

Laryngeal Mask Airway or Endotracheal Tube for Percutaneous Dilatational Tracheostomy: A Comparison of Visibility of Intratracheal Structures

Ulf Linstedt, MD, PhD,* Michael Zenz, MD,† Kirsten Krull, MD,* Dietrich Häger, MD,* and Andreas W. Prengel, MD, PhD†

PURPOSE: Some severe complications during percutaneous dilatational tracheostomy (PDT) may be related to poor visualization of tracheal structures. Subjectively, the bronchoscopic view obtained via a laryngeal mask airway (LMA) seems to be better than that obtained with an endotracheal tube (ETT). In this prospective, randomized study, we compared LMA and ETT as the ventilatory device during PDT mainly with respect to visualization of tracheal structures. The quality of ventilation and airway-related complications are also reported.

METHODS: In this prospective, randomized study, PDT was performed using an LMA ($n = 33$) or an ETT ($n = 30$). Quality of ventilation and visualization of tracheal structures (thyroid, cricoid, and tracheal cartilages) were rated as follows: very good (1), good (2), difficult (3), and not possible (4) with LMA/ETT. A rating of 4 required the alternate airway. Groups were compared using the χ^2 test.

RESULTS: Visualization of tracheal structures was better with the LMA: ratings were 1 or 2 in 94% of patients with an LMA, compared with 66% of patients with an ETT ($P < 0.05$). Visual control during puncturing the trachea was 1 or 2 in 97% of patients using an LMA and 77% of patients for an ETT ($P < 0.05$). A rating of 4 was assigned to 1 patient with an LMA and to 3 patients with an ETT. Hemodynamic variables were similar in both groups. Blood gas analysis during PDT showed decreased P_{aO_2} in both groups, and increased P_{aCO_2} , which was more pronounced with an ETT compared with an LMA (59 ± 14 mm Hg and 51 ± 11 mm Hg [$P < 0.05$]). In the ETT group, 2 patients were extubated accidentally, and in another patient, the bronchoscope was damaged because of insufficient visualization of the tracheal puncture site.

CONCLUSION: The LMA technique showed definite advantages regarding visualization of relevant tracheal structures and the dilation process compared with an ETT. This may be especially relevant in the hands of inexperienced intensivists and in cases of difficult patient anatomy where improved structural visualization optimizes operating conditions. (Anesth Analg 2010;110:1076–82)

Percutaneous dilatational tracheostomy (PDT) is a method routinely used to facilitate long-term ventilation in intensive care patients.¹ In Germany, PDT was used in >20,000 cases in 2001.² Despite the fact that PDT is technically easy to perform, complications may occur, some potentially serious, e.g., damage to the dorsal tracheal wall, punctures lateral to the midline, or above the first tracheal cartilage, injuries during dilation, endotracheal tube (ETT) cuff rupture, and loss of airway by accidental extubation with subsequent hypoxia.^{3,4} The rate of severe complications is 3% to 17%.^{4–8} The majority of these complications may be related to insufficient visualization of the puncture site or the dilating process.

Generally, ventilation and bronchoscopy are performed using an ETT. However, in our institutions, we use laryngeal

mask airways (LMAs) during PDT. The need to overcome some ETT-related problems, particularly damage to the bronchoscope led us to this change.⁹ Soon after introduction of the LMA in our institutions, the intensivists involved reported the impression that their ability to visualize the tracheal structures during PDT was improved; the thyroid, cricoid, and tracheal cartilages seemed to be more clearly identifiable. Apparently, positioning the bronchoscope's tip closer to the vocal cord level improved the ability to see all relevant structures inside the trachea simultaneously. These intensivists had the impression that the ETT often offered a poorer overview inside the trachea, because the bronchoscope's tip is placed at least 1 to 2 cm below the vocal cords, often causing the thyroid cartilage to not be visible.

No previous study has compared the quality of visualization of tracheal structures between an ETT and an LMA. This issue is important because improved visualization may result in decreased frequency of severe complications during PDT. We hypothesized that visualization of key anatomical structures during PDT is superior using LMA devices compared with standard access via an ETT.

