Comparison between use of neuromuscular blocking agent and placebo with the intubating larygeal mask airway

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ABSTRACT

Introduction: The intubating laryngeal mask airway (ILMA) is a specially-designed airway device that can be used for endotracheal intubation without direct laryngoscopy. The advantage of this device is that it allows blind endotracheal intubation with a predictably high success rate. The use of neuromuscular blocking agents in facilitating the use of the ILMA has been investigated in the Western population with a quoted successful intubation rate of 88–96 percent. This randomised, double-blind study aimed to see if the use of neuromuscular blocking agent is necessary for successful intubations.

Methods: A total of 150 patients, rated categories 1 and 2 on the American Society of Anesthesiology Physical Status Classification System, were induced with propofol 2.5 mg/kg and fentanyl 2 ug/kg. After insertion of the ILMA, the patients received either saline or 0.6 mg/kg of rocuronium. After 90 seconds, tracheal intubation was attempted using the specially-designed silicon endotracheal tube. In addition to the success rate of intubation, the incidence of complications was also recorded.

Results: The success rate for tracheal intubation within three attempts was 93.3 percent for the saline group and 92.0 percent for the rocuronium group; this was statistically insignificant. The time to securing the airway was 11.5 seconds for the saline group, compared to 10.0 seconds in the rocuronium group, but this was statistically insignificant. The incidence of coughing during insertion of the endotracheal tube was 42.7 percent in the saline group as compared to 1.3 percent in the rocuronium group (p-value is less than 0.001). 12 percent of the patients in the saline group moved during intubation, while none was reported to move in the rocuronium group (p-value is 0.003). These results compared favourably with rates quoted in studies conducted on Western populations.

Conclusion: The intubating laryngeal mask airway-assisted intubation yields a high success rate, which was similar between the paralysed and non-paralysed patients, with no statistical significance. However, the non-paralysed patients were prone to coughing and movements during intubation, requiring supplemental propofol.

Keywords: intubating laryngeal mask airway, intubation, laryngeal mask airways, laryngeal masks, neuromuscular blocking agents

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INTRODUCTION

The intubating laryngeal mask airway (ILMA) (LMA-Fastrach™ LMA North America Inc, San Diego, CA, USA), is an advanced form of the laryngeal mask airway that is designed to facilitate endotracheal intubation.[1,2] The success rate (93%–99%)[2-5] of the ILMA-assisted intubation adds to its value in the management of a difficult airway. It has been used successfully in the management of difficult airways,[3,6] even on patients where fibre-optic intubation has failed.[7]

Most clinical trials on this device have involved the use of a neuromuscular blocking agent to optimise the intubating conditions.[4,6,8] However, the use of any non-depolarising neuromuscular blocking agent is best avoided in patients with difficult airways.[9] There have also been reports of successful intubations using the ILMA without the use of any neuromuscular blocking agent.[10,11] This led to a randomised, double-blinded, placebo-control study by van Vlymen et al to evaluate the success rate and incidence of complications associated with the ILMA assisted tracheal intubation.[12] Tracheal intubation was successful in 76%, 88% and 96% of the patients in the saline, rocuronium 0.2 mg/kg and rocuronium 0.4 mg/kg groups, respectively (n = 25 in each group), though these results were not statistically significant. However, this study by van Vlymen et al was powered to detect a 15% difference in the intubation time rather than intubation success rate between the two groups. We designed a prospective, randomised, double-blinded, placebo-control trial, powered to assess the absolute difference in the rate of success when performing intubations in our patients, with and without the use of a neuromuscular blocking agent, using a silicone endotracheal tube as recommended by the manufacturer.

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Table I. Demographic data for the two study groups.

	Rocuronium group (n = 75)	Saline group (n = 75)
Age (years)	33.2 ± 10.9	34.83 ± 13.0
Gender		
Female	13 (17.3)	13 (17.3)
Male	62 (82.7)	62 (82.7)
Mean weight (kg)	66.52 ± 11.5	64.13 ± 11.3
Race		
Chinese	36 (48.0)	33 (44.0)
Indian	12 (16.0)	24 (32.0)
Malay	16 (21.3)	15 (20.0)
Others	11 (14.7)	3 (4.0)
ASA		
1	34 (45.3)	36 (48.0)
2	41 (54.7)	39 (52.0)
Mallampati score		
1	32 (42.7)	38 (50.7)
2	40 (53.3)	37 (49.3)
3	3 (4.0)	0 (0)
Smoker (%)	46.7	40

Data is expressed as mean ± SD or number (%). No significant difference between groups was found.
ASA: American Society of Anesthesiology Physical Status Classification System

METHODS

The hospital ethics committee's approval was sought, and informed consent was obtained from every patient prior to conducting the study. A power analysis was performed based on a success rate of 90% from previous studies.[2-5] Assuming a reduction of success rate to 80% when no neuromuscular blocking agent is used, 200 patients would be needed in each group to achieve a power of 80% and a p-value of less than 0.05. Patients above the age of 18 years presenting for orthopaedic or general surgery were recruited into the study. Patients who required nasal intubation or who had airway diseases like asthma and chronic obstructive pulmonary disease, known upper airway pathology, previous head and neck surgery or radiotherapy and coagulopathy; and patients with gastroesophageal reflux posing an increased risk for aspiration, were excluded. Patients who were on drugs that could potentially interfere with neuromuscular transmissions, such as gentamicin or magnesium sulphate, were also excluded from the study.

