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Original Contribution

Prewarming of the i-gel facilitates successful insertion and ventilation efficacy with muscle relaxation: a randomized study☆,☆☆

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Abstract
Study Objective: To determine if prewarming of the i-gel (Intersurgical, Wokingham, United Kingdom) improves insertion and ventilation efficacy with muscle relaxation in patients undergoing elective surgery.
Design: Clinical randomized study.
Setting: Operating room.
Patients: Sixty-eight adult patients scheduled for elective surgery under general anesthesia with American Society of Anesthesiologists physical status 1-3.
Interventions: The i-gel was warmed to 42°C for 30 minutes before insertion (W group; 34 patients) or kept at room temperature (approximately 23°C) (C group; 34 patients).
Measurements: The number of attempts for a successful insertion and the sealing pressure and leak volume 30 seconds and 30 minutes after initiating mechanical ventilation.
Main Results: The total insertion attempts were 1 (W group, 31 cases; C group, 24 cases) and 2 (W group, 3 cases; C group, 10 cases), which was significant ($P = .001$). Sealing pressure was significantly higher in the W group than the C group (W group, 21.8 ± 3.7 cm H_2O; C group, 18.5 ± 3.4 cm H_2O; $P = .001$). Leak volume was significantly smaller after 30 seconds in the W group than the C group ($P = .002$), but not after 30 minutes ($P = .69$).
Conclusions: Prewarming the i-gel to 42°C demonstrated a higher successful ventilation initiation.

1. Introduction

The i-gel (Intersurgical, Wokingham, United Kingdom) is a supraglottic device that contains a noninflatable, soft, gel-like cuff composed of a thermoplastic elastomer, which softens by body temperature to fit the laryngeal anatomy

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[1,2]. Previous studies have already shown that the i-gel has good airway sealing pressure and may be used for manual or mechanical ventilation under general anesthesia [3-7].

The i-gel cuff is usually used at room temperature, but we hypothesized that the i-gel cuff may mold to the laryngeal structure faster if prewarmed. However, a previous study did not demonstrate any significant difference in sealing pressure if an i-gel was prewarmed to 37°C [8]. Consequently, we believed an i-gel prewarmed to 37°C would cool during the insertion process and that a higher prewarming temperature could help the cuff exert a higher sealing pressure.

We performed this study to investigate this hypothesis by comparing the airway-sealing pressure and leakage volume amount between i-gel devices prewarmed to 42°C and those kept at room temperature (approximately 23°C).

The research ethics committee of Hokusetsu General Hospital approved this study. After obtaining written informed consent, 68 patients aged 20-85 years who were to have general anesthesia in a supine position were assigned at random by using an envelope method to 1 of 2 groups: 42°C prewarmed group (W group; 34 patients) and control group (C group; 34 patients). Exclusion criteria were any contraindication for the use of supraglottic devices (morbid obesity [body mass index, >35 kg/m^2], gastroesophageal reflux, and a previous upper abdominal surgery) or a recent (within 7 days) history of an upper respiratory tract infection [8].

Routine monitoring such as percutaneous oxygen saturation, noninvasive blood pressure, heart rate, electrocardiography, and end-tidal carbon dioxide was performed. Without any premedication, anesthesia was induced with propofol 1-2 mg/kg and remifentanil 0.3-0.5 μg/kg/min. Rocuronium 0.8-1.0 mg/kg was administered as a muscle relaxant. The i-gel was warmed to 42°C in a heating cabinet with an automatic temperature control for 30 minutes before insertion in the W group, whereas it was stored at room temperature (approximately 23°C) for the C group. The time from i-gel delivery was measured in the preliminary study. Randomization was performed by envelope method. A thermometer was used to directly measure the temperature of the heating cabinet. Using the patient's body weight, a sized 3 or 4 i-gel was determined according to the manufacturer's guideline. As there is an overlap from size 3 (30-60 kg) and size 4 (50-90 kg), the anesthesiologist determined the size selection for patients with 50-60 kg weight. After insertion of the i-gel, the sealing pressure was measured. Successful insertion was confirmed by bilateral chest wall movement, auscultation, and normal capnograph curves and a sealing pressure of >15 cm H_2O. In case of failed ventilation, an insertion trial was immediately performed, and the number of insertion attempts was recorded. However, if the third attempt failed, this was recorded as a failure, and then, airway management with an LMA-ProSeal or tracheal intubation was performed.

After successful ventilation, mechanical ventilation was immediately performed, and anesthesia was maintained with inhalation of sevoflurane and administration of remifentanil 33%-40% in oxygen. Patients were ventilated with a tidal volume of 8 mL/kg at 8 breaths per minute until 30 minutes after the initiation of mechanical ventilation. The leak volume was calculated as follows: inspiratory volume minus expiratory volume.

Furthermore, the leak volume 30 seconds and 30 minutes after initiating mechanical ventilation was measured.

After completion of the surgery, the i-gel was removed, and postoperative hoarseness, pharyngeal pain, and pharyngeal pain or damage after arousal were assessed.

Statistical analysis was performed using JM 11 (SAS Institute, Inc, Cary, NC, USA). The χ^2 test and Mann-Whitney U test were used for data pertaining to patient characteristics. The χ^2 test was applied for the number of insertion attempts and hoarseness and pharyngeal pain incidents. Two-way repeated-measures analysis of variance was used to compare sealing pressure and leak volume 30 seconds and 30 minutes after insertion. Data are presented as mean ± SD and 95% confidence interval. $P < .05$ was considered statistically significant.

As for the sample size calculation, the incidence of successful i-gel insertions (sealing pressure, >15 cm H_2O upon first insertion) in a nonwarming preliminary trial was approximately 50%. As such, we hypothesized that prewarming the i-gel would increase the successful insertion rate to 85%. To detect this difference with 80% power, we planned to recruit 34 patients for each group to adjust for missing data.

Patient characteristics are shown in Table 1. There were no significant differences regarding age, sex, body weight, height, body mass index, duration of surgery, duration of anesthesia, Mallampati score, or i-gel size used.

1.1. Number of attempts for a successful insertion and sealing pressure

The number of insertion attempts was 1 for 31 cases and 2 for 3 cases in the W group and 1 for 24 cases and 2 for 10 cases in the C group (Table 2). All insertions were successful through the second insertion. The number of successful ventilations in the first trial was significantly higher in the W group (31 cases) than the C group (24 cases) ($P = .001$). After successful insertion, the sealing pressure was significantly higher in the W group than the C group (W group, 21.8 ± 3.7 cm H_2O; C group, 18.5 ± 3.4 cm H_2O) ($P = .001$) (Fig. 1).

1.2. Leak volume 30 seconds and 30 minutes after mechanical ventilation initiation

The leak volume was calculated as follows: inspiratory volume minus expiratory volume. In both groups, the leak volume was significantly smaller after 30 minutes of mechanical ventilation than after 30 seconds ($P < .001$). Furthermore, the leak volume was after 30 minutes ($P = .69$)