approval provided by the Research Ethics Committees ('Commission cantonale d'éthique de la recherche sur l'être humain', Av. de Chailly 23, 1012 Lausanne, Suisse [Chairman: Prof. P. Francioli] and 'Comitato etico cantonale Ticino', approval 2016-00902 on the 05.12.2016), patients were included in this prospective randomised controlled patient-blinded multi-centre trial. The study was conducted at two tertiary centres (Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, Switzerland and Hospital Cardiocentro of Ticino in Lugano, Switzerland) and one secondary centre (Hospital Riviera-Chablais, Rennaz, Switzerland). Patients were included in the study after obtaining written informed consent. They were randomised to either the LMA Fastrach™ (LMA Fastrach™ group) or the iLTS-D™ (iLTS-D™ group) in a 1:1 ratio.

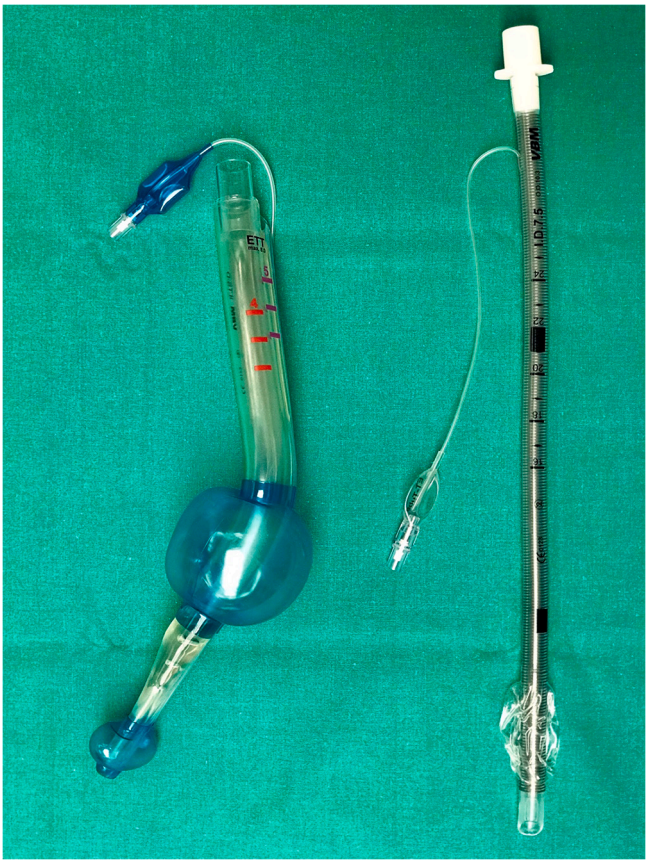

Fig. 1. The intubating Laryngeal Tube Suction-Disposable (iLTS-D™).

Randomisation for all three centres was performed by the primary investigator of the study using an online randomisation software (www.randomization.com) and stratified for each centre. Allocation was not disclosed and placed in sealed envelopes, which were opened by the investigator at each site after obtaining the patient's consent. The investigator enrolled the patients at each site. This manuscript adheres to the CONSORT guidelines.

All investigators were certified trained anaesthetists, and the procedure was always performed by the same investigator at each site. They were all experienced with the use of laryngeal masks (more than 100) as part of their routine practice. They also occasionally used Fastrach™ as a conduit for blind intubation for training and teaching purposes. None of them had extensive experience with laryngeal tubes (less than 10), but they trained on manikins and used them in a limited number of patients prior to the study. A senior anaesthetist with experience with a flexible endoscope provided endoscopic control of the procedure.

The study population comprised patients scheduled for different types of elective surgery: general surgery; ear, nose, and throat surgery; neurosurgery; and cardiothoracic surgery under general anaesthesia requiring tracheal intubation. Patients of both sexes with an American Society of Anesthesiologists (ASA) physical status of one to three were included. The exclusion criteria were: ASA physical status 4, patients with known difficult intubation or inability to insert a supraglottic device, height of less than 155 cm, previous airway surgery, risk of aspiration at the time of operation, or inability to provide informed consent.

