LMA-ProSeal™ for Elective Postoperative Care on the Intensive Care Unit

A Prospective, Randomized Trial

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Background: Compared to an endotracheal tube, laryngeal mask airways are known to cause less hemodynamic alteration during the extubation phase of routine perioperative airway management. This study aims to examine the hypothesis that the LMA-ProSeal™ (PLMA, The Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands) is an adequate tool for elective postoperative care in the intensive care unit (ICU) and potentially associated with less hemodynamic alteration during extubation in the ICU environment compared to an endotracheal tube.

Methods: Forty-eight patients were enrolled for this prospective randomized, controlled trial and were allocated to either control (ICU-T) or study group (ICU-P). In the ICU-P group, the endotracheal tube was replaced by a PLMA at the end of surgery.

Results: Forty-six patients completed the study. Cardiovascular parameters increased significantly less in the ICU-P group: systolic blood pressure increased by 18.10 ± 5.57 mmHg versus 34.65 ± 5.63 mmHg (P < 0.05), mean arterial blood pressure increased by 11.25 ± 3.25 mmHg versus 22.65 ± 3.36 mmHg (P < 0.05), and heart rate increased by 9.3 ± 2.9 versus 12.9 ± 2.2 min⁻¹ (P < 0.05). Ventilation via the PLMA during transfer from the operation room to the ICU as well as during ICU stay was successful and without any adverse events.

Conclusions: Removal of the PLMA after recovery from anesthesia was associated with less cardiovascular change compared to the endotracheal tube. Ventilation was possible without reported adverse events during the entire trial. Elective endotracheal tube replacement by the PLMA may be a useful procedure in selected patients.

EXTRAGLOTTIC airway devices have become routinely used for elective and emergency airway management.1,2 The LMA-ProSeal™ (PLMA; The Laryngeal Mask Company Limited, St. Helier, Jersey, Channel Islands) was introduced in 2000 as a further development of the LMA-Classic™ (LMA; The Laryngeal Mask Company Limited).3 The main modifications were a posterior extension of the mask cuff and a drainage tube exiting at the mask tip. Oropharyngeal leak pressures (OLP) ranging around 30 cm of water⁴,⁵ can be achieved, allowing ventilation with higher tidal volumes and airway pressures.⁵,⁶ Furthermore, the drainage tube provides a reliable separation of respiratory and gastrointestinal tract, reduces the risk of aspiration in cases of regurgitation,⁷–⁹ and offers the possibility of controlling the position of the mask tip in relation to the hypopharyngeal structures.⁵,¹⁰

Previous studies evaluated minor hemodynamic responses to LMA™ and PLMA™ insertion.¹¹⁻¹⁵ Furthermore, comparison of the endotracheal tube with the LMA™ has shown significantly less hemodynamic responses during insertion as well as removal during patient care in the operation room (OR).¹⁶,¹⁷

For the intensive care unit (ICU) setting, there exist only case reports of successful use of the PLMA, mainly in cases of unexpectedly difficult to manage airways.¹⁸,¹⁹ For patients with cardiovascular comorbidities or after neurosurgical interventions, ventilation via the PLMA in the ICU was addressed as a potentially favorable procedure, as reduced hemodynamic responses during extubation are described for patients in the OR.²,¹⁰

We therefore aimed to evaluate the PLMA versus the endotracheal tube in this, to our knowledge, first controlled, randomized manner for positive pressure ventilation in the ICU during postoperative recovery and during the extubation phase after major abdominal surgery. We hypothesized that removal of the PLMA after recovery from anesthesia in the ICU environment would result in less hemodynamic alteration compared to an endotracheal tube. Furthermore, we assumed that the PLMA would be a reliable tool for positive pressure ventilation during patient transfer from the OR to the ICU as well as during ICU ventilation.

