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Original Article

Comparison between I-gel® and endotracheal intubation in terms of the incidence of postoperative sore throat following thyroid surgery: a randomized observational trial

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Abstract: Background: Postoperative sore throat (POST) is a common complication following thyroid surgery with an endotracheal tube (ET). The I-gel® is a supraglottic airway device that has greater advantages in airway management compared with ET. This prospective trial aimed to explore the potential benefits of I-gel® compared with ET on POST. Methods: In this trial, 106 patients, classified using the American Society of Anesthesiologists (ASA) physical status classification system, belonging to classes I and II, aged 18-65 years old who were prearranged for elective radical thyroidectomy, were randomly divided into the ET and I-gel® groups. All patients underwent total intravenous anesthesia (propofol, sufentanil, and cisatracurium). The incidence and severity of POST and postoperative hoarseness (PH) at 1, 6, 24, and 48 h following the operation were assessed and compared between the two groups. Moreover, the hemodynamic data during anesthesia were recorded and compared. Opioid consumption (sufentanil, propofol, and remifentanil) and postoperative nausea and vomiting were recorded. The visual analog scale scores for pain at the incision site 1, 6, 24, and 48 h postoperatively and Ramsay Sedation Scale scores were also evaluated and recorded. Results: No significant difference was observed in the incidence of POST 1, 6, 24, and 48 h postoperatively (61.2% vs. 51.0%, P=0.309; 75.5% vs. 83.7%, P=0.316; 83.7% vs. 85.7%, P=0.779; and 12.2% vs. 22.4%, P=0.182, respectively) and the severity of sore throat (P=0.392) following surgery between the ET and I-gel® groups. The incidence of PH in the I-gel® group was significantly lower than that in the ET group 1, 6, 24, and 48 h postoperatively (all P<0.05). Compared with the ET group, a significantly less fluctuation in heart rate 1 min after intubation (P=0.045) and extubation (P=0.001) was observed in the I-gel® group. Conclusions: Although the I-gel® cannot reduce the incidence and severity of POST in patients with normal BMIs following thyroid surgery, it can reduce the occurrence and severity of PH compared with ET. The I-gel® showed superior results in terms of insertion time and better hemodynamic condition during intubation.

Keywords: Sore throat, thyroid surgery, hoarseness, I-gel®, endotracheal tube

Introduction

Endotracheal intubation can cause postoperative sore throat (POST) and postoperative hoarseness (PH), which are common complications following thyroid surgery. The incidence of these postoperative complications ranges from 30% to 70%. Inflammation and irritation of the airway caused by the endotracheal tube (ET), mucosal dehydration, and trauma during intubation are the potential mechanistic bases of POST [1-3]. Recently, a study has demonstrated that the laryngeal mask airway (LMA) is more beneficial to airway management compared with ET [4]. Compared with ET, the I-gel® and LMA, do not enter the glottis and trachea. Therefore, we hypothesize that the use of these devices reduces the incidence of POST and PH. The difference between the two supraglottic airway devices is that I-gel® has a gel-like flexible and non-inflatable cuff, which accommodates the anatomic surface after insertion, while the LMA has a curve shaped inflatable cuff to provide a characteristic sealing pressure. Given the limited studies on the use of I-gel® in thyroid surgery, we conducted this trial

to compare the effects of I-gel® with those of endotracheal intubation on the incidence of POST after thyroid surgery.

Methods

Trial design and participants

The trial was approved by the Ethics Committee of the First Affiliated Hospital of Anhui Medical University (AHMU; Ethical Application Ref: PJ2021-03-33, Anhui, China) and registered with the Chinese Clinical Trial Registry (registration no: ChiCTR2100043747) on February 27, 2021. The trial was implemented at the First Affiliated Hospital of AHMU. The outcome evaluators and data information analysts involved in the study were blinded to the trial intervention. In this trial, 106 patients aged 18-65 years, classified using the American Society of Anesthesiologists (ASA) physical status classification system, belonging to classes I-II, who were prearranged for elective radical thyroidectomy under general anesthesia (GA) from March 2021 to May 2021, were included. The exclusion criteria were reflux esophagitis, preoperative sore throat, chronic pharyngitis, preoperative hoarseness, use of anticoagulants or corticosteroids, high risk of regurgitation or aspiration, dysphagia, abnormal liver and kidney functions, previous surgical intervention of the oral cavity or pharynx, bleeding diathesis, upper respiratory infection within 2 weeks before operation, failure to I-gel® or ET insertion and estimated surgical time lasts for more than 4 hours.

