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ORIGINAL ARTICLE

Muscle relaxant effects on insertion efficacy of the laryngeal mask ProSeal® in anesthetized patients: a prospective randomized controlled trial

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Abstract
Background Anesthesiologists often encounter LMA-ProSeal® (ProSeal) insertion difficulty due to its large cuff size. We performed a randomized clinical trial to examine how insertion efficacy and sealing pressure of ProSeal are affected by muscle relaxant administration in anesthetized patients.
Methods Our adult patients were either administered rocuronium (0.9 mg kg^{-1}) as a muscle relaxant (R group; 40 patients) or not (C group; 40 patients). Anesthesia was induced with propofol and fentanyl. We compared the two groups with regard to the number of attempts required for successful insertion, sealing pressure, and subjective difficulty for insertion.
Results Total insertion attempts required for successful ventilation in the two groups were one (R group, 38 patients; C group, 28 patients), two (R group, one patient; C group, seven patients), and three (R group, one patient; C group, five patients), revealing a significant difference between groups ($p < 0.001$). Sealing pressure was significantly higher in the R group than in the C group (R group, 27.4 ± 5.4 cmH_2O; C group, 21.2 ± 5.2 cmH_2O; $p < 0.001$). Leakage volume by mechanical ventilation was significantly smaller in the R group than in the C group (R group, 17.4 ± 29.1 ml; C group, 46.8 ± 45.5 ml; $p < 0.001$). Subjective difficulty of insertion was significantly lower in the R group than in the C group (R group, 12.3 ± 23.1 mm; C group, 39.4 ± 31.9 mm; $p < 0.001$).
Conclusions Muscle relaxation appears to facilitate ProSeal insertion efficacy by enabling higher successful insertion rates, higher sealing pressure, lower leakage volume, and lower subjective difficulty of insertion in anesthetized patients.

Keywords LMA-ProSeal® · Muscle relaxant · Sealing pressure · Insertion efficacy

Introduction

The LMA-ProSeal® (ProSeal; Laryngeal Mask Company, Henley-on-Thames, UK) is a reusable supraglottic airway device with good airway sealing pressure that can be used for mechanical ventilation under general anesthesia [1, 2]. ProSeal is equipped with a double-cuff mechanism and can maintain a high seal pressure. However, due to its large cuff size, the insertion success rate on the first attempt is reported to be relatively low [3, 4]. To overcome the difficulty of ProSeal insertion, several technical insertion methods utilizing a budgie or stylet have been reported [5, 6]. However, no studies have evaluated patient muscle relaxation status with regard to ProSeal insertion efficacy.

Muscle relaxation has been found to affect upper airway anatomy and ventilation efficacy [7, 8]. Given that muscle relaxants facilitate the expansion of pharyngeal anatomy, we hypothesized that ProSeal insertion efficacy would be improved by muscle relaxant administration. We conducted a randomized study to test this hypothesis by comparing ProSeal insertion efficacy, airway-sealing pressure, leakage volume by mechanical ventilation, and subjective difficulty

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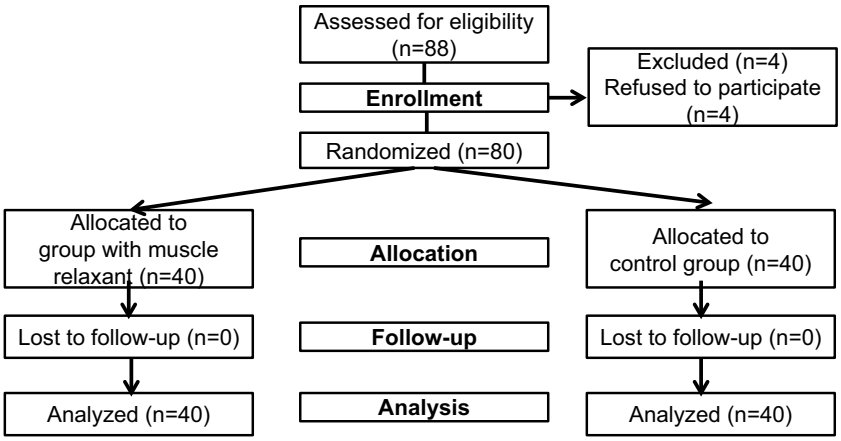

Fig. 1 CONSORT flowchart for patient recruitment

of insertion with or without muscle relaxation in anesthetized patients.

