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Use of the Intubating Laryngeal Mask Airway

Are Muscle Relaxants Necessary?

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Background: **The intubating laryngeal mask airway (ILMA) is designed to facilitate blind tracheal intubation. The effect of a muscle relaxant on the ability to perform tracheal intubation through the ILMA device has not been previously evaluated. This randomized, double-blind, placebo-controlled study was designed to evaluate rocuronium, 0.2 or 0.4 mg/kg administered intravenously, on the success rate and incidence of complications associated with ILMA-assisted tracheal intubation.**

Methods: **A total of 75 healthy patients were induced with propofol 2 mg/kg and fentanyl 1 μg/kg intravenously. After insertion of the ILMA device, patients were administered either saline, rocuronium 0.2 mg/kg, or rocuronium 0.4 mg/kg in a total volume of 5 ml. At 90 s after administration of the study drug, tracheal intubation was attempted using a disposable polyvinyl tube. If unsuccessful, a reusable silicone tube was tried. In addition to recording the time and number of attempts required to secure the airway, the incidence of complications during placement of the tracheal tube and removal of the ILMA were noted.**

Results: **Tracheal intubation was successful in 76–96% of the patients. The overall success rates and times required to secure the airway were similar in all three treatment groups. The high-dose rocuronium group experienced less patient movement (8 vs. 28 and 48%) and coughing (12 *vs.* 20 and 52%) than the low-dose rocuronium and saline groups, respectively. Use of rocuronium was also associated with a dose-related decrease in the requirement for supplemental bolus doses of propofol during intubation and removal of the ILMA device.**

Conclusions: **Use of rocuronium did not significantly improve the success rate in performing tracheal intubation through the ILMA. However, it produced dose-related decreases in coughing and movement after tracheal intubation and reduced difficulties associated with removal of the ILMA device.**
(Key words: Airway management; neuromuscular transmission; blockade.)

THE laryngeal mask airway (LMA) device has become a valuable asset in the management of the difficult airway by providing both a patent airway and acting as a conduit for blind endotracheal intubation.[1] The intubating LMA (ILMA) is a new airway device that is specifically designed as a tracheal intubation system and overcomes many of the problems commonly encountered during attempted tracheal intubation through the standard LMA.[2,3] A specially designed reusable silicone endotracheal tube with a low-volume cuff and soft tip is recommended for use with the ILMA to reduce resistance as the tube passes through the glottic structures. However, disposable cuffed polyvinyl chloride endotracheal tubes have been successfully used with the ILMA device.[4]

Blind tracheal intubation with the standard LMA has an overall failure rate varying from 10% to 70% in patients with "normal" airways.[5,6] Clinical trials involving the ILMA have demonstrated that it is easy to insert on the first attempt and allows adequate ventilation.[7] In addition, successful tracheal intubation has been reported in 93–99% of patients.[7,8] All clinical studies with the ILMA device have used intubating doses of nondepolarizing muscle relaxants "to provide optimum conditions." However, when a patient is known to have or is suspected of having a difficult airway, the use of muscle relaxants may be relatively contraindicated. Although anecdotal reports have described successful intubations using the ILMA without the use of muscle relaxants,[4,9] the effect of these drugs on the success rate when using

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this device for tracheal intubation has not been previously studied.

We designed a prospective, randomized, double-blind, placebo-controlled trial to assess the success rate and incidence of complications when performing blind tracheal intubation in patients with normal airway anatomy using the ILMA with or without a muscle relaxant. Initially, tracheal intubation was attempted using a conventional disposable polyvinyl chloride tracheal tube. If unsuccessful, intubation was attempted using the reusable silicone tracheal tube provided with the ILMA device.

Methods

After obtaining institutional review board approval, 75 consenting adult patients, American Society of Anesthesiologists physical status I–II, scheduled for minor orthopedic surgical procedures were enrolled in the study. Patients with cardiovascular, respiratory, hepatic, renal, or neuromuscular disease were excluded from the study. Exclusion criteria also included patients with known or suspected difficult airway, previous head and neck surgery or radiotherapy, and those with a history of gastroesophageal reflux or increased risk factors for aspiration. Patients were not taking drugs known or suspected to interfere with neuromuscular transmission. One anesthesiologist (W. K. T.), experienced in using the ILMA, was involved in the insertion of the ILMA and performed all of the tracheal intubations.