METHODS

This prospective, randomized study was approved by the IRB (ethics committee of the Medical Faculty of the University of Kiel).

After providing written informed consent, all patients assigned for PDT were randomized into groups of 33

From the *Department of Anesthesiology, Intensive Care Medicine and Pain Therapy, Diako Hospital, Flensburg, Academic Teaching Hospital of the University of Kiel; and †Department of Anesthesiology, Intensive Care Medicine, Pain Therapy and Palliative Care, Knappschaftskrankenhaus, Ruhr University, Bochum, Germany.

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Address correspondence and reprint requests to Priv.-Doz. Dr. Ulf Linstedt, Klinik für Anaesthesiologie, operative Intensivmedizin und Schmerztherapie, Diakonissenkrankenhaus Flensburg, Marienhölungsweg 2, D 24939 Flensburg, Germany. Address e-mail to linstedtul@diako.de.

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patients using either an ETT or an LMA as ventilatory devices during the procedure. This number of patients was calculated to achieve the statistical power ($\alpha < 0.05$, $\beta < 0.2$) with the assumption of improving the rate of very good/good visualization from 65% to 95%. Randomization was obtained by a computer-generated randomization list. Patients with contraindications for a PDT were not included, i.e., difficult airway, potentially difficult endotracheal intubation, oxygenation index ($\text{PaO}_2/\text{fraction of inspired oxygen} [\text{FiO}_2]) < 200$, and positive end-expiratory pressure (PEEP) ≥ 15 mbar.

In cases of mental incompetency as a result of sedation or cerebral illness, informed consent was obtained from the patient's legal representative.

Performance of PDT

FiO_2 was set at 1.0, the ventilation mode was "biphasic positive airway pressure" (BIPAP, Evita 4, Draeger, Germany). Sedation with sufentanil/midazolam was continued. Patients received cisatracurium $0.1 \text{ mg} \cdot \text{kg}^{-1}$ for muscle relaxation; additional sufentanil and propofol boluses were given when there were hemodynamic responses to surgical stimuli. After enteral nutrition had been stopped 6 hours before the procedure, the gastric tube was removed before PDT. Five milliliters bupivacaine 0.5% with epinephrine 0.01 mg/mL was injected locally at the site of designated tracheal puncture between the first and second or second and third tracheal cartilage.

PDTs were performed by intensivists with an experience of at least 10 PDTs (range was 10–200 PDTs).

LMA Group

An LMA Classic™ (LMA Deutschland, Bonn, Germany) or a single-use LMA (Solus, Teleflex Medical, Kernen, Germany) was introduced behind the ETT in situ, which was removed after the LMA was in the correct position. The LMA size was no. 4 in women and no. 5 in men. Subsequently, the LMA was secured with tape, and the patient's head was extended. Inspiratory pressure was adapted to reduce excessive air leakage, when necessary. The video bronchoscope (BF 18V, Pentax, Japan) was inserted through the LMA into the trachea, and the thyroid and cricoid cartilages and the upper 3 tracheal cartilages were identified. After this, the tip of the bronchoscope was placed 0 to 1 cm below the vocal cords to maintain thyroid cartilage visualization.

ETT Group

The cricoid and thyroid cartilages were palpated, and the first tracheal cartilage's position was marked. Afterward, the bronchoscope was inserted into the ETT up to the tip of the ETT. Subsequently, the ETT and bronchoscope were positioned directly above the marked position. This step was visualized by transillumination and assisted by an additional person responsible for positioning and fixation of the ETT. Besides inspiratory pressure, ventilation variables were not modified. The ETT size was 7.0 mm (internal diameter) in women and 7.5 mm in men.