Pre-operative evaluation, anaesthesia, and post-operative follow-up were provided by the anaesthetist in charge of the patient in accordance with the standard practice of the participating anaesthesia centre. After pre-oxygenation with a facemask delivering 100% oxygen to obtain an end-expiratory oxygen concentration above 90%, general anaesthesia was induced with propofol (1.5–3 $mg.kg^{-1}$) and fentanyl (2–3 $\mu g.kg^{-1}$). After successful mask ventilation, neuromuscular blockade was obtained with rocuronium (0.6 $mg.kg^{-1}$). Mask ventilation was performed until complete neuromuscular blockade was achieved (Train Of Four, 0/4).

The size of Fastrach™ was selected and inserted according to the manufacturer's recommendations [22]. The one-size iLTS-D™ is indicated for patients with a height greater than 155 cm. The SAD cuff was inflated to the manufacturer's specified volumes or pressure with a standard syringe (Fastrach™ group) or a specific colour-coded syringe, with each colour corresponding to a certain volume matching the patients' size (iLTS-D™ group) [18].

Ventilation was considered successful if an end-tidal carbon dioxide curve was obtained using capnography. The time required for ventilation was measured by an external observer from the time at which the investigator touched the supraglottic device to the time at which end-tidal carbon dioxide was identified on capnography on the anaesthesia machine. Continuous positive pressure was then applied to assess the presence of any audible air leak, and the leak pressure was recorded. A maximum of two ventilation attempts were allowed. If an air leak was audible below a positive pressure of 15 cmH_20, the SAD was withdrawn and a second attempt was initiated. If successful ventilation was not achieved after two attempted insertions of the supraglottic device, the procedure was considered to have failed, and the device was withdrawn. In such cases, facemask ventilation was resumed, and tracheal intubation was performed according to the standard practice of the participating anaesthesia centre.

In case of successful ventilation, the investigator performed "visualised blind" tracheal intubation through the supraglottic device. As already described in the literature [6,21,23], the 'visualised blind intubation' consists of the placement of a flexible endoscope (Karl Storz,

Tuttlingen, Germany) in the endotracheal tube, proximal to its tip, allowing visual control of the progression of the tube without providing guidance for tracheal intubation (Fig. 2). In our study, an experienced airway provider assessed tube insertion and interrupted the procedure if this person believed that there was a risk of laryngeal injury when the endotracheal tube impinged a laryngeal structure. The investigator performing the intubation was blinded to the endoscopic image during the procedure, and no information was provided by the second anaesthetist. The TT provided by the manufacturer was used for both devices. Intubation was considered successful once the end-tidal carbon dioxide was recorded on capnography on the anaesthesia machine. The time to intubation was defined as the time at which the TT was touched by the investigator until that at which the end-tidal carbon dioxide was recorded on capnography. A maximum of two intubation attempts were allowed, and the procedure was discontinued in case of a drop in the oxygen saturation (SpO2) below 90%. Between the two attempts, the investigator had the option to remove and reposition the supraglottic device. In cases of failed intubation, the anaesthetist who controlled the endoscope recorded the reason for failed intubation identified on the endoscopic image (oesophageal intubation, endotracheal tube impacting an identified laryngeal structure, or not).

After successful intubation in the iLTS-D™ group, a gastric tube was inserted and its correct positioning was confirmed via gastric auscultation of air injected into the tube.

The SAD was then withdrawn, leaving the endotracheal tube in place, using a stylet provided by the manufacturers.

The primary endpoint was the intubation's overall success rate (i.e. success in the first or second attempt). Success was defined as tracheal intubation confirmed via the end-tidal carbon dioxide recorded on the anaesthesia machine. The secondary endpoints included the first-attempt intubation success rate, time to intubation, successful ventilation rate, time to ventilation, and successful gastric tube insertion (only for the ITLS-D ™ group). Airway complications, defined as sore throat (EVA score), haemoptysis, dysphagia, and change in voice after 1 h in the recovery room and 24 h postoperatively, were recorded by a blinded independent observer.