Methods

The research ethics committee of Hokusetsu General Hospital approved this study. Figure 1 shows the CONSORT flowchart of our study. From August to October 2014, eligibility was assessed for 88 patients, of which four refused and four were excluded in accordance with the eligibility criteria. After obtaining written informed consent, 80 patients aged 20–85 years who were to undergo general anesthesia in a supine position were randomly assigned (envelope method) to one of two groups: rocuronium group (R group; 40 patients) or the control group (C group; 40 patients). Exclusion criteria included any contraindication for the use of supraglottic devices (e.g., morbid obesity defined by a body mass index >35, gastroesophageal reflux, and previous upper abdominal surgery) or a recent (within 7 days) history of upper respiratory tract infection [9].

Routine monitoring of parameters including non-invasive blood pressure, heart rate, electrocardiography, percutaneous oxygen saturation, bispectral index (BIS), and end-tidal carbon dioxide tension was performed. Without any premedication, anesthesia was induced with propofol 1–2 mg kg^{-1} and fentanyl 1.0 μg kg^{-1}. After loss of consciousness, mask ventilation was performed with 3–5 % sevoflurane. The R group was administered 0.9 mg kg^{-1} of rocuronium, while the C group was not [10]. To minimize the risk of laryngospasm, an anesthesiologist inserted the ProSeal after confirming that the BIS score was under 60. To ensure sufficient muscle relaxation, we inserted the ProSeal more than 3 min after rocuronium administration in the R group. Patient body weight was used as a reference to determine sizing (3, 4, or 5) according to the manufacturer's guidelines. Anesthesiologists with more than 9 years of experience (N.K., I.N., S.T., S.M., and W.N.) performed the insertions. All anesthesiologists had more than 200 clinical experiences for ProSeal insertion. The number of cases they performed in this study was 14–18 for each doctor. Following insertion of the ProSeal, the cuff was inflated by adjusting the pressure to 30 cmH_2O by a pressure transducer. Successful insertion was confirmed by bilateral chest wall movement, auscultation, and normal capnograph curves. Insertion with a sealing pressure >15 cmH_2O was considered successful. After successful insertion, the sealing pressure was measured. In cases of failed ventilation, a re-insertion trial was performed immediately, and the number of insertion attempts was recorded. However, cases for which the third attempt failed were recorded as failures; in these cases, airway management was performed using i-gel® or tracheal intubation. At the end of the insertion process, anesthesiologists rated the ProSeal insertion difficulty on a visual analog scale (VAS) ranging from 0 mm (extremely easy) to 100 mm (extremely difficult).

After successful ventilation, mechanical ventilation was performed immediately, and anesthesia was maintained with inhalation of sevoflurane and administration of remifentanil with 33–40 % oxygen. Patients were ventilated with a tidal volume of 8 ml kg^{-1} at eight breaths per minute after the initiation of mechanical ventilation. Leakage volume was measured and calculated as follows: (inspiratory volume)—(expiratory volume at the point of five min after initiation of mechanical ventilation). After the operation, muscle relaxation was reversed with 200 mg of sugammadex in the R group. After ProSeal removal and patient arousal, postoperative hoarseness and pharyngeal pain were assessed.

