Observational Study

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The frequency of gastroesophageal reflux when radiofrequency catheter ablation procedures for atrial fibrillation under general anesthesia with a supraglottic device

Observational pilot study

Jin Hee Ahn, MD, PhD[a], Jiyeon Park, MD[b], Jae Seong Jo, MD[a], Sung Hyun Lee, MD, PhD[a], Young Keun On, MD, PhD[d], Kyoung-Min Park, MD, PhD[d], Eun Jeong Oh, MD, PhD[c], Justin Sangwook Ko, MD, PhD[c], Ji Seon Jeong, MD, PhD[c,*]

Abstract

Gastroesophageal reflux (GER) in radiofrequency catheter ablation (RFCA) occurs due to vagal plexus damage during pulmonary vein isolation. We hypothesized that the frequency of GER in the oropharynx will be less compared to other areas (low-esophagus, mid-esophagus). We confirmed the frequency of GER before and after RFCA in 3 areas.

We studied 30 patients who were scheduled for RFCA under general anesthesia. Anesthesia was performed using supraglottic devices (SGD) with a suction port. Two esophageal temperature probes capable of suction and measuring temperature were inserted through the suction port. The pH of the 3 areas was measured before and after the RFCA at 3 areas (mid-esophagus, low-esophagus, and oropharynx).

GER was observed in 13 of 30 patients (43%). In one patient, it was observed in the oropharynx, in 4 patients it was observed in the mid-esophagus, and in 13 patients, it was observed in the low-esophagus. For patients with GER at the oropharynx and mid-esophagus, it was also observed at the low-esophagus. The difference in the pH before and after the RFCA was not significant at the oropharynx and mid-esophagus ($P = .726$ and $P = .424$, respectively), but it was significantly different at the low-esophagus ($P < .001$). The total ablation time was longer in the GER group compared to the non-GER group ($P = .021$).

GER after RFCA occurred in 43% of patients, only 1 patient in the oropharynx. And aspiration pneumonia after SGD extubation did not occur. Therefore, the use of SGDs in RFCA does not completely eliminate the possibility of aspiration, so care should be taken.

Abbreviations: GER = gastroesophageal reflux, GI = gastrointestinal, PVI = pulmonary vein isolation, RFCA = radiofrequency catheter ablation, SGD = supraglottic device.

Keywords: atrial fibrillation, gastroesophageal reflux, general anesthesia, radiofrequency catheter ablation, supraglottic device

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[a] Department of Anesthesiology and Pain Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, Seoul, [b] Department of Anesthesiology and Pain Medicine, Catholic Kwandong University College of Medicine, International St. Mary's Hospital, Incheon, [c] Department of Anesthesiology and Pain Medicine, Samsung Medical Centre, Sungkyunkwan University School of Medicine, [d] Department of Cardiology, Samsung Medical Centre, Sungkyunkwan University School of Medicine, Seoul, South Korea.

[*] Correspondence: Ji Seon Jeong, Department of Anesthesiology and Pain Medicine, Samsung Medical Centre, 81 Irwon-ro, Gangnam, Seoul 06352, South Korea (e-mail: jiseon78.jeong@samsung.com).

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1. Introduction

Radiofrequency catheter ablation (RFCA) is performed in patients with drug refractory atrial fibrillation, and pulmonary vein isolation (PVI) is the main procedure.[1] During RFCA, sedation or general anesthesia is required to relieve pain and discomfort.[2,3] RFCA under general anesthesia reduces the recurrence rate of atrial fibrillation by enhancing catheter stability and mapping system accuracy compared to conscious sedation.[3,4] A supraglottic device (SGD) is used instead of tracheal intubation to minimize the sympathetic response during general anesthesia in patients with tachyarrhythmia.[5] However, the use of a SGD during general anesthesia does not protect the airway and may cause reflux of gastric contents.[6]

Previous studies have demonstrated that gastroesophageal reflux (GER) can occur due to vagal plexus damage during PVI.[5–7] Martinet et al, reported that the pH of the lower esophageal area decreased immediately after PVI in 19.2% of the patients.[7,8] The explanation was that the left vagal nerve passing around the pulmonary vein was damaged by electrical stimulation, and the pH decreased due to gastric acid reflux as the lower esophageal sphincter relaxed and gastric hypomotility occurred.[7] Therefore, the use of SGD during RFCA cannot be excluded as a risk for GER.