Considering the published data on the success rate of blind intubation using LMA Fastrach™ [10,11,24], notably the 92.2% success rate obtained by Baskett et al. in a general population of 500 patients, the intubation success rate after two attempts with both devices was hypothesised to be 92%. With a non-inferiority margin of 10%, type I error rate of 5%, and desired achieved power of 80%, the calculation yielded a total sample size of 184 patients. Considering the potential dropouts, 198 patients were included and allocated to the three participating centres. To assess the improvement in our performance to achieve effective ventilation and successful intubation with both devices, we performed a Kruskal–Wallis equality-of-populations rank test. Since all investigators were accustomed to using laryngeal masks in their daily practice, we considered a bias in favour of the Fastrach™ group. We divided each group into three subgroups in chronological order to determine if there was a progression in our performance, especially with the iLTS-D™.

An interim analysis was planned after the inclusion of 50% of patients with regard to statistical safety and efficacy, and the study would be discontinued if the superiority of either group was already established. Microsoft Excel (Microsoft ® Corporate Headquarters, Redmond, USA) and STATA (Version 16.0, StataCorp, College Station, Texas, USA) were used for data collection and statistical analysis, respectively. The results of quantitative data are presented either as median plus interquartile ranges (for data with a non-Gaussian distribution) or mean ± standard deviation (SD) (for normally distributed data). Categorical data were summarised as the percentage of the total group. For quantitative data, differences in distribution between the two groups were evaluated using either the Wilcoxon/Mann–Whitney rank test (for data with non-Gaussian distribution) or Student's *t*-test (for normally distributed data). Statistical significance was set at $P < 0.05$.

3. Results

The study was terminated after the planned interim analysis because of a significant difference in the primary endpoint between the two groups. From January 2017 to July 2019, 99 patients were included without dropouts after randomisation into two groups: 50 patients in the Fastrach™ group and 49 in the iLTS-D™ group (Fig. 3). Each of the three participating centres recruited 33 patients. The patient characteristics are shown in Table 1.

The overall intubation success rate was significantly higher in the Fastrach™ group than in the iLTS-D™ group (91.8% vs. 70.0%, $p = 0.006$). After the first attempt, the intubation success rate was higher in the Fastrach™ group (81.6% vs 42.6%, $p = 0.001$). Table 2 documented

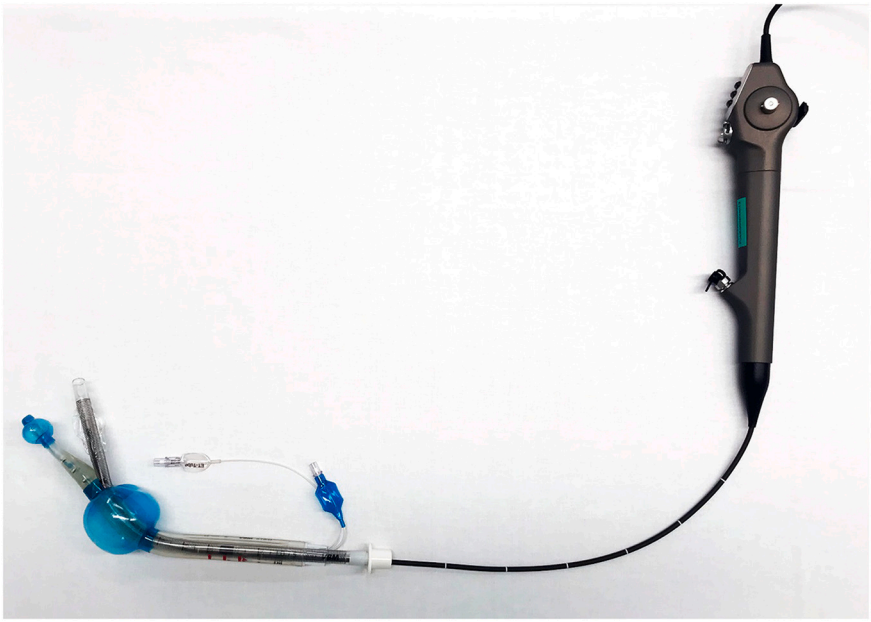

Fig. 2. Position of the flexible endoscope in the tracheal tube for intubation through the iLTS-D™.