Statistical analysis was performed utilizing JMP® 11 (SAS Institute Inc., Cary, NC, USA). Statistical analysis was performed with the χ^2 test and unpaired Mann–Whitney U test for data pertaining to patient characteristics. The χ^2 test was applied to evaluate the number of insertion attempts in relation to hoarseness and pharyngeal pain incidents. The Mann–Whitney U test was used to compare sealing pressure, leakage volume, and VAS. Data are

Table 1 Patient characteristics of each group presented as mean ± SD or number of patients

	C group ($n = 40$)	R group ($n = 40$)	p value
Age	58.1 ± 13.6	56.4 ± 17.7	0.63
Gender (male/female)	23/17	21/19	0.82
Body weight (kg)	60.7 ± 15.1	62.5 ± 12.2	0.51
Height (cm)	162.4 ± 9.8	163.1 ± 10.2	0.96
BMI (kg/m^2)	22.8 ± 4.0	23.4 ± 3.3	0.35
Duration of surgery (min)	79.0 ± 48.5	75.3 ± 51.2	0.55
Duration of anesthesia (min)	129.9 ± 50.1	123.8 ± 58.3	0.30
ASA classification (1/2/3/4)	15/21/4/0	14/19/7/0	0.82
Mallampati score (1/2/3/4)	25/11/2/2	21/14/5/0	0.90
ProSeal size (3/4/5)	14/21/5	14/19/7	0.94

No significant differences were observed between the two groups. C group: ProSeal® inserted without a muscle relaxant; R group ProSeal® inserted after rocuronium administration

Mean ± SD or number of patients. Data were analyzed using the Mann–Whitney U test or χ^2 test

BMI body mass index, *ASA* American Society of Anesthesiologists

presented as mean ± SD. $p < 0.05$ was considered statistically significant.

As for the sample size calculation, the incidence of successful ProSeal insertion without muscle relaxants (sealing pressure >15 cmH_2O upon first insertion) in the preliminary trial was approximately 60 %. As such, we hypothesized that muscle relaxation would increase the successful insertion rate to 90 %. To detect this difference with 80 % power at a 5 % significance level, 37 patients were required for each group. Therefore, we planned to recruit 40 patients for each group to adjust for missing data.

Results

Patient characteristics are shown in Table 1. Between the R and C groups, no significant differences were identified with regard to age, sex, body weight, height, body mass index, duration of surgery, duration of anesthesia, Mallampati score, or ProSeal size used.

Number of attempts required for successful insertion and sealing pressure

The number of insertion attempts was one for 38 patients, two for one patient, and three for one patient in the R group and one for 28 patients, two for seven patients, and three for five patients in the C group ($p < 0.001$) (Table 2). All insertions were successful by the third attempt. The number of successful ventilations in the first trial was significantly higher in R group than in C group ($p = 0.008$). After successful insertion, the sealing pressure was significantly higher in the R group than in the C group (R group, 27.4 ± 5.4 cmH_2O; C group, 21.2 ± 5.2 cmH_2O; $p < 0.001$) (Fig. 2). The leakage volume was calculated as (inspiratory volume)—(expiratory volume), and was significantly less in the R group compared to the C group (R group, 17.4 ± 29.1 ml; C group, 46.8 ± 45.5 ml; $p < 0.001$) (Fig. 3).

Incidence of hoarseness and pharyngeal pain after general anesthesia

The incidence of hoarseness and pharyngeal pain after general anesthesia are shown in Table 2. Hoarseness was noted in only one patient in the C group, but not in the R group ($p = 0.31$). In the C group, five patients reported pharyngeal pain, while only one did in the R group ($p = 0.08$).

Subjective difficulty of ProSeal insertion

As shown in Fig. 4, subjective difficulty of ProSeal insertion according to the VAS was significantly lower in the C group than in the R group (R group, 12.3 ± 23.1 mm; C group, 39.4 ± 31.9 mm; $p < 0.001$).