All the included patients were randomly divided into two groups according to computer generated sequence in a 1:1 ratio: ET (n=53) and I-gel® (n=53) groups. No restrictions were applied for random selection and the numbers assigned to each of the participants were sealed in opaque envelopes, which were permitted to be viewed only by the anesthesiologists. During a preanesthetic visit to the inpatient ward before surgery, the patients were asked to familiarize themselves with the questionnaire for POST.

Conduct of anesthesia

Standardized monitoring procedures were conducted during anesthesia and operation. GA was induced by intravenously injecting sufentanil (0.4 μg/kg), propofol (2.0 mg/kg), and cisatracurium (0.2 mg/kg). After attaining sufficient neuromuscular block, in the I-gel® group, a suitable-sized I-gel® (Intersurgical, UK) was utilized based on the patient's body weight (size 3 for weights <50 kg, size 4 for 50-70 kg, or size 5 for weights of >70 kg). After lubricating the surface with a water-soluble jelly, the I-gel® was inserted via intraoral manipulation. In the ET group, smaller endotracheal tubes (size 7.5 for males and 7.0 for females) were selected, which were associated with a lower incidence of POST. The air sac was inflated using air, and the cuff pressure was strictly adjusted to 25 cmH_2O using a pressure gauge. An anesthesiologist having more than 5 years of experience was arranged to intubate the patients. With the exception of the above-mentioned parameters, neuromuscular block was evaluated using the "train of four". All operations were performed by one surgical team.

Anesthesia was maintained using remifentanil (0.1-1.0 μg/kg/min), propofol (4-8 mg/kg/h), and cisatracurium (0.06-0.12 mg/kg/h). The bispectral index (BIS) was monitored in two groups, and the BIS values were maintained at 40-60; the end-tidal CO_2 ($EtCO_2$) was maintained between 35 and 45 mmHg. About 10 min before the end of subcuticular closure, the anesthesiologist stopped the administration of anesthetic agents and intravenously injected 5-μg sufentanil. After the operation, all patients were transported to post-anesthesia care unit. I-gel® and ET were removed when $EtCO_2$ was below 45 mmHg on spontaneous respiration and when the patient could follow voice commands.

The following observation variables at the time of extubation and intubation were recorded: insertion time defined as the time from the opening of the mouth to inserting I-gel® or laryngoscope blade to confirm the placement of ET, duration of intubation defined as the time from the placement of I-gel® or ET to its removal, repositioning of I-gel® or ET, blood stain on I-gel® or ET, and opioid consumption of the perioperative period.

In this study, the primary outcome was the incidence of POST, whereas the secondary outcomes were the severity of POST and the incidence and severity of PH. Before inducing anesthesia, the patients were assessed for

the presence/absence of preoperative sore throat or any preoperative hoarseness. Postoperatively, the patients rated their symptoms of POST, PH, and pain on the incision cite at four time points: 1, 6, 24, and 48 h postoperatively. POST was evaluated using the visual analog scale (VAS) score (0= none, 10= most severe). The intensity of voice hoarseness was evaluated using the scoring system described previously [5]: 0= no hoarseness at any time, 1= no hoarseness in the interview, 2= hoarseness in the interview noted by the patient only, and 3= hoarseness is easily noted in the interview. The aforementioned parameters were evaluated by the same nurse who was blinded to the different patient groups. In addition, the mean arterial pressure (MAP) and heart rate (HR) were noted down at different time points: before surgery; 1, 3, and 5 min after insertion of I-gel®/endotracheal intubation; end of surgery; and extubation. After surgery, the Ramsay Sedation Scale (RSS) scores and postoperative nausea and vomiting (PONV) were recorded.

Statistical analysis

In the published data, the incidence of POST 1 and 6 h following thyroid surgery was 68.9% and 84%, respectively [4, 6]. We selected the 68.9% as the scale of sample size evaluation. If a 30% reduction in the incidence of POST was be identified as clinically significant, the Power Analysis and Sample Size Software (version 15.0; NCSS, LLC, USA) calculated that 40 patients per group were required for a power of 80% and an error of 0.05. Considering the potential failure to follow-up, we enhanced the sample size of each group to 53 patients.

