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Original Contribution

Muscle relaxant facilitates i-gel insertion by novice doctors: A prospective randomized controlled trial☆,☆☆

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Abstract

Study objective: This study aimed to determine whether muscle relaxants facilitates insertion efficacy of the i-gel supraglottic device (i-gel) by novice doctors in anesthetized patients.

Design: Randomized clinical trial.

Setting: Operating room.

Patients: Seventy adult patients scheduled for elective surgery under general anesthesia.

Interventions: Seventy adult patients were assigned to the rocuronium (MR group; 35 patients) or control group (C group; 35 patients). Anesthesia was induced with propofol and remifentanil, and 0.9 mg kg^{-1} rocuronium was administered in the MR group.

Measurements: The number of attempts to successful insertion, sealing pressure, and subjective difficulty of insertion were compared between the groups.

Main results: The total number of insertion attempts were as follows: one (MR group, 17 cases; C group, 4 cases), two (MR group, 13 cases; C group, 14 cases), three (MR group, 4 cases; C group, 14 cases), and failure (MR group, 1 case; C group, 3 cases), which was significantly different ($P < .001$). Sealing pressure was significantly higher in the MR group than in the C group (MR group, 22.1 ± 5.4 cmH_2O; C group, 18.7 ± 3.2 cmH_2O, $P < .001$). Subjective difficulty of insertion was significantly lower in the MR group than in the C group (C group, 72.4 ± 19.0 mm; MR group, 29.4 ± 18.3 mm; $P < .001$).

Conclusions: Our randomized clinical trial suggests that muscle relaxation facilitates i-gel insertion efficacy in anesthetized patients, as assessed by successful insertion rate, sealing pressure, and subjective difficulty of insertion.

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1. Introduction

The i-gel (i-gel: Intersurgical, Wokingham, United Kingdom) is a relatively new supraglottic device made of a thermoplastic elastomer. The device also holds a drainage tube and bite-block mechanism [1,2]. Previous studies have shown that the i-gel shows sufficient airway sealing pressure and can be used not only for mechanical ventilation under general anesthesia, but also emergent airway management during cardiopulmonary resuscitation [3]. The i-gel can be rapidly and easily placed, providing a clear airway in most cases when performed by experienced anesthesiologists [4]. Some reports suggest that the i-gel requires less professional skill and is suited for occasional and novice operators [5]. However, insertion of supraglottic devices (SGDs) by novice doctors can lead to hemorrhage and postoperative pharyngeal pain. One possible reason for this is the difficulty of placing the i-gel at the appropriate position in the larynx.

Muscle relaxation affects the pharyngeal and laryngeal structure and thereby influences airway management [6]. However, it is unclear whether muscle relaxants facilitate i-gel insertion. Here, we hypothesized that muscle relaxants would facilitate i-gel insertion efficacy. The primary hypothesis was tested by assessing the success of i-gel insertion with sufficient sealing pressure. The secondary hypothesis was tested by assessing the subjective difficulty of insertion and incidence of postoperative pharyngeal pain or hoarseness. The present study aimed to investigate these hypotheses by comparing the insertion efficacy of the i-gel by novice doctors with or without muscle relaxants in anesthetized patients.

2. Methods

The research ethics committee of Osaka Medical College approved this study. This study was registered with the UMIN Clinical Trials Registry (UMIN000017488). From May to July 2015, 77 patients aged 20 to 80 years scheduled to undergo general anesthesia in the supine position were assessed for eligibility to participate. Four patients were excluded and 3 patients refused to participate. After obtaining written informed consent, 70 of these patients were randomly assigned using an envelope method to one of 2 groups: rocuronium group (MR group; 35 patients) and control group (C group; 35 patients) (Fig. 1). Exclusion criteria included any contraindication for the SGDs application (eg, morbid obesity [body mass index, >35], neuromuscular disorder, gastroesophageal reflux, and previous upper abdominal surgery) or a recent (within 7 days) history of upper respiratory tract infection [7,8].

Sixteen novice doctors who took an anesthesia module during their initial training (all non-anesthesiologists with clinical experience <1 year) were recruited. They are all initial trainee doctors in Japanese medical systems and had no clinical experience of the i-gel usage before anesthesia module. Before data collection, novice doctors had experienced i-gel insertion at least 5 times. Each doctor inserted the i-gel in 3–7 patients during the trial period. The training period is maximum 2 months.

Routine monitoring of heart rate, non-invasive blood pressure, electrocardiography, percutaneous oxygen saturation, bispectral index, and end-tidal carbon dioxide tension was performed [9]. Premedication was not performed. Anesthesia was induced with remifentanil 0.3–0.5 $\mu g\ kg^{-1}\ min^{-1}$ and propofol 1–2 $mg\ kg^{-1}$. After loss of consciousness, mask ventilation was performed with 3–5% sevoflurane; 0.9 $mg\ kg^{-1}$ of rocuronium was administered to the MR group, while 5 ml of normal saline was administered to the C group [8]. To provide sufficient depth of anesthesia, novice doctors inserted the i-gel after confirmation of a bispectral index score <60. The supervising anesthesiologists confirmed the zero count of train-of-four with TOF watch (NIHON KOHDEN, Tokyo, Japan) before the insertion trial. We used doubled-over normal cutout cushions which we usually use for anesthesia induction with approximately 8 cm height. A size 3 or 4 i-gel was selected based on the patient's body weight, according to the manufacturer's guidelines. A supervising anaesthesiologist determined the size for patients weighing 50–60 kg (between a size 3 or 4). Sealing pressure was measured with monitor after insertion of the i-gel by the supervising anaesthesiologist. Successful insertion was confirmed by the supervising anesthesiologist based on bilateral chest wall movement, auscultation, and normal capnograph curves; a sealing pressure of >15 cmH_2O was considered successful. When ventilation failed, a

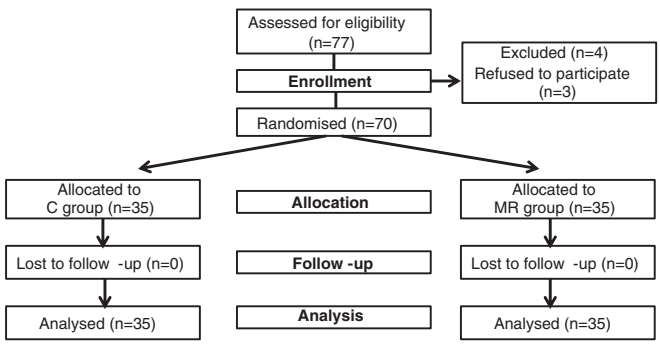

Fig. 1 Flowchart of patient recruitment.

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