Discussion

LMAs are recommended by professionals for airway rescue in cases of failed intubation, and various models have

Table 2 Comparison of several factors related to airway management between the group administered rocuronium and the control group

	C group ($n = 40$)	R group ($n = 40$)	p value
Number of attempts for successful ventilation (1/2/3/fail)	28/7/5/0	38/1/1/0	<0.001*
Number of patients with pharyngeal pain hoarseness	5	1	0.08
Number of patients with hoarseness	1	0	0.31

Data were analyzed using the Mann–Whitney U test or χ^2 test

C group: ProSeal® inserted without a muscle relaxant; R group: ProSeal® inserted after rocuronium administration

* $P < 0.05$ was considered statistically significant

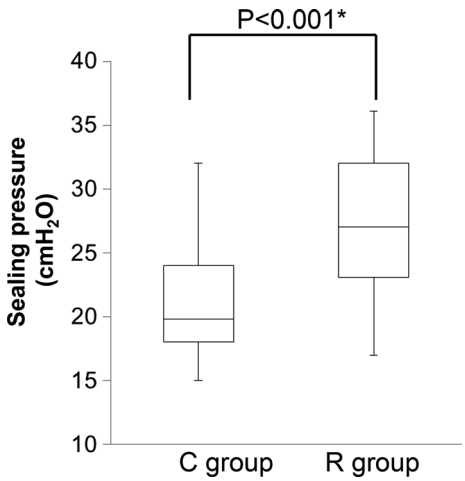

Fig. 2 *Box-and-whisker plot* (median, IQR, and range) of sealing pressures after successful insertion in C and R groups. C group: ProSeal® inserted without muscle relaxant; R group: ProSeal® inserted after rocuronium administration. *$p < 0.05$ was considered statistically significant

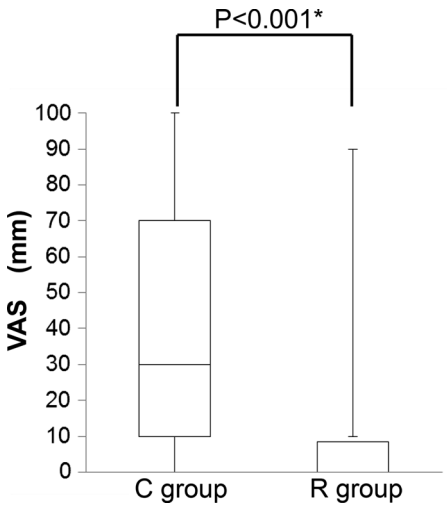

Fig. 4 *Box-and-whisker plot* (median, IQR, and range) of subjective difficulty of insertion (visual analog scale) in the C and R groups. C group: ProSeal® inserted without a muscle relaxant; R group: ProSeal® inserted after rocuronium administration. *$p < 0.05$ was considered statistically significant

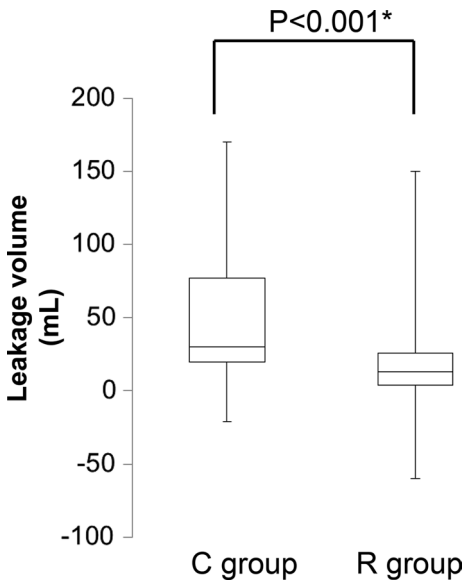

Fig. 3 *Box-and-whisker plot* (median, IQR, and range) of leakage volume (inspiratory volume minus expiratory volume) between the C and R groups. C group: ProSeal® inserted without muscle relaxant; R group: ProSeal® inserted after rocuronium administration. *$p < 0.05$ was considered statistically significant

been developed. The ProSeal is a modification of the LMA-Classic®, which has been available since 2000 [11]. The ProSeal has various enhanced features, and differs from original laryngeal mask models such as the LMA-Classic® and LMA-SoftSeal® [12]. Specifically, the ProSeal is equipped with a double cuff mechanism and can maintain a high seal pressure, which allows for safe positive-pressure ventilation. When correctly placed, it achieves a higher seal with the airway than the LMA-Classic® and functionally separates the gastrointestinal and respiratory tracts [13]. However, due to the large cuff volume, insertion of the ProSeal can be difficult even in routine anesthesia.