On arrival in the operating room, the standard anesthesia monitors were attached, and all patients were premedicated with midazolam, 2 mg administered intravenously. Anesthesia was induced with propofol 2 mg/kg and fentanyl 1 μg/kg intravenously. The intubating LMA (LMA-Fastrach; LMA North America, Inc., San Diego, CA) was inserted following the manufacturer's recommended technique with the patient's head in the neutral position. The cuff of the ILMA was completely deflated, and the posterior surface was well lubricated with a water-soluble lubricant before insertion. The size-5 ILMA was used for most male patients, whereas a size-4 ILMA was used for women and small men. The size-3 ILMA was reserved for use in small female patients. Once the ILMA was inserted and the cuff was inflated with the recommended volume of air, manual positive pressure ventilation was initiated while anesthesia was maintained with sevoflurane 3% inspired in oxygen.

After establishing the ability to provide adequate positive pressure ventilation (*i.e.*, oxygen saturation $>$ 95% and end-tidal carbon dioxide 35–40 mmHg) with the ILMA, patients were randomly assigned to one of three study groups according to the double-blind protocol design. Patients received either saline, rocuronium 0.2 mg/kg, or rocuronium 0.4 mg/kg intravenously in a total volume of 5 ml. The study medication was prepared by a second anesthesiologist not involved in the patient's care or data collection. Ninety seconds after the study drug was administered intravenously, a blind tracheal intubation was attempted using a well-lubricated 7.0-mm disposable polyvinyl chloride tracheal tube inserted in a reverse position into the ILMA and then rotated 180° after passing through the laryngeal inlet. Successful tracheal intubation was confirmed by the presence of bilateral breath sounds and detection of carbon dioxide in the expired gases. The ILMA device was subsequently removed using the extender to ensure that the endotracheal tube was not displaced. Patient movement, coughing, or laryngospasm during attempted insertion of the endotracheal tube was initially treated with a supplemental intravenous bolus dose of propofol 0.5 mg/kg. Severe coughing or desaturation (oxygen saturation $<$ 80%) was treated by a "rescue" dose of rocuronium 0.6 mg/kg. If resistance was encountered as the endotracheal tube was passed beyond 15 cm (*i.e.*, the point at which the tube advances through the ILMA aperture), the recommended maneuvers were performed according to the manufacturer's manual.[10] If resistance to passage of the disposable tracheal tube persisted despite the use of the appropriate maneuver, an attempt was made to intubate the patient through the ILMA using the manufacturer's reusable silicone tracheal tube.

Hemodynamic and respiratory variables were recorded at 1-min intervals before, during, and immediately after induction, tracheal intubation, and removal of the ILMA device. The time required for successful intubation and the number of attempts and maneuvers required were also recorded. During intubation and removal of the ILMA, the need for supplemental doses of propofol and rocuronium as well as the occurrence of respiratory complications (*i.e.*, coughing, laryngospasm, desaturation) were noted.

Statistical Analysis

A power analysis was performed assuming a mean intubation time of 60 s with an SD of 20 s. Twenty-five patients would be needed to detect a 15% difference in the intubation time between groups with a power of 80% and a P value of $<$ 0.05. Continuous variables were compared using one-way analysis of variance and are presented as mean values ± SD. When a significant

Table 1. Demographic Data for the Three Study Groups

	Saline	Rocuronium 0.2 mg/kg	Rocuronium 0.4 mg/kg
Number (n)	25	25	25
Age (yr)	35 ± 12	39 ± 11	38 ± 13
Gender, M/F (n)	13/12	13/12	14/11
Weight (kg)	74 ± 13	82 ± 22	80 ± 19
Height (cm)	166 ± 10	167 ± 16	170 ± 11
ASA I/II (n)	13/12	6/19	10/15
Mallampatti score 1/2 (n)	16/9	16/9	14/11
Smoker (n, %)*	15, 60	15, 60	12, 48

Data are expressed as mean values ± SD or number (n). There were no significant differences among the three groups.

* Smokes ≥ one pack of cigarettes per day.