Once recruited, the patient's airway was assessed in the sitting position where an appropriate Mallampati classification was assigned. Three anaesthetists who had performed at least ten successful ILMA insertions prior to the study were deemed proficient and were tasked with conducting the study. Patients were randomised, based on sealed opaque envelopes to receive either saline or 0.6 mg/kg of rocuronium. The sealed opaque envelopes were opened just prior to the induction of anaesthesia. The patient and the intubating anaesthetist were blinded from knowing what drug was used by having similarly labelled 10 ml syringes containing 10 ml of either solution. The drug was prepared by a second anaesthestist not involved in either care or data collection of the patient.

Prior to the induction of anaesthesia, standard monitors were attached (electrocardiography and noninvasive blood pressure, end-tidal carbon dioxide, oxygen saturation and inspired fraction monitors), and readings were taken at one-minute intervals until ten minutes had lapsed after a successful intubation. Thereafter, the readings were charted at five-minute intervals throughout the period of anaesthesia. Patients were required to be preoxygenated for three minutes. Intravenous fentanyl 2 µg/kg was then given to all patients, followed by an intravenous bolus of propofol 2.5 mg/kg three minutes later. Anaesthesia was then maintained at 2% of expired sevoflurane in 3 L/min of oxygen together with an intravenous infusion of propofol at 10 mg/kg/h. The ILMA was inserted after loss of the eyelash reflex, with the jaw relaxed and the head in neutral position, in accordance with the technique recommended by the manufacturer. ILMA sizes #3, #4 and #5 were used for the study. The size selection was based on the patient's weight: #3 for body weight < 30 kg, #4 for 30–70 kg and #5 for > 70 kg. After insertion, the ILMA cuff was inflated with the recommended volume of air and manual positive pressure ventilation was applied to ascertain air entry into the lungs. A good placement of the ILMA was ascertained by ease of manual ventilation and a good end-tidal carbon dioxide tracing of 35–40 mmHg.

90 seconds after the test solution was given, the reusable size seven silicone tube was inserted. Successful insertion was confirmed by auscultation and by the appearance of carbon dioxide tracing on the monitor. The intubation time was taken as the time from the disconnection of the ILMA from the circuit for the insertion of the endotracheal tube till successful intubation was confirmed by the first appearance of expiratory carbon dioxide tracing. The time taken for inserting, adjusting and confirming the placement of ILMA was not taken into account for the intubation time. If intubation was not possible, the ILMA was adjusted till a minimum resistance to ventilation was encountered. Intubation was then attempted again. If after three attempts, a successful intubation was still not possible, the technique was

Table II. Intubation success rate, intubation time, and complication rate for both rocuronium and saline groups.

	Rocuronium group (n = 75)	Saline group (n = 75)
Successful intubation	69 (92.0)	T70 (93.3)
Intubation time (sec)	10.0 (5–170)	11.5 (5–180)
Number of attempts at intubation		
1 attempt	57 (76.0)	59 (78.7)
2 attempts	10 (13.3)	11 (14.7)
3 attempts	2 (2.7)	0 (0)
Failed intubation	6 (8.0)	5 (6.7)

Data is expressed as number (%) or median (95% confidence interval). There was no significant difference between groups.

Table III. Adverse events encountered during intubation.

	Rocuronium group	Saline group	p-value
Coughing during intubation	1 (1.3)	32 (42.7)	< 0.001
Movement during intubation	0 (0)	9 (12.0)	0.003
Laryngospasm	0 (0)	0 (0)	1
Supplemental propofol	0 (0)	10 (13.3)	0.001

Data is expessed as number (%).

abandoned and the second solution was given. The second solution given was determined by the anaesthesiologist who prepared the test solution. If the first solution was rocuronium, the second solution would be saline, since the patient would have been sufficiently paralysed based on dosage. If the first solution used was saline, rocuronium would have been given as the second solution. This was to ensure that the intubating anaesthesiologist was blinded throughout the process. Intubation was then carried out under direct laryngoscopy. If the patient moved during the process, a supplement of propofol (0.5 mg/kg) was given. If the patient developed laryngospasm, an additional dose of rocuronium 0.6 mg/kg was given.

The primary outcome was successful intubation. The secondary outcomes were coughing, movement and laryngospasm during intubation and intubation time. Patient's heart rate, blood pressure and oxygen saturation were recorded during the intubation process. Upon successful intubation, propofol infusion was titrated downwards and anaesthesia maintained with sevoflurane alone. Data is presented as mean ± standard deviation (SD) or median with 95% confidence interval (CI) for non-Gaussian variables. Comparison of two means was performed using the Student *t*-test, and comparison of two medians was performed using the Mann-Whitney U-test. Comparison of percentages was performed using the Fisher exact method.