Several available insertion techniques allow easy and definite insertion of the ProSeal. A silicone-coated, malleable metal introducer is provided by the ProSeal manufacturer. The distal end is located in the retaining strap and the proximal end in the notch between the airway tube and esophageal drain tube. Some have reported bending the ProSeal to 90° with the intubating stylet inserted into the esophageal drain tube [6]. With these techniques, the ProSeal resembles the intubation laryngeal mask airway, enabling definite and easy insertion [14]. Another insertion technique involves placing a gum elastic budgie into the esophagus using a laryngoscope and railroading the ProSeal drain tube. This technique prevents folding of the mask tip and increases correct placement of the ProSeal [15, 16].

Several studies have examined the significance of muscle relaxants during mechanical ventilation with the ProSeal [17, 18]. Chen et al. showed that there was no difference of sealing pressure of mechanical ventilation during laparoscopic surgery between with or without muscle relaxation. Though they describe that all insertions were successful at the first attempt, they do not show the criteria or definition of successful insertion of ProSeal.

The present study is the first to evaluate muscle relaxation with regard to insertion efficacy and sealing pressure of the ProSeal. In our study, muscle relaxants were found to significantly improve the ProSeal insertion success rate

with lower subjective difficulty. Furthermore, our results showed higher sealing pressure and lower leakage volume in the R group compared to the C group. One possible reason for muscle relaxants contributing to high insertion efficacy may be the increased pharyngeal space created by muscle relaxation [19]. The relative position with pharyngeal space and ProSeal may be attributed to the fitting and sealing pressure difference with or without muscle relaxant. Sufficient pharyngeal and laryngeal muscle relaxation may ease insertion and facilitate ProSeal adhesion to the pharyngeal structure, leading to higher insertion efficacy and sealing pressure.

There are two main limitations worth noting. First, though we inserted ProSeal under BIS 60 to minimize the occurrence of laryngospasm, there are no definite methods to exclude the possibility of laryngospasm. Second, a double-blinded placebo-control trial utilizing saline in the control group is more favorable for study design.

For future directions based on present study are as follows. First, as sealing pressure is partially affected by cuff pressure, evaluating different cuff pressures may be important in future studies [20]. Second, evaluation by more inexperienced trainees may further clarify the utility of the ProSeal. Third, size selection of the ProSeal by the new criteria may provide more reliable data [21, 22]. Fourth, a multi-center study or a meta-analysis would clarify the utility of muscle relaxants for ProSeal insertion.

In conclusion, muscle relaxation facilitated ProSeal insertion efficacy by increasing the successful insertion rate and sealing pressure, while lowering the subjective difficulty of insertion in anesthetized patients.

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Conflict of interest The authors have no affiliation with any manufacturer of any device described in the manuscript and declare no financial interest in relation to the material described here.