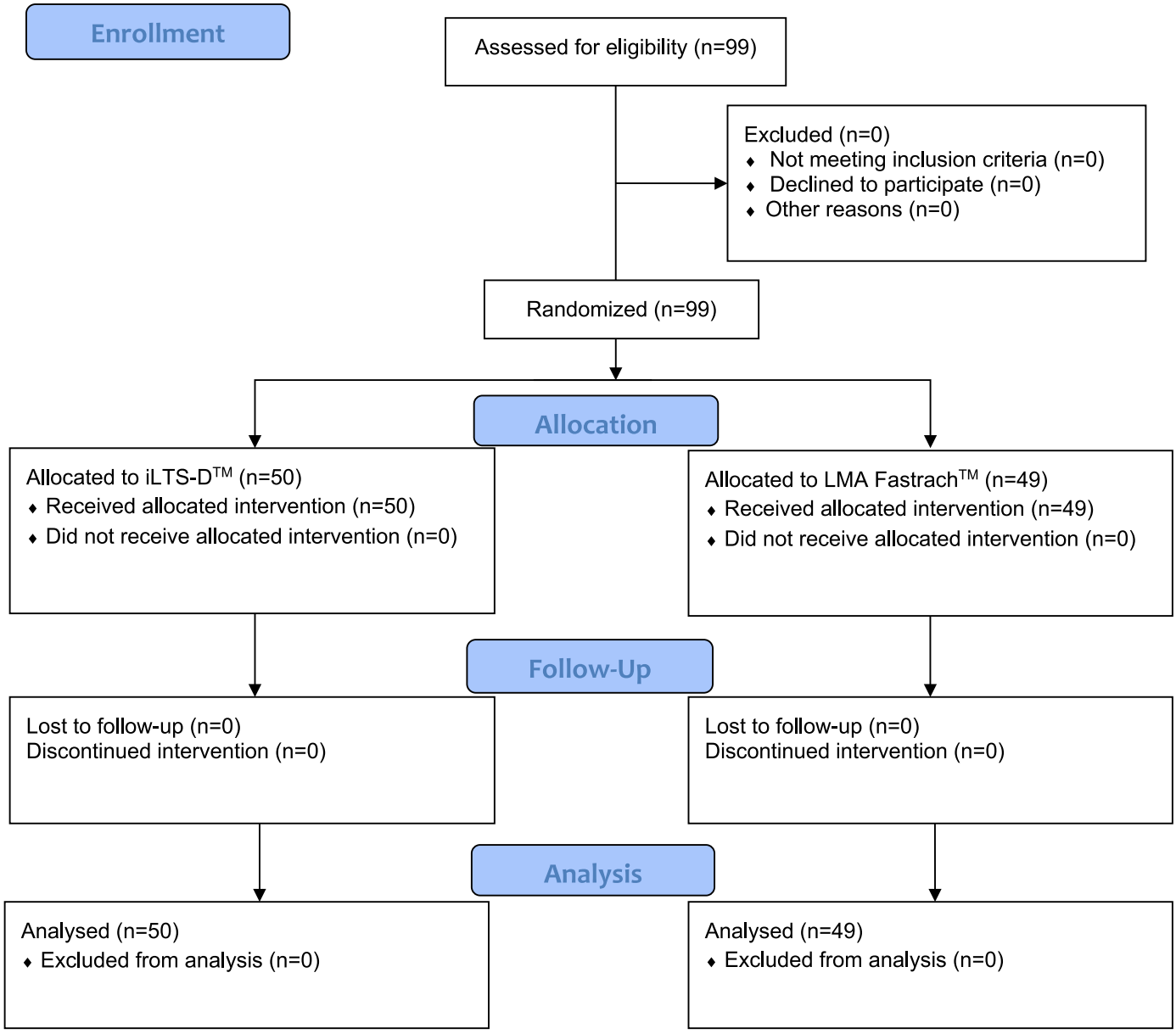

Fig. 3. Consolidated Standards of Reporting of Trials (CONSORT) flow diagram.

