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Risk factors for postoperative sore throat associated with i-gel™, a supraglottic airway device

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ABSTRACT

i-gel™ is a supraglottic airway device widely used for airway management during general anesthesia as an alternative to tracheal intubation. It sometimes results in a sore throat postoperatively; however, the risk factors for a postoperative sore throat caused by i-gel remain unclear. Here, we clarify the risk factors for a postoperative sore throat associated with i-gel insertion. We retrospectively reviewed the data of 426 adult patients who received general anesthesia with i-gel at our institution from January 2018 to December 2019. The incidence of postoperative sore throat and intraoperative data (size of i-gel, number of insertion attempts, total insertion time, and dose of the neuromuscular blocker and opioid) were evaluated. Logistic regression analysis was performed to identify the risk factors. Postoperative sore throat following i-gel insertion occurred in 24/426 patients (5.6%). The insertion time was significantly associated with the incidence of postoperative sore throat in the univariate analysis, but not in the multivariate analysis (P=0.519). Increased doses of neuromuscular blockers before i-gel insertion (odds ratio [OR], 5.46; 95% confidence interval [CI], 1.50–19.80; P=0.001) and reduced doses of intraoperative fentanyl (OR, 0.51; 95% CI, 0.28–0.93; P=0.028) were risk factors in the univariate and multivariate analyses. In the subgroup that used neuromuscular blockers before i-gel insertion, only an increased dose of neuromuscular blocker (OR, 17.2; 95%, CI 1.06–280; P=0.046) was an associated risk factor in the univariate and multivariate analyses. Overall, increased doses of neuromuscular blockers before i-gel insertion could contribute to the development of postoperative sore throat.

Keywords: i-gel, neuromuscular blocker, perioperative complication, postoperative sore throat, supraglottic airway device

Abbreviations:
SAD: supraglottic airway devices
OR: odds ratio
CI: confidence interval

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INTRODUCTION

Supraglottic airway devices (SADs) are widely used as alternatives to tracheal intubation for airway management during general anesthesia. They are accompanied by a reduced incidence of a postoperative sore throat (approximately 5.8–49%) compared with that of tracheal intubation.[1-6] The i-gel™ (Intersurgical Ltd., Wokingham, UK) is a new single-use SAD with a non-inflatable cuff (Figure 1), which results in an even lower incidence of a postoperative sore throat (5–17%).[7-10] Overinflation of the cuff, duration of surgery, size of the device, and use of neuromuscular blockers are considered risk factors for a postoperative sore throat associated with SADs and tracheal intubation.[11-13] However, the risk factors associated with a postoperative sore throat induced by i-gel have not been clarified. We predicted that the same factors could be associated with an i-gel-induced sore throat. Therefore, we retrospectively assessed the risk factors for a postoperative sore throat associated with the use of i-gel.

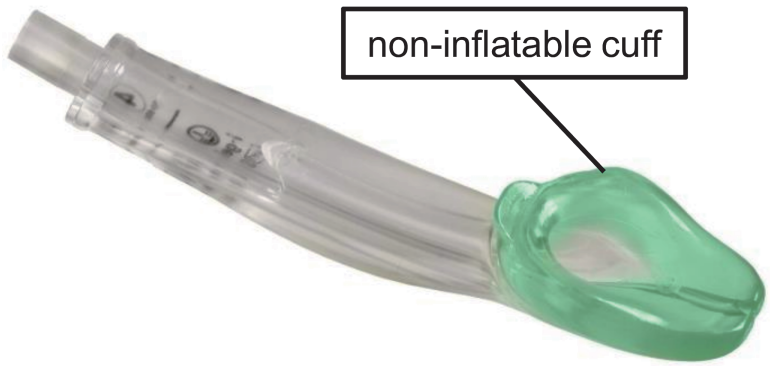

Fig. 1 Photo of the i-gel, a single-use supraglottic airway device with a non-inflatable cuff (Intersurgical Ltd., Wokingham, UK)

METHODS

Study Design and Patients

This single-center, retrospective observational study was approved by the Nagoya University Hospital Ethics Committee (approval number: 2020-0062). Written informed consent was not obtained from the patients, as the opt-out method was implemented for recruiting all the participants. We retrospectively reviewed the data of 596 adult patients who underwent general anesthesia using i-gel at our institution between January 2018 and December 2019. Patients below the age of 15 years (n = 61) or those with a pre-existing sore throat (n = 8) were excluded. Patients who underwent awake craniotomy were also excluded (n = 74), since i-gel was inserted at least twice during the induction of general anesthesia and reinduction following functional testing. Patients with missing data on i-gel size were excluded (n = 27). Thus, 426 patients were enrolled in this study based on these eligibility criteria.