The PDT was performed according to the Griggs method¹⁰ (Portex Griggs-Set, Smiths Medical, Colonial Way, Watford, UK). After skin incision, puncture of the

trachea was guided bronchoscopically to the midline of the trachea below the first or second tracheal cartilage. Introducing the guidewire, the dilation process with Griggs dilating forceps, and introducing the tracheostomy tube were also monitored bronchoscopically. Before connecting the ventilator, the intratracheal position of the cannula was verified by a tracheobronchoscopy through the tracheostomy tube.

Evaluation of PDT Using ETT Versus LMA

The operating intensivist evaluated the practicability of PDT steps with the LMA and ETT, respectively, using a standardized 4-step rating from 1 (very good) to 4 (not possible with the randomly selected airway) (more detailed description in Appendix 1, see Supplemental Digital Content 1, <http://links.lww.com/AA/A116>). The following steps and events were evaluated during PDT:

- Degree of difficulty: LMA, insertion; ETT, preparation.
- Degree of difficulty in introducing the bronchoscope into the LMA and ETT, respectively.
- Identification of thyroid cartilage, cricoid cartilage, and first to third tracheal cartilage.
- Visualization of tracheal circumference.
- Monitoring puncture in the midline + below first or second tracheal cartilage.
- Monitoring of anterior wall and pars membranacea during dilation.
- Quality of ventilation before puncture and most impaired ventilation during PDT, respectively.

According to the study protocol, a rating of 4 required a change of the airway to the alternative route (ETT to LMA and LMA to ETT). These patients were rated 4 in this and in the following items (intent to treat).

For comparison of hemodynamics, blood gases, and ventilatory variables between groups, the unpaired *t* test was used. Sequential analysis was corrected according to Bonferroni. These parameters are presented as mean \pm SD. The assessment of the feasibility of PDT with an ETT and LMA was compared between groups with the χ^2 test. $P < 0.05$ was regarded as significant. For statistical analysis, we used SPSS, Version 11.0 (SPSS, Chicago, IL).

RESULTS

Patients in both groups were comparable with respect to demographic characteristics and to initial ventilatory and hemodynamic variables. In the ETT group, consent was withdrawn in 3 cases, resulting in a group size of 30 patients (Table 1).

The time necessary for placing the bronchoscope and the airway at the site sufficient to identify all relevant structures inside the trachea (LMA 4 ± 4 minutes; ETT 4 ± 3 minutes) and the time from tracheal puncture to insertion of the tracheal tube (LMA 11 ± 6 minutes; ETT 13 ± 10 minutes) did not differ between the groups.

Ventilation, Cardiovascular System, and Complications

Minute ventilation and PaO_2 (Table 2) decreased in both groups but were not significantly different between the groups. Immediately before tracheal puncture, PaO_2 was

Table 1. Patient Characteristics

| | LMA | ETT |
|------------------------------------|--------------------|-------------------|
| Age (y) | 55 ± 18 | 58 ± 15 |
| Sex (M/F) | 17/16 | 18/12 |
| Weight (kg) | 78 ± 19 (50–135) | 82 ± 20 (50–130) |
| Height (cm) | 173 ± 11 (154–196) | 174 ± 7 (164–187) |
| Body mass index | 26 ± 5 (18–42) | 27 ± 6 (18–46) |
| Pao ₂ /Fio ₂ | 382 ± 117 | 391 ± 116 |
| Neurosurgery | 25 | 21 |
| Trauma surgery | 1 | 2 |
| General surgery | 6 | 4 |
| Medicine | 1 | 2 |
| Neurology | 0 | 1 |

LMA = laryngeal mask airway; ETT = endotracheal tube. Data are presented as mean ± sd, (range), and count.

<100 mm Hg in 1 patient in the LMA group (76 mm Hg) and in 3 patients in the ETT group (57, 57, and 48 mm Hg). Paco₂ increased in both groups and was higher during PDT with an ETT than with an LMA (*P* < 0.05) (Table 2). Arterial blood pressure did not differ between groups (Table 2).

In the ETT group, 2 accidental extubations, 1 laceration of the rear tracheal wall, and 1 damage of the bronchoscope occurred (Table 3).