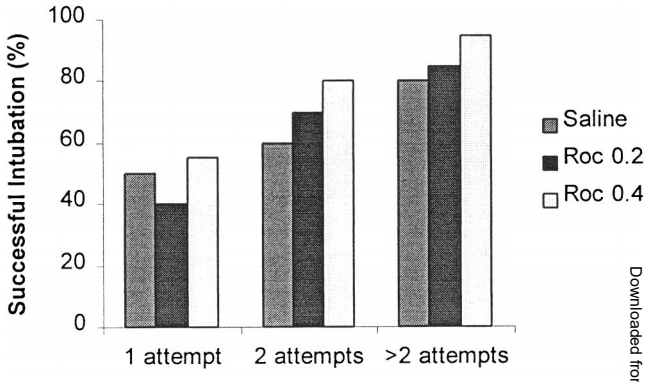

Fig. 1. The cumulative number of attempts required to successfully place a tracheal tube through the intubating laryngeal mask airway in the saline, rocuronium 0.2 mg/kg (Roc 0.2), or rocuronium 0.4 mg/kg (Roc 0.4) groups. No significant differences were found among the three groups.

difference was noted using analysis of variance, a Newman-Keuls test was performed for *post hoc* intergroup comparisons. Categoric variables were analyzed using the chi-square and Kruskal-Wallis tests with data expressed as median values or percentages. P values < 0.05 were considered statistically significant.

Results

Demographic Values

Demographic data for the three study groups were similar (table 1).

Success Rates and Complications during Intubation and Intubating Laryngeal Mask Airway Removal

Overall, tracheal intubation through the ILMA was accomplished in 76%, 88%, and 96% of the patients in the saline, rocuronium 0.2 mg/kg, and rocuronium 0.4 mg/kg groups, respectively (table 2). The cumulative number of attempts required for successful intubation in the three groups are illustrated in figure 1. There were no differences in success rates for intubation or in the time required to achieve successful intubation among the three treatment groups (table 2). The frequency of encountering resistance when advancing the endotracheal tube and the need for manipulation of the ILMA during intubation were also similar between groups. The incidences of successful intubations using the disposable polyvinyl chloride tracheal tube were 76%, 80%, and 84% in the saline, low-dose rocuronium, and high-dose rocuronium

Table 2. Ability to Successfully Intubate the Patient, Intubation Time, and Need to Manipulate the Intubating Laryngeal Mask Airway Device

	Saline (n = 25)	Rocuronium 0.2 mg/kg (n = 25)	Rocuronium 0.4 mg/kg (n = 25)
Overall successful intubation (n, %)	19, 76	22, 88	24, 96
Intubation time (s)	114 ± 171	64 ± 67	80 ± 91
Median no. of attempts to intubate (n)	2	2	1
Patient movement during intubation (n, %)	12, 48	7, 28	2, 8*
Coughing during intubation (n, %)	13, 52	5, 20	3, 12*
Laryngospasm (n, %)	1, 4	1, 4	0, 0
Resistance to passing ETT (n, %)	8, 32	4, 16	9, 36
Need to manipulate the ILMA during intubation (n, %)	9, 36	13, 52	8, 32
Supplemental propofol required (n, %)	5, 20	4, 16	0, 0*
Dose of propofol (mg)	27 ± 51	13 ± 28	0, 0*
Supplemental muscle relaxant required (n, %)	2, 8	2, 8	0, 0
Change to silicone ETT (n, %)	6, 24	5, 20	4, 16
Intubation failed with silicone EET (n, %)	6, 24	3, 12	1, 4*

Data are expressed as mean ± SD or number and percentage unless otherwise stated.

* Significantly different from the saline group ($P < 0.05$).

ETT = endotracheal tube; ILMA = intubating laryngeal mask airway.

Table 3. Complications during Intubation and Removal of the ILMA Device

	Saline (n = 25)	Rocuronium 0.2 mg/kg (n = 25)	Rocuronium 0.4 mg/kg (n = 25)
Regurgitation during intubation (n, %)	1, 4	0, 0	0, 0
Difficulties removing ILMA (n, %)	19, 76	5, 20*	0, 0*†
Desaturation during ILMA removal (n, %)	2, 8	1, 4	0, 0
Coughing during ILMA removal (n, %)	21, 86	5, 20*	0, 0*
Biting during ILMA removal (n, %)	3, 12	3, 12	0, 0
Supplemental propofol for ILMA removal (n, %)	12, 48	4, 16*	0, 0*
Dose propofol for ILMA removal (mg)	87 ± 62	65 ± 34	0, 0*
Supplemental muscle relaxant required for ILMA removal (n, %)	6, 24	2, 8	0, 0*
Extubation during ILMA removal (n, %)	2, 8	0, 0	0, 0

Data are expressed as mean ± SD or number and percentage.