Materials and Methods

In accordance with the local ethics committee of the University of Göttingen, Germany, patients gave their written and informed consent before entering the study. From August 2006 until June 2007, 48 patients with the American Society of Anesthesiologists status I to III and scheduled for elective major urological (radical prostatectomy, vesical tumor with neo-vesica, nephrectomy) or gynecological (hysterectomy with radical lymphadenectomy [Wertheim-Meigs], bilateral ovariectomy with...
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lymphadenectomy) surgery were enrolled in the study at the University Hospital of Göttingen, Germany. Patients selected for the study were older than 18 yr and had no signs of a difficult airway. Preoperative exclusion criteria were body mass index greater than 35 kg/m², cardiac insufficiency (clinically or a reported ejection fraction less than 30%), chronic and allergen-related obstructive lung diseases, known gastric reflux and past medication-related allergic reactions. Patients were excluded at any time during the study if one of the following situations occurred: difficult mask ventilation during induction of anesthesia, Cormack and Lehane Score III or IV, \( \text{Pao}_2/\text{FiO}_2 < 200 \), or the need for intravenous opioids after induction of general anesthesia.

Patients received 10 to 20 mg of temazepam orally the evening before scheduled surgery as well as 7.5 mg of midazolam orally at the day of intervention after call up to the OR. As it is the standard of care in our department, an epidural catheter was placed before induction of general anesthesia for thoracic spine level of T8–12. Three milliliters of bupivacaine 0.5% with adrenaline (1:100,000) were given to exclude catheter displacement. Thereafter, patients were preoxygenated with 100% of oxygen for 3 min before inducing anesthesia with 0.2 \( \mu \)g/kg sufentanil and 2 mg/kg propofol. After successful bag mask ventilation, full paralysis was induced and verified by train-of-four measurements. Patients were intubated by direct laryngoscopy using a Macintosh blade size 3 or 4 and an endotracheal tube size with an ID of 7 mm (female) or 8 mm (male). Intraoperative sedation was maintained with isoflurane. After correct tube placement and establishment of stable ventilation, a gastric tube was placed as well as central venous line in the internal jugular or subclavian vein. Thereafter, a PiCCO® catheter (Pulsion Medical Systems, München, Germany) was inserted in the left or right femoral artery. Twenty minutes before the start of surgery, a bolus of 10–14 ml of ropivacaine 0.5% was administered via the epidural catheter followed by a continuous infusion of 6–8 ml/h. Noradrenaline was given in the range of 3 to 10 \( \mu \)g/min if necessary. Fluid and muscle relaxation was given according to the individual patients’ interventional needs. Ventilator settings were adapted with tidal volumes of 6–8 ml/kg and an end expiratory carbon dioxide of 35–40 mmHg. Positive end expiratory pressure was always set to 5 cm H2O during the entire study period. No other anesthesia-related adjuvant (e.g., \( \alpha_2 \)-agonist or benzodiazepines) was administered.

At the end of surgery, ropivacaine 0.5% was replaced by ropivacaine 0.2% for postoperative analgesia. Isoflurane administration was terminated, and sedation was maintained with propofol infusion to a bispectral Index of 40 to 50 (A-2000™ Bispectral Index Monitoring System; Aspect Medical Systems, Norwood, MA). Thereafter, patients were randomly allocated to either the study (ICU-P) or the control group (ICU-T).

The ICU-T group was transferred directly to the intensive care unit. The following interventions were made in the ICU-P group. Glycopyrolate (0.2 \( \mu \)g/kg) was given to reduce salivation. Patients were ventilated with 100% oxygen until \( \text{F}_{\text{eO}} \) reached a minimum of 0.8. The gastric tube was removed under continuous suction. Due to patient safety and according to the study protocol, a direct laryngoscopy was performed before the endotracheal tube was removed. To evaluate the best achievable Cormack and Lehane Score in case of an unexpected need for reintubation, patients were fully paralyzed. Endotracheal tube removal was facilitated under vision and a PLMA (size 4 in women and size 5 in men) was inserted using the gum-elastic boogie technique known to have a higher first success rate than conventional digital insertion. The cuff was inflated to a just-airtight-seal but not more than 60 cm H2O. Subsequently, before inserting a gastric tube, the position of the mask tip was verified to be in the upper esophagus sphincter by using the lube-tube-test. The PLMA was fixed and secured with tape while exerting little inward force to reduce the risk of extrusion and dislocation.