One patient in the LMA group was rated 4 because of failure of LMA insertion. In this patient, it was not possible to place the LMA without excessive air leakage. The PDT in this patient was performed after reintubation of the trachea with an ETT; oxygen saturation was always >95% during

this period. All of the following items for this patient were rated 4 as well (Table 3). Two LMA insertions were successful only after a few attempts (rating 3).

After successful LMA insertion or tube retraction, ventilation was rated “good” or “very good” in most cases. No complications were observed using an LMA. Ventilation was rated 4 in 3 patients using an ETT (Table 3).

Visualization of Tracheal Structures and Feasibility

Ratings were not different between groups for insertion of the bronchoscope through the ETT or LMA (Fig. 1). However, in 1 patient in the LMA group, it was difficult to guide the bronchoscope through the vocal cords (rating 3).

Visualization and identification of relevant intratracheal structures were rated differently between the groups. Only 1 patient (3%) in the LMA group was not rated “good” or “very good” before tracheal puncture. In contrast, relevant structures could not be reliably identified in 10 patients in the ETT group (*P* < 0.01) (Appendix 2, see Supplemental Digital Content 2, <http://links.lww.com/AA/A117>; Fig. 2A).

There were no restrictions during tracheal puncture and dilation in the LMA group; all ratings were “good” or “very good.” In the ETT group, in 5 patients, tracheal structures were only poorly visible during puncture and dilation of the trachea (*P* < 0.01) (Figs. 2, B and C, 3, and 4).

DISCUSSION

This study shows that the use of an LMA instead of an ETT during bronchoscopically controlled PDT significantly improves the visualization of relevant tracheal structures.

Table 2. Minute Ventilation (MV) (L/min), Positive End-Expiratory Pressure (PEEP) (mm Hg), Mean Arterial Blood Pressure (MAP) (mm Hg), Before Percutaneous Dilatational Tracheostomy (PDT), Before Puncture of the Trachea (Bronchoscope Inserted), and Minimal Values for at Least 1 min. Pao₂ and Paco₂ (mm Hg) were Obtained Before PDT, Before Puncture of the Trachea, and 1 min After Completing PDT

| | Before starting PDT (Fio ₂ = 1.0) | | | Before puncture of the trachea | | | Minimal value during PDT | | |
|-------------------|--|-----------|----------|--------------------------------|-----------|----------|--------------------------|-----------|----------|
| | LMA | ETT | <i>P</i> | LMA | ETT | <i>P</i> | LMA | ETT | <i>P</i> |
| MV | 8.2 ± 2.4 | 8.7 ± 3 | 0.5 | 5.4 ± 3 | 4.8 ± 4.2 | 0.5 | 4.8 ± 4 | 3.7 ± 4.2 | 0.3 |
| PEEP | 8 ± 3 | 9.6 ± 4.5 | 0.06 | 6.3 ± 3 | 6.9 ± 4.6 | 0.6 | — | — | — |
| MAP | 87 ± 16 | 87 ± 17 | 0.9 | 91 ± 20 | 98 ± 26 | 0.3 | 84 ± 18 | 82 ± 19 | 0.7 |
| | Before starting PDT (Fio ₂ = 1.0) | | | Before puncture of the trachea | | | 1 min postoperatively | | |
| Pao ₂ | 384 ± 118 | 393 ± 113 | 0.7 | 371 ± 129 | 383 ± 141 | 0.7 | 285 ± 152 | 296 ± 150 | 0.8 |
| Paco ₂ | 43 ± 8 | 44.4 ± 12 | 0.7 | 51 ± 11 | 59 ± 14 | 0.01 | 55 ± 16 | 63 ± 17 | 0.07 |

Data are presented as mean ± sd; the *P* value indicates the significance level for the comparison between patients ventilated with laryngeal mask airway (LMA) and endotracheal tube (ETT).