Data were reported as mean ± standard deviation or median (range) for continuous variables according to the normality of distribution or as the number (percentage) of patients for categorical variables. Group differences between the two groups were tested using unpaired t tests for normally distributed continuous variables, Mann-Whitney U tests for non-normally distributed continuous variables, or χ^2 tests for categorial variables. The effects of intervention over time for the outcomes of interest (incision pain scores and hemodynamics values) were assessed using the repeated-measures analysis of variance (ANOVA) model group by time interaction. For measures that indicated significant group by time interaction effects, post hoc analysis on differences between the two groups were assessed by the independent sample t-test with Bonferroni correction. The statistical analyses were performed by SPSS 22.0 (SPSS Inc., Chicago, IL, USA), and two-sided *P*-values of less than 0.05 were utilized to denote statistical significance.

Results

A total of 106 patients were enrolled in the study and 8 were excluded from the analysis: 3 had a surgery time of more than 4 h, 2 were lost to follow-up, 2 experienced I-gel® insertion failure and required intubation, and 1 had changed surgery plan (**Figure 1**). Then, 98 patients were included in the per protocol analysis. The patients' demographic profiles were comparable between the two groups (**Table 1**). No differences in age, gender, body weight, and height were observed between the two groups. The perioperative profiles of the patients, such as operative and anesthetic time, retention time, and anesthetic consumption (**Table 2**), showed no significant differences between both groups. However, significant differences in the insertion time (*P*=0.002) and time from the end of surgery to extubation (*P*=0.007) were observed between the I-gel® and ET groups.

No difference in the incidence of sore throat 1, 6, 24, and 48 h postoperatively was observed between the I-gel® and ET groups (61.2% vs. 51.0%, *P*=0.309; 75.5% vs. 83.7%, *P*=0.316; 83.7% vs. 85.7%, *P*=0.779; and 12.2% vs. 22.4%, *P*=0.182, respectively). The incidence of PH in the I-gel® group was significantly less than that in the ET group 1, 6, 24, and 48 h postoperatively (30.6% vs. 69.4%, *P*<0.001; 63.3% vs. 83.7%, *P*=0.022; 57.1% vs. 79.6%, *P*=0.017; and 2.0% vs. 16.3%, *P*=0.031, respectively) (**Table 3**). The severity of PH in the I-gel® group was also significantly less than that in the ET group (*P*<0.001). Postoperative RSS scores between the two groups were comparable, and the difference was insignificant (**Table 4**). The difference in the severity of sore throat and high VAS scores for sore throat between the I-gel® and ET groups following surgery was also not significant (**Table 4**).

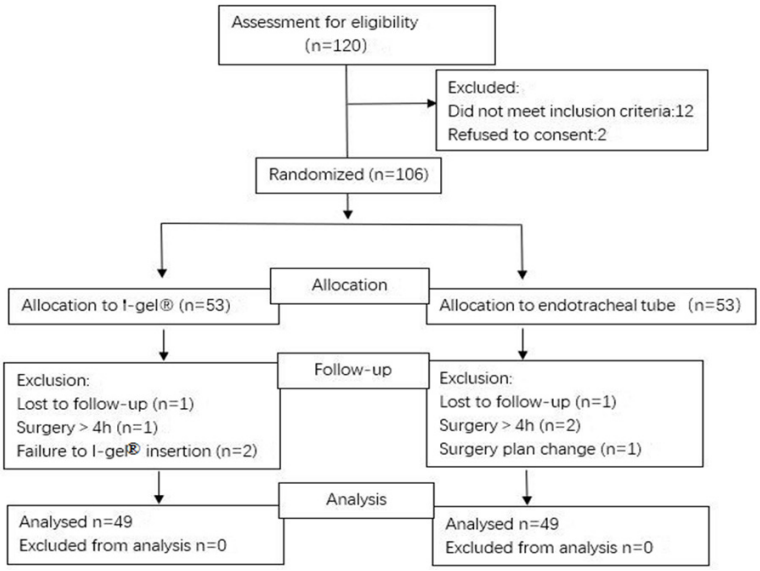

Figure 1. Consort flow chart that outlines patients assignment and treatment protocols. Patients were allocated into two groups (Group I-gel®, Group ET) to receive airway management with I-gel® or tracheal tube respectively, following a computer-generated randomization code.