The OLP was measured by setting the adjustable pressure limiting valve of the circle system to 35 cm H2O and applying a fixed fresh gas flow of 3 l/min oxygen. The airway pressure at which an audible airway leakage could be detected was considered the OLP. Patients where subsequently transferred to the ICU.

The following management was identical for both groups on the ICU. Analgesia was maintained with continuous epidural infusion of 6–8 ml/h ropivacaine 0.2% and sedation with continuous propofol infusion to a bispectral index level of 40–50. During propofol infusion, patients were set to biphasic positive airway pressure ventilation. Ventilator settings were adapted to arterial gas analyses. Patients’ vital signs were monitored with a GE Healthcare Marquette Dash 3000 patient monitor (GE Healthcare, Helsinki, Finland). Online data acquisition was facilitated by an ethernet connection to the Dash monitor. All data were transferred and saved on a Windows-based (Micrssoft Deutschland GmbH, Unterschleißheim, Germany) notebook computer. Sample rate was 0.0066 Hz (during steady state) and 0.5 Hz (one datapoint every 2 s) during extubation phase. The exact moment of extubation was marked. Subsequently, five data points (10 s) around the extubation time point were averaged and taken as the peak value.

The rate-pressure product (RPP) was calculated by multiplying systolic blood pressure by heart rate. Oxygen consumption (\( \text{VO}_2 \)) was recorded by respiratory gas analyses (Datex Ohmeda, GE Healthcare, Helsinki, Finland) from the steady state phase until extubation. Baseline measurements were performed for 15 min before termination of propofol sedation during stable
hemodynamic and respiratory conditions. Stable conditions were defined as \( \text{FiO}_2 \) of 0.3 with a \( \text{PaO}_2/\text{FiO}_2 \) greater than 300, no need for catecholamine therapy, no blood loss more than 100 ml during the last 60 min, diuresis of a minimum of 0.5 ml \( \cdot \) kg\(^{-1} \) \( \cdot \) h\(^{-1} \) and a body core temperature of at least 36.5°C.

Spontaneous breathing patients were extubated once they were capable of giving adequate motoric response on verbal stimulation and lifting up their head for 3 s. According to the common practice in our institution, all patients were extubated by the ICU nurses, who were informed about the ongoing study but not about the study parameters.

All adverse events such as airway dislocation or loss, laryngospasm during ventilation or extubation were recorded. Signs for aspiration or undetected mask dislocation were evaluated by fiberoptic inspection of the mask bowl, larynx, and upper trachea during baseline measurements in the ICU-P group. At 1, 6, and 24 h after extubation, patients were asked by a blinded observer to rate sore throat, dysphagia, and surgical wound pain with a visual analog scale.

**Statistics**

Statistical analyses were performed with Statistica 7.1 (Statsoft GmbH, Hamburg, Germany). For group comparisons and comparisons of one parameter at two different times within one group, \( t \) tests for independent and dependent samples were computed, respectively. Pearson-correlations were calculated and used to evaluate relations between recorded parameters and preexisting factors such as age or inter-operative need for vasopressor therapy. To compare the increase of parameters from baseline to point of extubation between the two groups, two-way analyses of variance were carried out on the respective parameters. Patients in the ICU-P and the ICU-T group were two levels of a between-subjects factor. Baseline and point of extubation were two levels of a repeated-measurement factor. In case of significant interactions, the increase from baseline to point of extubation was expressed as individual difference score for each patient. With \( t \) tests for independent samples, these difference scores were compared between both groups.

\( P < 0.05 \) was considered as significant. If not otherwise stated, results are indicated as mean (±SEM). With a sample size of 20 per group, statistical \( t \) tests applied to examine differences of target variables between the two groups have a power of 0.80 to detect large effects (\( d = 0.80 \)), whereas smaller effects have a reduced probability of detection.

**Results**

Forty-eight patients were recruited to participate in the study. Six patients were excluded after recruitment due to insufficient analgesia provided solely by the epidural catheter. Two patients were excluded because of Cormack and Lehane Scores of III during direct laryngoscopy (one after induction of anesthesia and one during intended endotracheal tube removal). A total number of 40 patients completed the study.