* Significantly different from the saline group ($P < 0.05$).

† Significantly different from the rocuronium 0.2 mg/kg group ($P < 0.05$).

ILMA = intubating laryngeal mask airway.

groups, respectively. In the 15 patients (20%) who could not be intubated with the disposable tube, the manufacturer's silicone endotracheal tube was tried. The success rate for intubation in these 15 patients was 33% but was significantly higher in the high-dose rocuronium group (75%) compared with the saline group (0%). However, in 10 of the 75 patients studied (13%), we were unsuccessful in intubating through the ILMA despite using both tracheal tubes.

There was significantly less patient movement and coughing during tracheal intubation, and a reduced need for supplemental propofol, in the high-dose rocuronium group compared with the saline group (table 2). There were also significantly more difficulties during removal of the ILMA in both the saline and low-dose rocuronium groups compared with the high-dose rocuronium group (table 3). In addition, supplemental propofol and muscle relaxants were more frequently required in the saline (*vs.* high-dose rocuronium) group during removal of the ILMA device.

Hemodynamic Variables

During intubation, systolic blood pressure was higher in the saline group compared with both rocuronium groups (data not reported), and mean arterial pressure was significantly lower in the high-dose rocuronium group compared with the saline and low-dose rocuronium groups ($P < 0.05$; fig. 2). Heart rate was significantly higher in the saline group compared with the high-dose rocuronium group when the ILMA device was removed (fig. 2).

Discussion

In the three previous studies evaluating the use of the ILMA, all patients received a standard intubating dose of a nondepolarizing muscle relaxant.[7,8,11] Because the ILMA may well be chosen for patients with a known or suspected difficult intubation, the anesthesiologist may prefer not to fully paralyze these patients until after the airway is secured. Therefore, we felt it was important to determine the success rates and complications when tracheal intubation is performed using the ILMA in nonparalyzed as well as paralyzed patients.

This study was performed in patients with normal airway anatomy. The overall success rate for intubation through the ILMA was 87% (ranging, 76–96%). The success rate during the first attempt at intubation through the ILMA was 48%, similar to the first attempt success rate reported by Brain *et al.*[7] in a study involving 150 paralyzed patients. Although there were no differences between the three groups in the overall success rate for intubation, the success rate was highest (96%) in the high-dose rocuronium group and lowest (76%) in the nonparalyzed (saline) group. However, if the ILMA-assisted intubation is used in a patient with a difficult airway (or after a previous failed intubation), the success rate and response to muscle relaxation may well be different.

Although the success rates for tracheal intubation were not significantly different between paralyzed and unparalyzed patients, there was a greater need for supplemental propofol in the saline group because of patient movement and coughing. It is possible that patient coughing could be minimized by the administration of