Table 1
Patient characteristics. Values are mean (SD), if variable is normally distributed, or median (IQR), when the variable is not normally distributed. Categorical variables will be presented as raw numbers (proportion). Inter-dental distance (IDD).

	iLTS-D™ group (*n* = 50)	LMA Fastrach™ group (*n* = 49)
Mean (SD) age [years]	52 (18.1)	58 (15.4)
Sex [n(%)]		
Male	30 (60%)	25 (51.0%)
Female	20(40%)	24 (49.0%)
Mean (SD) height [cm]	170.5 (8.4)	170.4 (8.6)
Mean (SD) weight [kg]	77.3 (15.7)	75.9 (17.6)
Mean (SD) BMI [Kg/m^2]	26.5 (4.9)	26.0 (5.0)
Median (IQR) Mallampati score	2 (1–2)	2 (1–2)
Mean (SD) thyromental distance [cm]	7.92 (2.07)	8.09 (1.75)
Mean (SD) mouth opening [cm]	4.72 (0.86)	4.64 (0.68)
Mean (SD) IDD [cm]	4.9 (0.8)	4.5 (1)

Table 2
Success rate and time for overall and first-attempt intubation and ventilation with iLTS-D™ and LMA Fastrach™. Values are mean (SD) or raw numbers (proportion).

	iLTS-D™ group (n = 50)	LMA Fastrach™ group (n = 49)	*p* value
Overall intubation success rate	35/50 (70%)	45/49 (91.8%)	0.006
First attempt intubation success rate	21/50 (42.6%)	40/49 (81.6%)	0.001
Intubation time; *sec*	43.6 (14)	50.4 (19)	0.59
Overall ventilation success rate	47/50 (94%)	49/49 (100%)	0.829
Effective ventilation time; sec	30.7 (11)	35.9 (18)	0.15

reasons for failed intubation in the iLTS-D™ group were impingement of the TT with an undefined laryngeal structure (83.3%, [20/24]) or oesophageal intubation (12.5%, [3/24]). In one patient in the iLTS-D™

group (4.2%, [1/24]), the procedure was discontinued due to desaturation below 90%. In the Fastrach™ group, 75% (6/8) of the documented failed intubations were associated with oesophageal intubation, while 25% (2/8) were caused by the TT contacting an undefined laryngeal structure.

In case of success, time to achieve intubation was similar between the two groups (43.6 s for the iLTS-D™ group vs 50.4 s for the Fastrach™ group, $p = 0.59$).

The successful ventilation rate was similar in the two groups, with 94% for the iLTS-D™ and 100% for the LMA Fastrach™ group ($p = 0.829$). The time required for effective ventilation did not reveal any significant differences between the two groups. Successful ventilation was achieved in 30.7 s in the iLTS-D™ group and in 35.9 s in the LMA Fastrach™ group ($p = 0.15$). No air leakage was detected in either device with cuffs inflated, as recommended by the manufacturer, when ventilation was successfully achieved.

In the iLTS-D™ group, successful gastric tube placement after intubation was achieved in 100% of the patients.

No major complications occurred during the study, and all patients recovered uneventfully owing to minor airway complications (Table 3). No significant difference was found between the two groups for all complications, while one patient in the iLTS-D™ group presented with transient bloody cough 1 h after the procedure. No accidental extubation was recorded while withdrawing the SAD.

There was no significant improvement in the investigators' performance for any outcome when each group was divided into three chronological subgroups.

Table 3
Airway complication rate after 1 and 24 h with iLTS-D™ or LMA Fastrach™. Pain is evaluated with visual analogue scale (EVA). Values are numbers (rate).