RESULTS

After 150 patients were included in this study, with 75 patients in the rocuronium group and 75 patients in the saline group, an interim study was performed. Patient characteristics, including age, weight, sex, race, American Society of Anesthesiology Physical Status Classification System (ASA) scoring and criteria of anticipated difficult intubation according to Mallampati Scores in both groups, were recorded and shown in Table I.

All the patients in both groups were ventilated successfully with the ILMA. Insertion of the ILMA was also successful in all the patients. Intubation with the ILMA was successful in 92.0% of patients in the rocuronium group and 93.3% in the saline group within three attempts (p = 0.537) (Table II). In the rocuronium group, successful intubations were achieved within the first attempt in 76.0% of patients, 13.3% at the second attempt, and 2.7% at the third attempt. In the saline group, successful intubation was achieved within the first attempt in 78.7% of patients, 14.7% at the second attempt, and none at the third attempt. Failure rate was 8.0% in the rocuronium group and 6.7% in the saline group. The results of the two groups were similar and no significant differences were observed. Intubation time for both groups was also similar with no significant difference (Table II). Mean intubation time was 10.0 seconds in the rocuronium group, compared to 11.5 seconds in the saline group. As the success rates for both groups were very similar from the interim study, the decision was made to terminate the study since the outcome is unlikely to differ with a larger sample size.

The incidence of adverse events was significantly greater in the saline group (Table III). 42.7% of patients in the saline group coughed during intubation compared to only 1.3% in the rocuronium group ($p < 0.001$). 12.0% of the patients in the saline group moved during intubation while no patients in the rocuronium group did (p = 0.003). The use of supplemental propofol in patients who moved did not result in hypotension. No laryngospasm was encountered in both groups; hence, supplemental rocuronium was not used.

DISCUSSION

From this study, we observed that there was a high overall success rate (93.3%) of endotracheal intubations with the ILMA, even without the use of a neuromuscular

blocking agent. This is similar to the reported rates in other studies where neuromuscular blocking agents were used routinely.[2-5] The rates of successful intubation on the first, second and third attempts do not differ significantly between the two groups. The time taken for intubation was also similar for both groups.

The complications, in terms of coughing and movement during intubation, were significantly higher in the saline group for which supplemental propofol had to be administered subsequently. However, this did not result in any adverse effect such as desaturation or an increase in the failure rate. The advancement of the endotracheal tube may inadvertently reach the carina, provoking a strong cough reflex. A higher dose of propofol could be given during induction to reduce the incidence of coughing or movement, but this may be associated with a greater degree of hypotension, which may not be well-tolerated by a haemodynamically unstable patient. Alternatively, patients could be paralysed after insertion of the ILMA to facilitate intubation, since a reasonable airway has been secured. However, in patients with poor lung compliance or some degree of airway obstruction, the ILMA may not provide a sufficient seal for ventilation with a high positive airway pressure. Hence, clinical judgment is necessary concerning the use of a neuromuscular blocking agent in these instances.

A similar study by van Vlymen et al also showed comparable success rates between patients who were given saline and patients who were given low (0.2 mg/kg) and high dose (0.4 mg/kg) rocuronium. However, the success rate was highest with the high dose rocuronium group (96%) and lowest with the saline group (73.0%), though they were not statistically significant.[12] The success rate of intubation in our study was found to be higher than the study by van Vlymen and colleagues.[12] This may be due to the difference in the type of endotracheal tubes used. During the study by van Vlymen et al, disposable poly-vinyl chloride (PVC) was used instead of the reusable size seven soft silicone tube as recommended by the manufacturer. With the use of a PVC endotracheal tube, it may exit the ILMA anterior to the position a silicone tube would normally exit. This may have contributed to their lower success rate.

From previous studies, the ILMA has been reported to be an effective airway device for patients with difficult airways.[3,6] The success rate of intubation was found to be comparable to even that of fibre-optic intubation. In situations of an anticipated difficult airway, it is logical to assume that most anaesthetists would rather not paralyse their patients so that emergence would not be delayed should the intubation prove difficult. The presence of the ILMA will also serve as an effective airway device allowing ventilation to continue when intubation fails. On the other hand, a neuromuscular blocking agent may be useful in reducing complications during intubation, such as coughing and movement, thereby avoiding the need for a supplemental dose of an induction agent. But the problems encountered during intubation with the ILMA, in the absence of a neuromuscular blocking agent, were almost readily overcome by administering higher doses of propofol.

The ILMA is a useful tool for endotracheal intubation. It is capable of achieving an overall high success rate of more than 92%. A similarly high success rate of endotracheal intubation with the ILMA is still possible without use of a neuromuscular blocking agent, although its use has the advantage of preventing coughing and movement during intubation. However, for patients with a known or suspected difficult airway, it is preferable not to paralyse the patients until the airway is secured. Hence, the decision to use a neuromuscular blocking agent during an ILMA assisted intubation depends greatly on the balance between these risks and benefits.

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