Data Collection

All the data were acquired from electronic anesthesia charts and medical records. We collected each patient's baseline characteristics (ie, sex, age, weight, height, and American Society of Anesthesiologists physical status), and intraoperative data, including the size of i-gel, number of insertion attempts, total insertion time, dose of neuromuscular blocker (dose before i-gel insertion and intraoperative dose), and total dose of intraoperative fentanyl. The fentanyl dose was calculated as the total fentanyl dose divided by the patient's weight and anesthesia delivery time (μg/kg/h). Based on the user guide for i-gel, we considered cases of patients whose weight was outside the standard i-gel size as mismatches. The insertion time was defined as the time between the insertion and removal of the i-gel. In our hospital, the ward nurses routinely perform pain assessments with the Numerical Rating Scale, including checking for a sore throat at least twice daily. We assessed the presence or absence of a sore throat by reviewing the nurses' and doctors' records up to five days following surgery.

Outcome Measurements

The primary outcome was the incidence of postoperative sore throat. Moreover, the factors associated with postoperative sore throat was evaluated. As the secondary outcome, we selected patients who received neuromuscular blockers before i-gel insertion for the subgroup analysis. The association between these factors and postoperative sore throat in this subgroup was assessed. In addition, the factors associated with dose of rocuronium before i-gel insertion were evaluated.

Statistical Analyses

Univariate and multivariate logistic regression analyses were performed to identify the risk factors for postoperative sore throat. The risk factors for inclusion in the multivariate analysis were determined on the basis of previous studies and our clinical experience.[11,12,14] Multiple regression analysis was performed to predict the dose of rocuronium before i-gel insertion based on sex, age, height, weight, American Society of Anesthesiologists Physical Status, and i-gel size mismatch as a post-hoc analysis. Continuous variables are expressed as the mean ± standard deviation or median (interquartile range), and categorical variables are expressed as the number (proportion). Fisher's exact test was used to compare the categorical variables. Student's *t*-test or the Mann–Whitney U test was used to compare the continuous variables. $P < 0.05$ was considered indicative of statistical significance. R software version 4.0.2 (The R Foundation for Statistical Computing, Vienna, Austria) was used to conduct the statistical analyses.

RESULTS

Patient Characteristics

This study analyzed the data of 426 patients (Figure 2) and divided them into two groups: those with or without a postoperative sore throat. The baseline characteristics and perioperative data of the two groups are summarized in Table 1.

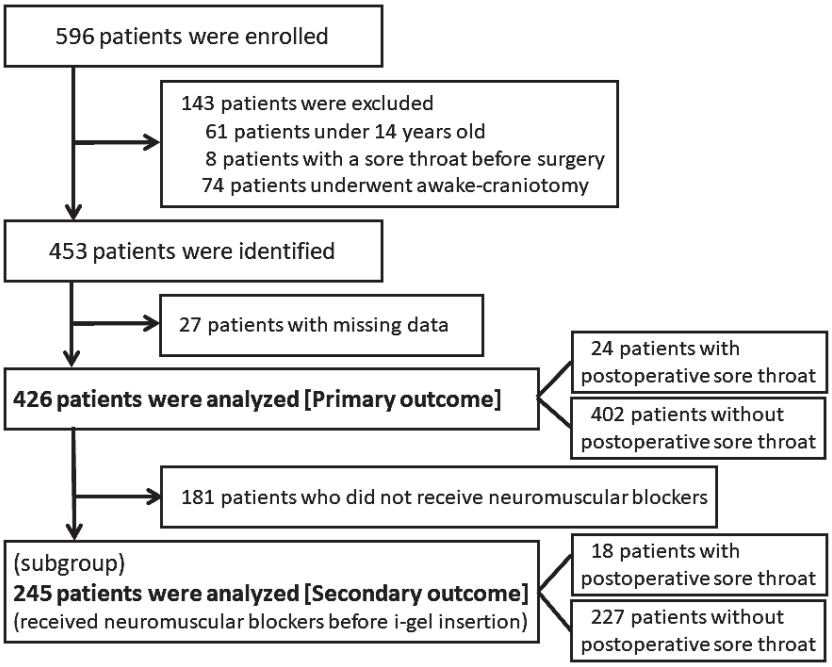

Fig. 2 Flow diagram of the study population
Patients underwent general anesthesia with i-gel insertion between January 2018 and December 2019.