Table 3. Patients with Assessment of Grade 4 and with Severe Complications During Percutaneous Dilatational Tracheostomy (PDT)

| Patient no., sex | Group | Description of the complication | Management of the complication |
|------------------|-------|--|---|
| 17, male | ETT | No adequate position for the bronchoscope was found. | Insertion of LMA and further procedure without any problem |
| 19, female | ETT | No ventilation possible after puncture of the trachea 1 min postoperatively: Pao ₂ 22 mm Hg | Advancing PDT and inserting tracheostomy tube within <1 min (faster than changing airway) |
| 40, male | ETT | Accidental extubation No view on structures inside trachea Puncture of bronchoscope | Insertion of LMA and further procedure without any problem |
| 45, male | ETT | Accidental extubation Damage of rear tracheal wall | Reintubation Advancing PDT with ETT |
| 62, female | LMA | Insertion of LMA not possible | Tracheal intubation with ETT and further procedure without any problem |

LMA = laryngeal mask airway; ETT = endotracheal tube.



Figure 1. Ventilation with the laryngeal mask airway (LMA). The tip of the bronchoscope inside the LMA is situated above the aperture of the larynx. Introduction and passage of vocal cords were rated “1.”

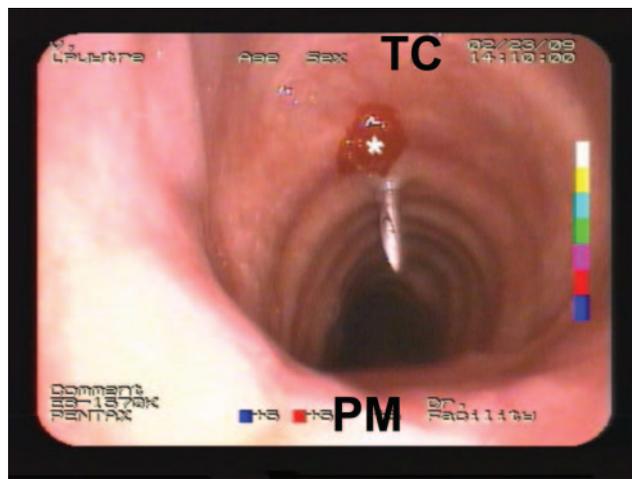


Figure 3. Ventilation with a laryngeal mask airway, and puncture of the trachea. *First puncture attempt, which was considered above the first tracheal cartilage. TC = thyroid cartilage; and PM = pars membranacea.

This was presumed by some observational studies^{4,9,11} but never before documented in a prospective, randomized study. In our opinion, the improved visibility of tracheal structures should decrease the incidence of such complications that are related to impaired overview inside the trachea. These complications are damage to the rear tracheal wall,^{12–14} puncture lateral to the midline or above the first tracheal cartilage,¹⁵ injury during dilation,^{6,13,15} ETT cuff rupture^{4–8,13,14} and loss of airway by accidental extubation^{4,5,8} with subsequent hypoxia,^{5,13,14} and puncture of the bronchoscope.^{16,17}

In this study, it was shown that improved visualization with an LMA was achieved because the tip of the bronchoscope could be positioned at the level of the vocal cords. Thus, in contrast to an ETT, the thyroid cartilage was almost always

identified easily (Fig. 5). Identification of the prominent thyroid cartilage allowed for reliable and easy definition of the cricoid and tracheal cartilages. Furthermore, unwanted displacement of the bronchoscope was recognized immediately by the disappearance of the thyroid cartilage from the visual field. Besides the probability of decreasing the frequency of some complications, the performance of PDT is clearly facilitated both in patients with anatomical difficulties (short neck and obesity) and in the education of PDT to inexperienced physicians. Furthermore, placing the bronchoscope’s tip at the vocal cord level prevented the bronchoscope from being damaged by the puncture needle during PDT.