There were no statistical differences between the two groups regarding biometric data except for an unequal distribution of gender (table 1). The length of the entire patient care averaged 399 ± 22 min for the ICU-P group and 406 ± 22 min for the ICU-T group. The mean (±SD) period of ventilation on the ICU was 78 ± 14 and 79 ± 8 min for the ICU-P and ICU-T groups, respectively.

Baseline values did not differ between the two groups (table 1). Pearson correlations revealed no relation between any biometric values and hemodynamic values except for a significant negative correlation (\( r = -0.40; P < 0.05 \)) for age and heart rate changes from baseline to extubation. Subsequently, age was considered as covariate for further comparisons of heart rate between the two groups. For detailed hemodynamic parameters and statistic analyses see table 2 and figure 1.

Bispectral indices significantly increased from baseline to extubation, but no statistically significant differences were found between the two groups. Central venous pressure did not change significantly from baseline to extubation.

Results regarding \( \text{VO}_2 \) lacked significance. Nevertheless, during baseline measurement in ICU, the mean \( \text{VO}_2 \) was higher for the ICU-T group than for the ICU-P group, 3.65 ± 0.3 and 3.39 ± 0.2 ml \( \cdot \) min\(^{-1} \) \( \cdot \) kg\(^{-1} \), respectively. The increase of \( \text{VO}_2 \) from baseline to the extuba-

<table>
<thead>
<tr>
<th>Table 1. Biometric Data and Parameters during Baseline Measurement</th>
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<tbody>
<tr>
<td><strong>ICU-P Group</strong></td>
</tr>
<tr>
<td>Age, yr</td>
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<tr>
<td>Weight, kg</td>
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<tr>
<td>Height, m</td>
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<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
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<tr>
<td>BMI, kg/m(^2)</td>
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<tr>
<td>ASA status</td>
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<tr>
<td>Mallampati</td>
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<tr>
<td>Level of epidural catheter placement*</td>
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<tr>
<td>Patients pretreated with</td>
</tr>
<tr>
<td>ACE inhibitors</td>
</tr>
<tr>
<td>Beta-blockers</td>
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<tr>
<td>ITBVi (baseline values)</td>
</tr>
<tr>
<td>EWLVi (baseline values)</td>
</tr>
<tr>
<td>BIS (baseline values)</td>
</tr>
<tr>
<td>Ropivacaine 0.2%, ml/h†</td>
</tr>
</tbody>
</table>

* Thoracic level calculated by considering catheter placement, for example, between level 10 and 11 as 10.5; † via epidural catheter.

ACE = angiotensine-converting enzyme; ASA = American Society of Anesthesiologist; BIS = Bispectral Index; BMI = body mass index; EWLVi = index of extravascular water lung volume; ICU-P = study group; ICU-T = control group; ITBVi = index of intrathoracic blood volume.
The LMA™ is known to produce less hemodynamic alteration during insertion and removal in the OR when compared to the endotracheal tube.\textsuperscript{14,16,17,20,27} In the current study, we found that systolic blood pressure, mean arterial blood pressure, diastolic blood pressure, heart rate, and RPP increased to a significantly lesser extent from baseline to extubation in the ICU-P compared to the ICU-T group, supporting the data of previous studies for the extubation phase. Fujii \textit{et al} reported RPP (± SD) of 15,000 (± 2,700) for endotracheal tube