	iLTS-D™ group (n = 50)	LMA Fastrach™ group (n = 49)	P value
Haemoptysis			
No	43 (97.7%)	45 (100%)	0.309
Yes	1 (2.3%)	0	
Sore throat after 1 h; EVA score			
No	29 (65.9%)	34 (75.6%)	0.860
EVA 1	1 (2.3%)	1 (2.2%)	
EVA 2	6 (13.6%)	5 (11.1%)	
EVA 3	5 (11.4%)	4 (8.9%)	
EVA 4	2 (2.3%)	1 (2.2%)	
EVA 7	1 (2.3%)	0	
Sore throat after 24 h; EVA score			
No	38 (90.5%)	39 (86.7%)	0.555
EVA 1	1 (2.4%)	1 (2.2%)	
EVA 2	3 (7.1%)	1 (2.2%)	
EVA 3	0	1 (2.2%)	
EVA 4	0	1 (2.2%)	
EVA 5	0	1 (2.2%)	
EVA 6	0	1 (2.2%)	
Voice change after 1 h			
No	39 (88.6%)	42 (93.3%)	0.439
Yes	5 (11.4%)	3 (6.7%)	
Voice change after 24 h			
No	41 (97.6%)	44 (97.8%)	0.961
Yes	1 (2.4%)	1 (2.2%)	
Dry throat after 1 h			
No	32 (72.7%)	28 (62.2%)	0.290
Yes	12 (27.3%)	17 (37.8%)	
Dry throat after 24 h			
No	41 (97.6%)	45 (100%)	0.298
Yes	1 (2.4%)	0	
Dysphagia after 1 h			
No	43 (97.7%)	43 (95.6%)	0.570
Yes	1 (2.3%)	2 (4.4%)	
Dysphagia after 24 h			
No	42 (100%)	43 (95.6%)	0.167
Yes	0	2 (4.4%)	

4. Discussion

In this multicentre randomised study, we demonstrated that the LMA Fastrach™ has a significantly higher overall success rate for tracheal intubation than the laryngeal tube iLTS-D™ in a population of 99 adult patients scheduled for different types of elective surgery without known previous difficult intubations. The intubation success rate was also significantly higher with the LMA Fastrach™. No significant differences were identified in terms of the effective ventilation or time to ventilation.

The study was discontinued after the planned interim analysis because a significant difference was identified between the two devices in terms of the successful blind intubation rate.

The blind intubation success rates with the LMA Fastrach™ range from 91% to 100% [9,11,12,20,24–27] depending on the population studied, the number of attempts, and manoeuvres undertaken after a failed intubation. Our results concerning intubation after two attempts with the LMA Fastrach™ (91.8% success rate) are consistent with those of previous studies. Baskett et al. reported a 92.2% success rate after two attempts in a 500-patient multicentre trial [11]. Many studies have compared other supraglottic devices to the LMA Fastrach™ for blind intubation, but all have confirmed the superiority of the LMA Fastrach™ in this setting [7,9,20]. Studies have also reported a low blind intubation success rate with supraglottic devices in adult and paediatric patients [8,23]. The first studies on iLTS-D™ use have shown encouraging results, although they were mainly performed on manikins or a small number of patients. Ott et al. conducted a study on manikins, which showed comparable success rates and times between iLTS-D™ and LMA Fastrach™ [18]. The first clinical study conducted by Bergold et al. showed a success rate of 29 out of 30 patients without difficult intubation criteria after two attempts with fibrescopic assistance [17]. The first study to investigate iLTS-D™ for blind intubation was conducted in a specific population of 20 super-obese patients (BMI $> 50\ kg/m^2$) with an overall intubation success rate of 65% [28]. In an observational study, Reviriego-Agudo et al. studied the success rate of blind intubation with the iLTS-D™ in 31 patients from a general population and found a success rate of 32% after one attempt, and 61% after videoscope-guided correction manoeuvres [21]. These results are consistent with our low success rate (42.6%) after one and two attempts (70.0%) with reinsertion or mobilisation of the iLTS-D™, although we did not use endoscopic guidance.

In 83.3% of the cases, the reason for failed intubations with the iLTS-D™ device in our study was the tube being hindered forward in the device because of an impingement of the TT against a laryngeal structure. This occurred when the intubating channel was not properly aligned with the axis of the glottis. Although the laryngeal structure could not always be properly identified by the flexible endoscope operators, the TT was mostly positioned to the left of the glottis. One potential reason for the failure to intubate is the position of the gastric access channel on the right side of the device, which automatically shifts the intubation channel to the left side of the larynx. Furthermore, the iLTS-D™ is a one-size device for adult patients, and it is possible that the size does not match the laryngeal structures of all patients. Finally, the intubation channel lies immediately below the inflated pharyngeal cuff. This insufficient space between the device and laryngeal structures may prohibit the passage of the endotracheal tube into the glottis and may prevent adequate visualization for endoscopic-assisted intubation. iLTS-D™ may require changes in its design to be more suitable for intubation.