Table 1 Baseline characteristics and perioperative data

	Without a postoperative sore throat (n = 402)	With a postoperative sore throat (n = 24)	*P-value*
Sex; Male / Female	163 / 239	7 / 17	0.293
Age; years	55.9 ± 18.5	53.0 ± 16.6	0.454
BMI; kg/m^2	23.8 ± 8.2	22.7 ± 3.8	0.525
ASA-PS ≥ 2	251 (63%)	15 (63%)	1.000
Operation time; min	66 [33–103]	100 [51–126]	0.026*
i-gel size mismatch (+)	94 (23%)	7 (29%)	0.470
i-gel insertion attempts ≥ 2	25 (6%)	2 (8%)	0.658
i-gel insertion time; min	111 (70–155)	156 (98–188)	0.018*
Rocuronium use (+)	264 (66%)	20 (83%)	0.079
Rocuronium dose before i-gel insertion; mg/kg	0.36 (0.00–0.64)	0.69 (0.22–0.85)	0.002*
Fentanyl dose; μg/kg/h	1.53 (1.00–2.15)	0.92 (0.22–1.63)	0.004*
Acetaminophen dose; mg	690 (0–1000)	675 (0–1000)	0.967
NSAIDs (flurbiprofen) dose; mg	0 (0–40)	0 (0–50)	0.229

Values are presented as the mean ± standard deviation, median [interquartile range], or number (proportion, %) of patients.
BMI: body mass index
ASA-PS: American Society of Anesthesiologists physical status

NSAIDs: non-steroidal anti-inflammatory drugs
The fentanyl dose was calculated as the total fentanyl dose divided by the patient's weight and the anesthesia delivery time (μg/kg/h).
*Statistically significant difference ($P < 0.05$).

Postoperative Sore Throat

Postoperative sore throat was observed in 24/426 patients (5.6%). The insertion time and operation time were significantly longer, the fentanyl dose was significantly lower and the rocuronium dose was significantly higher in patients with a postoperative sore throat than in patients without a postoperative sore throat (Table 1). The results of the univariate and multivariate logistic regression analyses for the risk factors for a postoperative sore throat associated with i-gel are shown in Table 2. The insertion time was significantly associated with a postoperative sore throat according to the univariate analysis but not according to the multivariate analysis (odds ratio [OR], 1.02; 95% confidence interval [CI], 0.96–1.09; $P = 0.519$). A lower fentanyl dose (OR, 0.51; 95% CI, 0.28–0.93; $P = 0.028$) and higher rocuronium dose before i-gel insertion (OR, 5.46; 95% CI, 1.50–19.80; $P = 0.001$) were significantly associated with an increased risk of postoperative sore throat according to the univariate and multivariate analyses. There was no correlation between the dose of rocuronium before i-gel insertion (mg/kg) and the intraoperative fentanyl dose (μg/kg/h); the analyzed Spearman's rank correlation coefficient was −0.045 ($P = 0.351$).

Table 2 Risk factors for a postoperative sore throat associated with i-gel

	Univariate logistic regression analysis		Multivariate logistic regression analysis	
	Odds ratio (95% CI)	*P-value*	Odds ratio (95% CI)	*P-value*
i-gel insertion time (×10 min)	1.07 (1.01–1.12)	0.016*	1.02 (0.96–1.09)	0.523
i-gel size mismatch (+)	1.35 (0.54–3.35)	0.519	1.23 (0.46–3.24)	0.682
i-gel insertion attempts ≥ 2	1.37 (0.31–6.16)	0.681	1.79 (0.36–8.86)	0.474
Fentanyl dose; μg/kg/h	0.46 (0.27–0.78)	0.004*	0.51 (0.28–0.93)	0.028*
Rocuronium dose before i-gel insertion; mg/kg	6.41 (1.78–23.10)	0.005*	5.46 (1.50–19.80)	0.010*

CI: confidence interval
The fentanyl dose was calculated as the total fentanyl dose divided by the patient's weight and the anesthesia delivery time (μg/kg/h).
*Statistically significant difference ($P < 0.05$).

Subgroup Analysis

Table 3 presents the results of the univariate and multivariate logistic regression analyses in the subgroup of patients who received neuromuscular blockers before the insertion of i-gel (ie, the secondary outcome). Postoperative sore throat occurred in 18 of the 245 patients (7.4%) in this group. The insertion time (OR, 1.05; 95% CI, 0.97–1.14; $P = 0.220$) and a lower fentanyl dose (OR, 0.57; 95% CI, 0.28–1.20; $P = 0.139$) were significantly associated with a postoperative sore throat in the univariate analysis but not in the multivariate analysis. Only a higher dose of rocuronium before i-gel insertion was significantly associated with an increased risk of postoperative sore throat in both the univariate and multivariate analyses (OR, 17.2; 95% CI,

1.06–280; $P = 0.046$).