In 2 patients with the ETT, difficulty identifying the thyroid cartilage required the withdrawal of the ETT until its tip came very close to the level of the vocal cords and

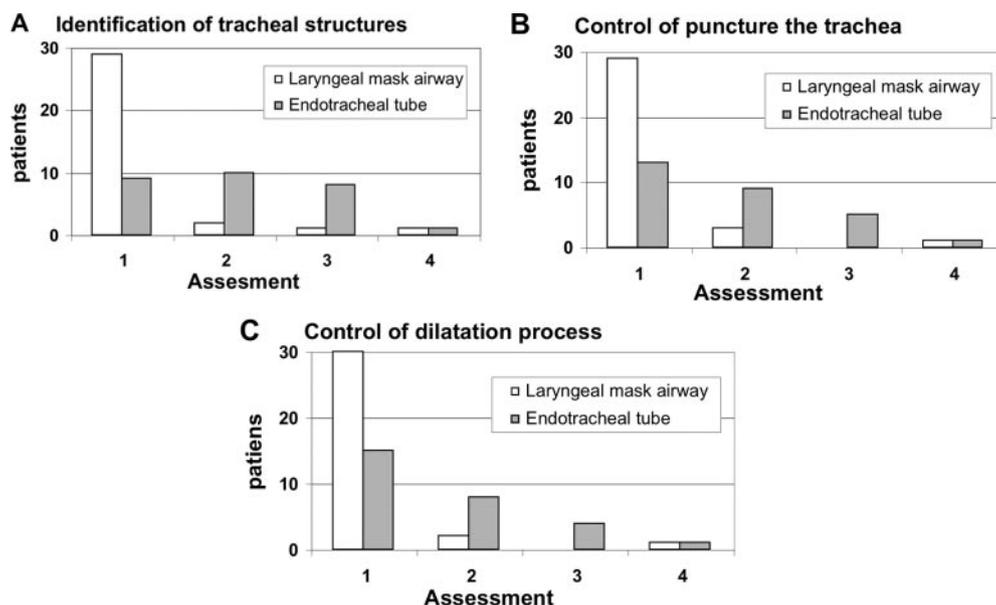


Figure 2. Rating of the bronchoscopic visualization of structures inside the trachea (thyroid cartilage, cricoid cartilage, and first to third tracheal cartilages [A]), of the monitoring of the puncture of the trachea (B), and of the dilatational process (C). The assessment was “very good” (1), “good” (2), “difficult” (3), and “impossible” (4) during percutaneous dilatational tracheostomy.

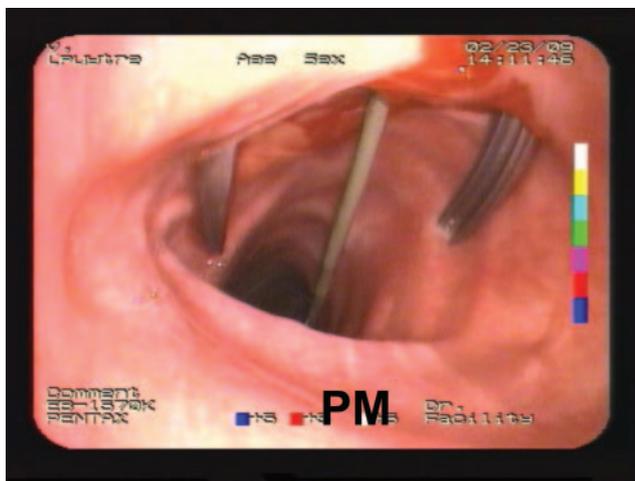


Figure 4. Ventilation with a laryngeal mask airway. View inside the trachea during the dilation procedure. The wall of the pars membranacea (PM) seems to be stressed, and the dilating force has to be reduced to avoid damage to the PM. Monitoring of dilation was rated “1.”