Table 1. Demographic data

		Group I-gel® (n=49)	Group ET (n=49)	t/χ^2	*P*-value
Age (y)		45.41±10.17	46.08±10.08	-0.33	0.742
Gender	Male	12 (24%)	11 (22%)	0.057	0.812
	Female	37 (76%)	38 (78%)		
Body Height (cm)		163.29±6.39	162.41±6.98	0.649	0.518
Body Weight (kg)		63.00±8.70	61.30±8.74	0.96	0.339
BMI (kg/m^2)		23.61±2.64	23.19±2.44	0.813	0.418
ASA	I	14	13	0.051	0.821
	II	35	36		

Values are means ± SD or number of patients. ET, endotracheal tube; ASA, American Society of Anesthesiologists.

Hemodynamic profiles, such as HR and MAP, were compared between the two groups. No significant difference was observed in MAP at baseline, intubation, 1 min, 3 min, 5 min after intubation, end of surgery, and extubation between both groups (**Figure 2A**). However, the HR values in the I-gel® group were significantly lower than those in the ET group 1 min after endotracheal intubation (*P*=0.045) and extubation (*P*=0.001) (**Figure 2B**). Postoperative VAS scores for incision site pain between the two groups were not significantly different (**Figure 2C**) and the difference in the incidence of PONV between both groups was also not significant (**Table 4**).

Discussion

Compared with ET, the use of I-gel® in thyroidectomy did not decrease the incidence and severity of POST in patients intubated for less than 2 h but could reduce the incidence and severity of PH. Furthermore, I-gel® achieved better hemodynamic profile with HR 1 min after intubation and extubation.

In patients undergoing tracheal intubation, preexisting lung disease, young age, female gender, and blood-stained tracheal tube on extubation are associated with POST [7, 8]. Tracheal intubation without adequate neuromuscular block, large tubes, and high cuff pressures may also increase the risk of POST [9-12]. To strictly control these potential confounding factors, achievement of adequate neuromuscular block before intubation, low cuff pressures, and a smaller ET were applied in this study, and the operation was performed by the same surgical teams. It has previously been shown that the incidence of POST following thyroid surgery was higher than that after general surgeries that did not involve the neck. In this study, the incidence of POST 1 and 6 h after thyroid surgery was 61.2% and 83.7%, respectively, which were similar to the results of previous studies (68.9% and 84%, respectively) [4, 6]. The mechanistic bases for this phenomenon may be inflammation and irritation of the airway due to the pressure exerted on tracheal wall by the ET [3], tracheal mucosal trauma, vocal cord hematoma, mucosal dehydration [12, 13], or laryngeal edema [14-16]. Several interventions, such as pharmacological and nonpharmacological measures, have been attempted to reduce the incidence and severity of POST with different success rates, but none of them could eliminate POST [11, 17].

Table 2. Perioperative profiles of the patients

	Group I-gel® (n=49)	Group ET (n=49)	t/χ^2	*P*-value
Operative time (min)	79.51±20.21	78.85±21.34	0.155	0.877
Anesthetic time (min)	99.46±21.10	98.46±22.78	0.225	0.822
Insertion time (s)	3.55±1.68	4.73±2.06	-3.106	0.002#
Blood stain	0	0		NA
Retention time (min)	104.08±21.30	105.28±23.30	-0.267	0.790
Time to extubation (min)	8.55±3.96	11.26±5.58	-2.773	0.007#
Propofol consumption (mg)	423.77±117.42	387.49±91.45	1.706	0.091
Remifentanil consumption (ug)	695.31±186.23	753.76±190.36	-1.536	0.128
Sufentanil consumption (ug)	32.96±3.80	34.13±3.48	-1.592	0.115

Values are means ± SD or number of patients. #P<0.05.

Table 3. Postoperative laryngopharyngeal symptoms

	Group I-gel® (n=49)	Group ET (n=49)	*P*-value
Postoperative sore throat (n, %)			
1 h	30 (61.2%)	25 (51.0%)	0.309
6 h	37 (75.5%)	41 (83.7%)	0.316
24 h	41 (83.7)	42 (85.7%)	0.779
48 h	6 (12.2%)	11 (22.4%)	0.182
Hoarseness (n, %)			
1 h	15 (30.6%)	34 (69.4%)	<0.001#
6 h	31 (63.3%)	41 (83.7%)	0.022#
24 h	28 (57.1%)	39 (79.6%)	0.017#
48 h	1 (2.0%)	8 (16.3%)	0.031#

Values are expressed as number of patients (percentage). #P<0.05.