### Table 2. Hemodynamic Parameters and Statistical Analyses* for the Absolute Values and Relative Changes

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>Extubation</th>
<th>Baseline vs. Extubation, (P)</th>
<th>Exubation ICU-P vs. ICU-T</th>
<th>Relative Change ICU-P vs. ICU-T</th>
</tr>
</thead>
<tbody>
<tr>
<td>(BP_{sys}) mmHg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU-P</td>
<td>112.1 (23.6)</td>
<td>130.2 (18.5)</td>
<td>&lt;0.001</td>
<td>18.1 (24.9)</td>
<td>-2.46; (P &lt; 0.05)</td>
</tr>
<tr>
<td>ICU-T</td>
<td>112.5 (15.1)</td>
<td>147.5 (25.4)</td>
<td>&lt;0.001</td>
<td>34.7 (25.2)</td>
<td>-2.09; (P &lt; 0.05)</td>
</tr>
<tr>
<td>MAP, mmHg</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>ICU-P</td>
<td>77.6 (12.7)</td>
<td>88.8 (11.4)</td>
<td>&lt;0.01</td>
<td>11.2 (14.5)</td>
<td>-2.23; (P &lt; .05)</td>
</tr>
<tr>
<td>ICU-T</td>
<td>76.6 (10.7)</td>
<td>99.3 (17.2)</td>
<td>&lt;0.001</td>
<td>22.7 (15.0)</td>
<td>-2.44; (P &lt; .05)</td>
</tr>
<tr>
<td>(BP_{dia}) mmHg</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>ICU-P</td>
<td>55.7 (10.0)</td>
<td>63.2 (10.6)</td>
<td>&lt;0.05</td>
<td>7.5 (11.8)</td>
<td>-1.8; (P &lt; 0.05)</td>
</tr>
<tr>
<td>ICU-T</td>
<td>54.0 (9.0)</td>
<td>70.2 (12.7)</td>
<td>&lt;0.001</td>
<td>15.2 (11.6)</td>
<td>-2.0; (P &lt; 0.05)</td>
</tr>
<tr>
<td>HR, min (^{-1})</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ICU-P</td>
<td>67.7 (12.5)</td>
<td>77.2 (13.9)</td>
<td>&lt;0.001</td>
<td>9.5 (9.2)</td>
<td>-1.74; (P &lt; 0.05)</td>
</tr>
<tr>
<td>ICU-T</td>
<td>67.9 (11.9)</td>
<td>84.9 (14.2)</td>
<td>&lt;0.001</td>
<td>17.0 (11.8)</td>
<td>-1.8; (P &lt; 0.05)</td>
</tr>
<tr>
<td>RPP</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>ICU-P</td>
<td>7,576 (2093)</td>
<td>10,057 (2329)</td>
<td>&lt;0.001</td>
<td>2,481 (2630)</td>
<td>-2.69; (P &lt; 0.05)</td>
</tr>
<tr>
<td>ICU-T</td>
<td>7,663 (1831)</td>
<td>12,594 (3512)</td>
<td>&lt;0.001</td>
<td>4,931 (3210)</td>
<td>-2.64; (P &lt; 0.05)</td>
</tr>
</tbody>
</table>

* * Corrected for age; † t-tests (df).

Regarding visual analog scale values for sore throat, dysphagia and surgical wound pain, analyses detected no differences between the two groups. OLPs for the PLMA were 29.26 ± 2.21 Cm H\textsubscript{2}O.

### Discussion

This study evaluated the endotracheal tube versus the PLMA for postoperative use on the ICU in patients undergoing elective major urological or gynecological surgery. In contrast to existing case reports,\textsuperscript{18,19} we here present a prospective controlled study of two different airway devices for ventilation and recovery from anesthesia in the ICU.

Biometric data did not differ between the groups. After induction of anesthesia, no further opioids were used. Furthermore, during baseline measurement, patients had no need for vasopressor therapy, and intravascular volume status was comparable in both groups as indicated by the indices of intrathoracic blood volume. Extubation was performed after comparable time intervals after termination of sedation. Therefore, we conclude that the varying changes of hemodynamic parameters from baseline to extubation in the ICU-T and ICU-P groups were primarily caused by the different airways used.

The LMA™ is known to produce less hemodynamic alteration during insertion and removal in the OR when compared to the endotracheal tube.\textsuperscript{14,16,17,20,27} In the current study, we found that systolic blood pressure, mean arterial blood pressure, diastolic blood pressure, heart rate, and RPP increased to a significantly lesser extent from baseline to extubation in the ICU-P compared to the ICU-T group, supporting the data of previous studies for the extubation phase. Fujii \textit{et al} reported RPP (± SD) of 15,000 (± 2,700) for endotracheal tube
and 10,700 (± 1,900) for LMA™ removal for nonhypertensive patients in the OR. The RPP in the current study were slightly lower but comparable. Since Fuji et al. found in hypertensive patients that endotracheal tube but not LMA™ removal resulted in RPP up to the critical level of myocardial ischemia of 20,000,27-29 the results of our study may be of particular importance for patients with manifest hypertension.