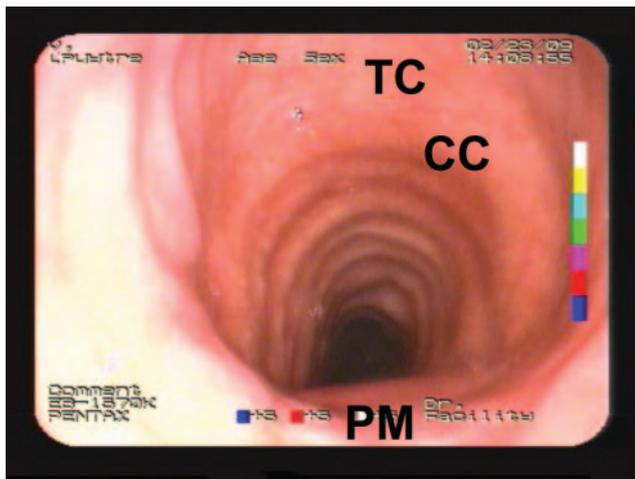


Figure 5. Ventilation with the laryngeal mask airway (LMA). View inside the trachea after passage of the vocal cords. Cricoid tracheal cartilage (CC), thyroid cartilage (TC), tracheal cartilages and pars membranacea (PM) were identified easily. Quality of identification of these structures was rated “1.” View of trachea’s circumference was rated “2.”

resulted in accidental extubation. This complication using an ETT was reported to occur in 1.4% to 3.3% of procedures performed.^{4,7,8,13} Furthermore, in 1 patient in the ETT group, the bronchoscope was damaged by the puncture needle.

In our opinion, there are further advantages of LMA use. First, optimal position of the LMA could be ensured by a simple medical strip. With the ETT, it is common practice to secure the ETT throughout the entire procedure with the assistance of another person. Second, with the LMA, it was possible to determine the site of tracheal puncture by bronchoscopy alone. With an ETT, additional indirect measures such as palpation of laryngeal structures and transillumination are recommended. This may be difficult in anatomical variations, e.g., in obese patients.

Overall, the rate of complications in this study (Table 3) is comparable with findings in the literature. Many studies and meta-analyses described accidental extubations,^{4,5,8} episodes of hypoxia,^{5,13,14} hypercapnia,^{18–20} and impossibility of LMA introduction.⁸

During PDT, PaO_2 was decreased in both groups. Whereas 3 patients with ETTs showed critically impaired ventilation and hypoxia ($\text{PaO}_2 < 60$ mm Hg), with an LMA, no case of hypoxia occurred in this study.

In 1 patient, attempts to insert the LMA failed, and PDT was continued after reintubation. Because this happened at the beginning of the procedure, the patient was well oxygenated and neither desaturation nor hypercapnia occurred.

Most studies using an LMA for PDT found minor changes in ventilation or at least a ventilation comparable with an ETT.^{8,20–24} However, Ambesh et al.⁷ rated ventilation with an LMA inferior compared with an ETT. This may have been caused by a very high rate of 33% of “potentially disastrous complications” with the use of an LMA (loss of airway, inadequate ventilation of lungs leading to significant hypoxia, gastric distension, and regurgitation) in their study. Experiences in our institutions and by others showed a definitely lower rate of ventilation-associated complications.^{4,8,9,23,24}

Whether using an ETT or LMA, the airway resistance increases by introducing the bronchoscope. Obviously, this results in decreased minute ventilation and consecutive hypercapnia. An increased Paco_2 value as a result of decreased minute ventilation is a well-known problem during PDT, observed with the LMA and with the ETT.^{18–20} Because the internal diameter of an LMA is larger than an ETT, the increase of resistance will be less pronounced with an LMA than with an ETT (whereas a 5.5-mm bronchoscope reduces the internal cross-sectional area of a 7.5-mm ETT by approximately 44%, the cross-sectional area of an LMA is reduced approximately 17%). Reilly et al.^{18,19} suggested a relationship between residual cross-sectional area and Paco_2 . They found lower Paco_2 values using external ultrasound instead of a bronchoscope for localization of the PDT puncture site. This hypothesis is supported in this study and by other investigations showing lower Paco_2 values during PDT when the LMA was used.^{8,23} Hypercapnia is of particular importance in neurosurgical patients with decreased intracranial compliance. As cerebral blood flow increases with increased Paco_2 , intracranial pressure may increase during PDT in these patients.²⁵