Table 4. Severity of POST and PH within 24 h after surgery, RSS scores and incidence of PONV

	Group I-gel® (n=49)	Group ET (n=49)	F/χ^2	*P*-value
VAS of POST more than 3 (n, %)	21 (42.9%)	24 (49.0%)	0.37	0.543
VAS of POST			0.741	0.392
1 h	1 (0-4)	0 (0-5)		
6 h	1 (0-5)	2 (0-6)		
24 h	2 (0-5)	2 (0-5)		
48 h	0 (0-3)	0 (0-3)		
Intensity scores of PH			32.266	<0.001#
1 h	0 (0-3)	1 (0-3)		
6 h	1 (0-3)	2 (0-3)		
24 h	1 (0-2)	1 (0-3)		
48 h	0 (0-1)	0 (0-2)		
PONV (n, %)	15 (30.6%)	13 (26.5%)	0.2	0.655
RSS	2 (2-4)	2 (2-4)	-0.466	0.641

Data were presented as number of patients (percentage) or median (range). ET, endotracheal tube; RSS, ramsay score; POST, postoperative sore throat; PH, postoperative hoarseness; PONV, postoperative nausea and vomiting. #P<0.05.

As a second-generation supraglottic airway device (SAD), I-gel®, which was clinically introduced in 2007, comprises a soft gel-like mask, an integral bite block, and a narrow-bore gastric drain tube, which is positioned superior to the larynx and can lead to less tracheal injury [18]. However, the results of this study indicated that I-gel® cannot decrease the incidence and severity of POST in patients within 2 h following thyroid surgery. This is different from what was previously reported. Although I-gel® is positioned superior to the larynx, the surgical position with overextension of the neck and traction and compression in thyroid surgery may have been attributable to this phenomenon (**Figure 3**). A recent study has indicated that flexible reinforced LMA (FLMA) can reduce the incidence of POST [4]. But different cuff pressures of FLMA and duration of operation may contribute to this difference. Park et al. suggested that a high-dose remifentanil infusion contributed to increased incidence

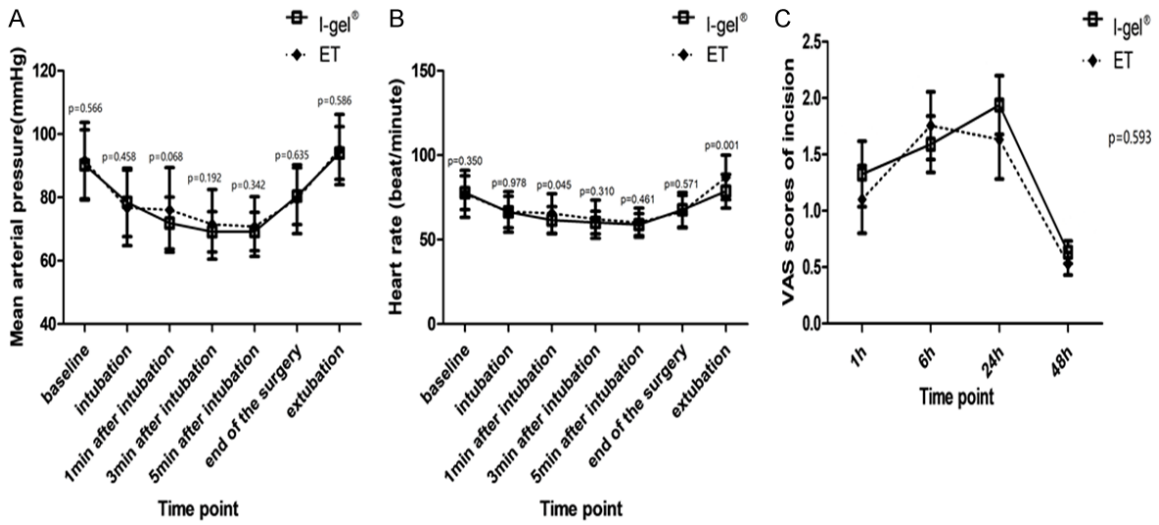

Figure 2. A. Hemodynamic profiles mean artery pressure (MAP); B. Hemodynamic profiles heart rate (HR); C. VAS scores of the incision site at different time points after thyroid surgery. No significant difference was observed in MAP at baseline, intubation, 1 min after intubation, 3 min after intubation, 5 min after intubation, end of surgery, and extubation between both groups. However, the HR values were significantly lower in the I-gel® group than in the ET group 1 min after endotracheal intubation (P=0.045) and extubation (P=0.001). Postoperative VAS scores for incision site pain between the two groups were not significantly different. MAP, mean artery pressure; HR, heart rate; ET, endotracheal tube.