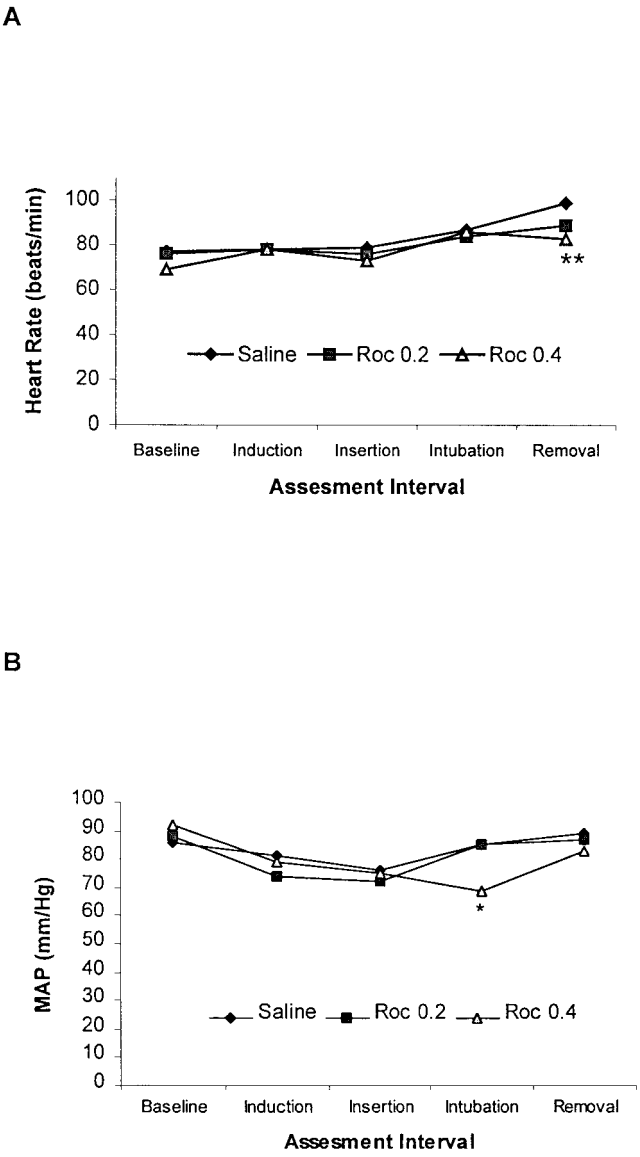

Fig. 2. Perioperative heart rate (*A*) and mean arterial pressure (MAP; *B*) values in the saline (closed diamonds), rocuronium 0.2 mg/kg (closed squares), and rocuronium 0.4 mg/kg (open triangles) groups. **P* < 0.05 *versus* the saline and rocuronium 0.2 mg/kg groups; ***P* < 0.05 *versus* the saline group.

local anesthetics through the ILMA to anesthetize the vocal cords before attempted insertion of the endotracheal tube, but this approach would require further investigation. In any case, if intubation is attempted through the ILMA in unparalyzed patients, additional propofol and a muscle relaxant should be immediately available.

Although muscle relaxants may not be necessary for intubation through the ILMA, there are clear advantages to the administration of nondepolarizing muscle relaxants once the airway is secured. The incidence of complications during removal of the ILMA after successful intubation was significantly greater in both the saline and low-dose rocuronium groups. In the saline group, there were difficulties in removing the ILMA in 76% of patients. Eighty-six percent of the nonparalyzed patients coughed during the removal of the ILMA, and two patients were accidentally extubated. The high incidence of coughing during removal of the ILMA is likely a result of both the pharyngeal stimulation of the ILMA itself and irritation of the trachea as the endotracheal tube is advanced. As the ILMA is removed, the extender is used to stabilize the endotracheal tube. While trying to prevent accidental extubation, the endotracheal tube may inadvertently advance to the carina, provoking vigorous coughing. There were no episodes of coughing or inadvertent extubations during removal of the ILMA in the high-dose rocuronium group. The lower incidences of coughing in the high-dose rocuronium group may explain the significantly lower blood pressure value during intubation and lower heart rate values during ILMA removal compared with the saline or low-dose rocuronium groups.

The use of the disposable polyvinyl chloride tracheal tubes can be criticized. The manufacturer recommends using their reusable, soft silicone tracheal tube. It has been suggested that the tracheal tube must reverse its curvature 30° from the plane of the laryngeal inlet to pass into the trachea.[3] In evaluating polyvinyl chloride tracheal tubes, the manufacturer reportedly found that these tubes retain the curvature imposed by the ILMA and as a result, exit the ILMA too "anteriorly." However, when polyvinyl chloride tubes were inserted 180° from the usual direction, they exited the ILMA in a similar direction to the silicone tubes.[4] Advantages of the polyvinyl chloride tracheal tubes relate to the fact that they are more readily accessible, disposable, and considerably less expensive (*e.g.*, a polyvinyl chloride tube cost $2–3 *vs.* $45–55 for a silicone tube). In this study, tracheal intubation was unsuccessful in 20% of patients even after repeated attempts with the disposable tracheal tube. Using the silicone tube, tracheal intubation was successfully accomplished in 33% of these patients, suggesting that the use of the silicone tracheal tube may result in a higher initial success rate.

In conclusion, intubation through the ILMA has a high success rate in the hands of an experienced anesthesiologist; however, repeated attempts (and the use of appropriate maneuvers) may be required. Although the use of a nondepolarizing muscle relaxant did not significantly

improve the success rate for tracheal intubation using the disposable tube, it markedly reduced the incidence of difficulties during the removal of the ILMA device after the airway had been secured. Disposable tracheal tubes may be used successfully with the ILMA, but the initial success rate would likely be higher with the reusable silicone tracheal tubes.

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