Mean VO₂ values as well as VO₂ increase from baseline to extubation were higher for the ICU-T than for the ICU-P group. Although these differences failed to reach statistical significance, they may indicate a higher stress level for the ICU-T group.

Stable hemodynamic recovery from anesthesia in the context of major neurosurgical or cardiovascular interventions is preferable.2 Furthermore, stable systolic blood pressures are favorable to prevent hyperperfusion syndrome, intracranial hemorrhage, and wound hematoma after carotid artery interventions.30,31 For many major surgical interventions, the endotracheal tube is most likely still considered mandatory. The most frequent method of circumventing adverse events due to hemodynamic alterations is probably the use of cardiovascular and sedative therapy, albeit with the potential to lead to an impaired validation of neurologic status and the risk of reduced respiratory function and hemodynamic suppression. Therefore, the approach of an elective replacement of the endotracheal tube by the PLMA for recovery from anesthesia may be a viable alternative in certain patients.

The correlation between heart rate and age revealed a significant negative correlation, even when controlled for β-blocking therapy. This negative correlation is interesting but difficult to interpret on the basis of our data. A presumed higher airway sensibility in younger subjects may be a potential explanation.

Ventilatory patterns were stable until extubation, and no adverse events were noted. Even potentially critical procedures such as the transfer to and care on the ICU were uneventful with the PLMA. Evaluated OLPs were comparable with other studies.3,4 However, the time of positive pressure ventilation on the ICU with the PLMA in this study was relatively short compared to existing case reports.19 We cannot rule out that potential complications such as airway obstruction, mucus retention, or mask dislocation would have occurred during longer ventilation periods. However, we believe that this is unlikely to happen because as ventilation far beyond 80 minutes is common practice for the PLMA in the OR.

Although extraglottic airways and especially the PLMA have proven to be reliable devices for positive pressure ventilation,2 this application may not be common in all anesthesia societies. However, assuming an adequate level of anesthesia, laryngeal mask airways are insertable without paralysis, consequently allowing early spontaneous ventilation and extubation.

Although hemodynamic changes were highly significant, these changes may be of minor clinical relevance for our study subjects but of clinical importance for other patients (e.g., after cardiovascular or neurosurgical interventions). However, to test our hypothesis in this first controlled trial, we preferred a more conservative approach regarding the selected study group. We recognize that our study population in other institutions may not require postoperative ventilation, although infrastructural settings allowed us to recruit our study population. Sympatholytic effects of epidural local anesthesia and the potential loss of the cardiac accelerators may interfere with hemodynamic parameters. In this study, both groups were comparable regarding lower thoracic epidural catheter placement, flow rate of low-dose Ropivacaine 0.2%, and the absence of vasopressor therapy during baseline measurements and extubation. Therefore, we assume that the epidural infusion of local anesthetic—the only suitable alternative for strictly avoiding the application of narcotics—is unlikely to have influenced the hemodynamic parameters; even if it did, it would have changed them to a comparable extent in both groups. We show that the PLMA may be a feasible tool for elective postoperative care, however the number of patients may be too small to draw strong conclusions about patient airway safety. Although the nurses who removed the airway were blinded for the study parameters, the overall study design was not blinded.

In conclusion, hemodynamic changes during extubation were significantly less pronounced during PLMA removal compared to endotracheal tube removal in the ICU environment. Ventilation within the ICU-P group was possible without adverse events. The PLMA may be a reliable and suitable alternative to the endotracheal tube for recovery from anesthesia on the ICU for select patients (e.g., those with increased risk for cardiovascular adverse events or after neurological and cardiovascular interventions). Further research is needed to reproduce the current results in those high-risk patients who may derive greater clinical benefit from the presented approach than our study subjects. Furthermore, it seems important to elucidate the influence of mitigating factors such as age or comedication and to provide more robust evidence regarding patient safety during elective ventilation via the PLMA on the ICU.

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