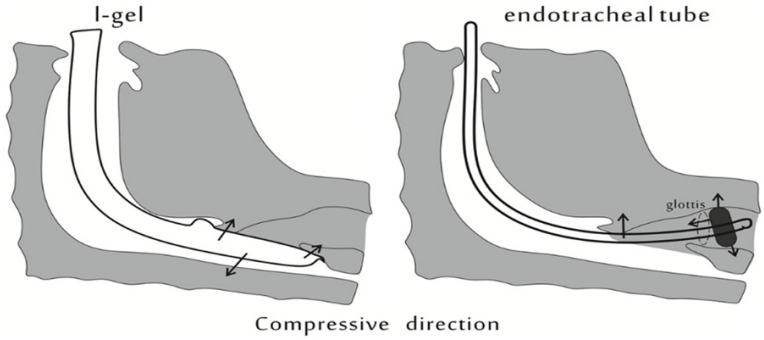

Figure 3. The force diagram of laryngeal mask or endotracheal tube on pharynx in the surgical position with overextension of the neck in thyroid surgery. Patients are maintained at supine position with the neck extended. The arrow represents the direction of compression. In the hyperextension position, the posterior pharyngeal wall, epiglottis and entrance of the esophagus are under compression by I-gel®. The epiglottis, vocal cords, and trachea wall are compressed by the tracheal tube.

of POST [19]. The consumption of remifentanil (695.31±186.23 μg vs. 753.76±190.36 μg, P=0.128) between the two groups was comparable (**Table 2**). I-gel® could minimize the incidence of PH as it did not touch the glottis and vocal cords. It is the main characteristic of SADs. Furthermore, I-gel® can be easily inserted at the first attempt and is associated with shorter effective airway time than other SADs [20, 21]. This was also confirmed in this study: insertion time of I-gel® was shorter than that of ET (P=0.002). Extubation was faster in patients in the I-gel® group than those in the ET group (P=0.007, **Table 2**), which may contribute to meeting a strong need for fast and predictable anesthesia recovery with few side effects [22].

Before the study, we hypothesized that I-gel® reduces laryngopharyngeal discomfort in patients undergoing thyroid surgery. However, the results were contrary to our expectations. During the operation, due to traction and compression, I-gel® needs to be repositioned to achieve better ventilation in several patients, whereas ET does not need to be repositioned and this was associated with POST in the I-gel® group. However, this adjustment may be a warning for surgeons to avoid excessive traction and decrease the force of pulling. The I-gel® SAD is placed in the pharyngeal cavity

and does not enter the glottis, which may cause less injury to the vocal cords. ET is placed using an anesthetic laryngoscope across the glottis and has pressure on the vocal cords. As the traction and compression are high, damage to airway is hard to avoid, which contributes to the occurrence of POST and PH. The incidence of POST increased from 1 to 24 h following surgery and decreased significantly 48 h postoperatively, and this can be attributed to the perioperative pesticide effect of sufentanil as well as the progression of inflammatory edema within 24 h and improvement at 48 h. The aforementioned facts are the reasons for the results of this trial.

This trial has several limitations. First, this is only a single-center study. Thus, a multicenter study would be better to further test our hypothesis. Second, the force that compressed the pharynx due to the neck hyperextension position cannot be measured, and we simply adjusted the position of I-gel® according to the ventilation status. Third, the duration of surgery was short, and the use of I-gel® in longer procedures is unknown.

Conclusions

In conclusion, this study demonstrated that in patients with normal BMIs undergoing thyroid surgery, I-gel® cannot reduce the incidence and severity of POST but could reduce the occurrence and severity of PH compared with ET. The I-gel® SAD produced superior results in the insertion time and better hemodynamic profiles during intubation.

Acknowledgements

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Disclosure of conflict of interest

None.

Abbreviations

BIS, Bispectral index; ET, Endotrachealtube; I-gel®, i-gel®; GA, general anesthesia; HR, Heart rate; LMA, Laryngeal mask airway; MAP, Mean arterial pressure; PH, Postoperative hoarseness; PONV, Postoperative nausea and vomiting; POST, Postoperative sore throat; RSS, Ramsay Sedation Scale; SAD, Supraglottic airway device; VAS, Visual analog scale.

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