Table 3 Risk factors for a postoperative sore throat associated with i-gel in the patients who received neuromuscular blockers before i-gel insertion

	Univariate logistic regression analysis		Multivariate logistic regression analysis	
	Odds ratio (95% CI)	*P-value*	Odds ratio (95% CI)	*P-value*
i-gel insertion time (×10 min)	1.10 (1.03–1.17)	0.007*	1.05 (0.97–1.14)	0.220
i-gel size mismatch (+)	1.43 (0.49–4.22)	0.513	1.34 (0.40–4.53)	0.634
i-gel insertion attempts ≥ 2	2.06 (0.43–9.92)	0.369	2.81 (0.45–17.50)	0.267
Fentanyl dose; μg/kg/h	0.44 (0.23–0.84)	0.014*	0.57 (0.28–1.20)	0.139
Rocuronium dose before i-gel insertion; mg/kg	35.00 (2.64–465)	0.007*	17.20 (1.06–280)	0.046*

CI: confidence interval

The fentanyl dose was calculated as the total fentanyl dose divided by the patient's weight and the anesthesia delivery time (μg/kg/h).

*Statistically significant difference ($P < 0.05$).

Furthermore, no factor was significantly associated with the dose of rocuronium before i-gel insertion using a multiple regression analysis.

DISCUSSION

We assessed the risk factors for postoperative sore throat associated with i-gel insertion in this study and found that the dose of neuromuscular blocker administered before i-gel insertion was one of the risk factors.

Combes et al demonstrated that the use of neuromuscular blockers reduced the incidence of a postoperative sore throat when using conventional tracheal intubation tubes.[15] This could be attributed to the fact that the neuromuscular blocker helps in opening the mouth and glottis during tracheal intubation, allowing the anesthesiologist to reveal the vocal cords with less force, which may reduce the incidence of a sore throat. In our study, however, a higher dose of a neuromuscular blocker appeared to be a risk factor resulting in a sore throat following the insertion of i-gel. Although neuromuscular blockers enable easier insertion of i-gel,[16] i-gel can be inserted easily and reliably without the use of a direct laryngoscope and neuromuscular blocker. Sivsrajan et al demonstrated that anesthesia and muscle paralysis caused posterior displacement of the epiglottis and narrowing of the oropharynx with head flexion.[17] Therefore, the i-gel would get pushed deeper into the narrowed oropharynx. Consequently, the insertion of i-gel in conjunction with a neuromuscular blocker may exert more pressure on the wall of the oropharynx than insertion without a neuromuscular blocker, resulting in a postoperative sore throat. Furthermore, Na et al demonstrated that a sore throat caused by LMA® ProSeal, another type of SAD insertion, was associated with the use of neuromuscular blockers.[18]

The subgroup analysis performed herein also suggested that a higher dose of rocuronium administered before i-gel insertion was significantly associated with a postoperative sore throat. Hence, lower doses of neuromuscular blockers may not cause a postoperative sore throat with

i-gel insertion.

In this study, the insertion time was not statistically associated with a postoperative sore throat, which contrasts with the results reported for other SADs and tracheal intubation.[11,12] However, minor trends related to the incidence of a sore throat were observed; thus, this relationship could have attained statistical significance with a larger study sample. Further prospective studies with larger sample sizes are required.

There are some limitations to our study. First, this was a retrospective observational study in which patients were not randomized according to the postoperative sore throat incidence. Some cases of a sore throat may have been missed due to omission of descriptions in the medical records. Moreover, ventilator settings were not examined, and the relationship between the effects of ventilator settings, such as mandatory ventilation or spontaneous breathing, and postoperative sore throat was not evaluated. Although there was no statistically significant difference between the patient characteristics of the two groups in this study, future randomized controlled trials are required. Second, our data were collected from patients in whom i-gel was inserted under general anesthesia at a single-center, and the sample size may have been too small to effectively compare the incidence of a postoperative sore throat. Therefore, the generalizability of these findings remains debatable. Finally, the optimal dose of neuromuscular blockers for i-gel insertion is unknown. In this study, the dose of neuromuscular blockers was left to the discretion of individual anesthesiologists; a neuromuscular blocker was not used during the insertion of i-gel in 33% of the cases. According to the manufacturer's recommendation, the patient can be examined to ensure that he/she has reached the optimal level of i-gel insertion by checking for muscle relaxation using a nerve stimulator.[19] A particular dose of neuromuscular blockers may facilitate insertion and reduce the incidence of a postoperative sore throat. Thus, further studies are needed to determine the optimal dose of neuromuscular blockers during i-gel insertion.

In conclusion, we retrospectively assessed the risk factors for postoperative sore throat associated with i-gel insertion. Our study suggested that a higher dose of neuromuscular blockers administered before i-gel insertion may contribute to the development of a postoperative sore throat.

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DISCLOSURE STATEMENT

All the authors declare that they have no conflicts of interest.

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