According to the study protocol, tidal volume, respiratory frequency, and PEEP setting at the ventilator remained unchanged, and only excessive leakage volume was minimized by reducing inspiratory pressure. Obviously, in our patients, ventilation was not satisfactory, because Paco_2 increased markedly in both groups. Whereas Dosemeci et al.⁸ were able to ventilate their patients during PDT via LMA without increased mean Paco_2 (but increase in 38.5% of patients), results of most other studies show increased mean Paco_2 and suggest hypoventilation to be a common problem during PDT.^{13,18–20}

LMA use is frequently rejected because of concerns about the reliability of this type of artificial airway with regard to regurgitation of gastric contents, maintenance of minute ventilation, and PEEP. However, the basis for these concerns has been ameliorated, both in our institutions and by other authors who have investigated the LMA.^{4,8,9,21,23,24,26} It has been argued that an LMA is not a completely “safe” airway.^{27,28} However, during PDT, this holds true for an ETT as well. During PDT, the ETT’s cuff has to be deflated, and the ETT is situated only 1 or 2 cm inside the trachea, resulting in a partially unsecured airway and decreased minute ventilation. Therefore, we do not consider the LMA to be less secure when compared with an ETT during PDT. Aspiration of gastric contents during PDT²⁹ seems to be a rare complication; it was never observed in our institutions and was not reported in studies and meta-analyses on complications during PDT.^{4,5,7,13,24,26,30} Nevertheless, the LMA ProSeal™ is recommended for use in patients at risk for aspiration.^{4,24,26,30}

Some intensivists using an LMA did not use the LMA Classic.^{24,30} Verghese et al. used the intubating laryngeal mask™, as we did in our previous investigation,^{9,21} mainly because of the facility to reintubate the trachea in case of any emergency.^{31–34} However, in some cases, the intubating laryngeal mask was situated above the base of the tongue.⁹ In our trials using the LMA Classic, we did not encounter this problem because the aperture of the LMA could always be placed above the larynx. The ProSeal LMA, which is equipped with an additional drainage lumen, was also used with success.^{24,30} The assumed advantage regarding the drainage of gastric fluids during PDT is discussed above. However, a disadvantage of the lumen of a ProSeal LMA is that it is comparable with that of an ETT, which may result in greater airway obstruction than with the LMA Classic.

This study has several limitations. The assessment of visibility and quality of ventilation with a semiquantitative score is potentially biased by the knowledge of the airway used. However, a double-blinded assessment is difficult to achieve, because the airway used is inevitably identified during the PDT procedure. To minimize any potential bias, we used strict and clear descriptions of each quality criterion (Appendix 1). Furthermore, the number of patients was too low to prove the effect of improved visualization on the rate of complications. To prove an effect of an LMA on reducing the complication rate from 10% to 5%, a sample size of 159 patients would have been necessary. Also, the assigned patients manifested only minor disturbed pulmonary function with a mean PaO₂/Fio₂ of approximately 380. In our study, the indication for tracheostomy was mainly related to neurologic disturbances, and PDT was performed early, within the first week. Therefore, it was not possible to document how well this technique might work in patients with severe lung injury requiring higher peak inspiratory pressure or PEEP.

In summary, the LMA technique showed definite advantages regarding visualization of relevant tracheal structures and the dilation process compared with an ETT. Ventilation during PDT was superior with the LMA, and

bronchoscope damage and accidental loss of airway occurred in the ETT group only. ■■

AUTHOR CONTRIBUTIONS

Ulf Linstedt, MD, PhD, was involved in planning, study design, conduct, analysis, and manuscript preparation of the study; Michael Zenz, MD, and Andreas W. Prengel, MD, PhD, were involved in study design, analysis, and manuscript preparation of the study; Kirsten Krull, MD, was involved in conduct, analysis, and manuscript preparation of the study; and Dietrich Häger, MD, was involved in conduct of the study.

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