Both devices achieved effective ventilation and sufficient oropharyngeal sealing without any significant differences. Only one clinical study evaluated the success rate of ventilation for iLTS-D™ in the general population, with a success rate of 100% [21]. The iLTS-D™ differs slightly from the Laryngeal Tube Suction-Disposable LTS-D™, which is commonly used and studied [29–31]. Thee et al. notably compared the

LTS-D™ and the LMA Fastrach™ for ventilation with a 96.6% and 100% success rate, respectively [14]. One study performed by Schalk et al. found a ventilation success rate of 96.8% with LTS-D™ for out-of-hospital airway management by paramedics or emergency physicians [32]. Other studies have found success rates of 94%–96% for ventilation with LTS-D™ [15,16].

The time required to achieve ventilation was also similar for both the devices. Owing to the different methods used to measure the time required for insertion or to obtain effective ventilation, it is difficult to compare these results with those of previous studies. However, previous studies have shown a similar ventilation success rate between laryngeal tubes and LMA Fastrach™ [14,29].

No major airway complications were observed during the study, and minor airway complications were not significantly different between the two groups. The most common issues were sore throat and dry throat both at 1 and 24 h after recovery. Only one study has reported the incidence of minor airway complications after blind SAD intubation. Thee et al. reported a 30% incidence of sore throat, and bloody secretions were found in only one out of 30 patients in their LMA Fastrach™ group [14].

Our study had several limitations. All investigators had significantly more clinical experience with laryngeal masks than laryngeal tubes for both ventilation and intubation. To the best of our knowledge, there is no data on the learning curve of laryngeal tubes. Previous data have suggested that the learning curve flattens after 20 insertions of an intubating laryngeal mask [33]. We analysed three chronological subgroups which did not reveal any improvement in performance over time when using the iLTS-D™; however, the small number of patients analysed in each subgroup might have been too small to be able to identify a difference. This limitation could have influenced the time and success rate of intubation with this device, although the performance for insertion and ventilation was consistent with those reported in previous studies. Therefore, we could not document a change in the success rate that could be explained by the learning curve for iLTS-D™. The presence of a flexible endoscope inside the TT during intubation changes the configuration of the intubation. Although the latter was not used to guide the intubation, it might have changed the ease of intubation. Furthermore, the withdrawal of the flexible endoscope from the TT increased the time to record end-tidal CO_2 on capnometry, making it difficult to compare with other studies. Unfortunately, we did not record the investigators' subjective assessments of SAD insertion and intubation. The cuffs of both devices were inflated according to the manufacturer's recommendations; however, we did not measure the pressure needed to obtain a good seal. Our study did not standardise a specific head positioning for SAD placement. The head positioning was determined according to the investigator's preference. Recent data suggest that neck extension has a direct effect on the success rate of blind intubation using a laryngeal mask [34]. Conversely, another study did not find any significant difference in blind intubation success rate with the LMA Fastrach™ when comparing two different head positions [35]. Finally, patients with a known difficult intubation were excluded from the study. Our data cannot be extrapolated to this population, although these difficult patients may require blind SAD-guided intubation after failed laryngoscopic intubation.

As our study reveals, laryngeal tubes are recognised devices for effective ventilation; however, the LMA Fastrach™ remained superior for SAD-assisted intubation in our population of 99 adult patients scheduled for elective surgery. Although iLTS-D™ bears the advantage of gastric access, it requires design modifications to be suitable for blind intubation. The preliminary results provided by our study need to be confirmed in studies with larger populations, including patients with known difficult intubation.

Assistance with the article

None.

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Presentation

Results were presented as a poster at the World Airway Management Meeting (WAMM) in Amsterdam, NL, 13–16 November 2019 and as an oral presentation at the Swiss Anaesthesia 2021 congress in Geneva, Switzerland, 28–30 October 2021.

Disclosures

The study was funded by the Department of Anaesthesiology of the University Hospital of Lausanne (CHUV), Switzerland.

Declaration of Competing Interest

None.

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