References

1. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: a randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. Anesthesiology. 2000;93:104–9.
2. Asai T, Murao K, Shingu K. Efficacy of the ProSeal laryngeal mask airway during manual in-line stabilisation of the neck. Anaesthesia. 2002;57:918–20.
3. Goldmann K, Hechtfischer C, Malik A, Kussin A, Freisburger C. Use of ProSeal laryngeal mask airway in 2,114 adult patients: a prospective study. Anesth Analg. 2008;107:1856–61.
4. Brimacombe J, Keller C. A proposed algorithm for the management of airway obstruction with the Proseal laryngeal mask airway. Anesth Analg. 2005;100:298–9.
5. Eschertzhuber S, Brimacombe J, Hohlrieder M, Stadlbauer KH, Keller C. Gum elastic bougie-guided insertion of the ProSeal laryngeal mask airway is superior to the digital and introducer tool techniques in patients with simulated difficult laryngoscopy using a rigid neck collar. Anesth Analg. 2008;107:1253–6.
6. Okutani R, Ogawa S. Utility of the ProSeal laryngeal mask airway creating a 90 degree angle with an intubating stylet. J Anesth. 2010;24:492–3.
7. Ikeda A, Isono S, Sato Y, Yogo H, Sato J, Ishikawa T, Nishino T. Effects of muscle relaxants on mask ventilation in anesthetized persons with normal upper airway anatomy. Anesthesiology. 2012;117:487–93.
8. Warters RD, Szabo TA, Spinale FG, DeSantis SM, Reves JG. The effect of neuromuscular blockade on mask ventilation. Anaesthesia. 2011;66:163–7.
9. Komasawa N, Nishihara I, Tatsumi S, Minami T. Pre-warming i-gel® to 42°C facilitates successful insertion and ventilation efficacy with muscle relaxation: a randomized study. J Clin Anesth 2014;26:663–667.
10. Wright PM, Caldwell JE, Miller RD. Onset and duration of rocuronium and succinylcholine at the adductor pollicis and laryngeal adductor muscles in anesthetized humans. Anesthesiology. 1994;81:1110–5.
11. Komasawa N, Ueki R, Yamamoto N, Atagi K, Nishi S, Kaminoh Y, Tashiro C. Comparison of air-Q® and Soft Seal® laryngeal mask for airway management by novice doctors during infant chest compression: a manikin study. Resuscitation. 2012;83:365–8.
12. Natalini G, Lanza G, Rosano A, Dell'Agnolo P, Bernardini A. Standard laryngeal mask airway and LMA-ProSeal during laparoscopic surgery. J Clin Anesth. 2003;15:428–32.
13. Cook TM, Lee G, Nolan JP. The ProSeal laryngeal mask airway: a review of the literature. Can J Anaesth. 2005;52:739–60.
14. Komasawa N, Ueki R, Kaminoh Y, Nishi S. Evaluation of chest compression effect on airway management with air-Q®, aura-i®, i-gel®, and Fastrack® intubating supraglottic devices by novice physicians: a randomized crossover simulation study. J Anesth. 2014;28:676–80.
15. Howath A, Brimacombe J, Keller C, Kihara S. Gum elastic bougie-guided placement of the ProSeal laryngeal mask. Can J Anaesth. 2002;49:528–9.
16. Howath A, Brimacombe J, Keller C. Gum-elastic bougie-guided insertion of the ProSeal laryngeal mask airway: a new technique. Anaesth Intensive Care. 2002;30:624–7.
17. Keller C, Brimacombe J. Influence of neuromuscular block, mode of ventilation and respiratory cycle on pharyngeal mucosal pressures with the laryngeal mask airway. Br J Anaesth. 1999;83:480–2.
18. Chen BZ, Tan L, Zhang L, Shang YC. Is muscle relaxant necessary in patients undergoing laparoscopic gynecological surgery with a ProSeal LMA™? J Clin Anesth. 2013;25:32–5.
19. Kuna ST. Respiratory-related activation and mechanical effects of the pharyngeal constrictor muscles. Respir Physiol. 2000;119:155–61.
20. Asai T, Brimacombe J. Review article: cuff volume and size selection with the laryngeal mask. Anaesthesia. 2000;55:1179–84.
21. Kihara S, Brimacombe JR, Yaguchi Y, Taguchi N, Watanabe S. A comparison of sex- and weight-based ProSeal laryngeal mask size selection criteria: a randomized study of healthy anesthetized, paralyzed adult patients. Anesthesiology. 2004;101:340–3.
22. Asai T, Murao K, Yukawa H, Shingu K. Re-evaluation of appropriate size of the laryngeal mask airway. Br J Anaesth. 1999;83:478–9.