We hypothesized that in the RFCAs has a risk of GER. Therefore, we planned a pilot study that measures the frequency of GER by dividing the presence of GER into 3 areas before and after the procedure: mid-esophagus, low-esophagus, and oropharynx. The primary outcome was the incidence of GER. The secondary outcome was the change in the pH before and after the RFCA in 3 areas.

2. Methods

This prospective, observational, pilot study was approved by our Institutional Review Board (Samsung Medical Center, South Korea, IRB No. 2018-08-047). The trial was registered before patient enrollment at Clinical Trial Registry of Korea (KCT0003370, Date November 23, 2018). This study included American Society of Anesthesiologists physical status classification II to III patients between 19 years and 70 years of age scheduled for elective radiofrequency ablation of paroxysmal atrial fibrillation (pAF). Those patients received general anesthesia between Feb. 2019 and May 2019 at the Samsung Medical Center, Seoul, South Korea. Exclusion criteria included age <19 years old, a history of RFCA, existing gastroesophageal reflux disease (GERD) under screening tests, expected aspiration pneumonia, renal disease, hepatic disease, metabolic disease, pregnancy, and unstable vital signs. A statement to confirm that all methods were carried out in accordance with Samsung medical center Institutional Review Board guidelines and regulations. Written informed consent was obtained from all subjects participating in the study.

2.1. Study protocol

Before the 1-day procedure, we screened for GERD using the Frequency Scale for Symptoms of GERD.[9] On the day of the procedure, patients did not receive premedication; and standard monitoring including electrocardiography, pulse oximetry, noninvasive blood pressure, and bi-spectral index monitoring were performed on arrival at the operating room. Anesthesia was induced using 2 mg kg^{-1} of propofol and 8 vol% of sevoflurane, and intubation was performed 2 minutes after administration of 0.4 mg kg^{-1} of rocuronium. A sampling of the oropharyngeal secretions to measure pH before RFCA at the oropharynx was performed using a rubber catheter, and the SGD (LMA Protector, Teleflex Medical Ltd, Athlone, Ireland) was then inserted. Mechanical ventilation was set to a tidal volume of 8 ml kg^{-1}, and the frequency of ventilation was adjusted to maintain end-tidal CO_2 at 30 to 40 mm Hg. If the airway pressure exceeded 20 mm Hg, the position of the SGD was adjusted. Two esophageal temperature probes (ST probe, Lucky Medical Co, LTD, Seoul, South Korea) capable of suction and measuring temperature were inserted through the suction port of the SGD (Fig. 2B). The location of the tip of each ST probe was determined by the fluorescence guidance: ST probe 1 (mid-esophagus, 12 Fr, esophageal type) was placed between the left superior pulmonary vein and the left inferior pulmonary vein, and ST probe 2 (low-esophagus, 10 Fr, Gastric type) was placed just above the lower esophageal junction (Fig. 2A). The pH before the RFCA was measured through ST probes at the mid-esophagus and low-esophagus, after which new ST probes were placed at each location. Temperature monitoring was performed through ST probe 1. After completion of the procedure, 2 to 4 mg kg^{-1} of sugammadex, determined by the train of four value, was administered to reverse the neuromuscular block. The SGD and 2 ST probes were simultaneously removed so that the tip of the ST probe did not contaminate the tip of the SGD.

2.2. Outcome measurement

The pH was measured at 2 time points: the induction of anesthesia and the end of the procedure. The secretion of the rubber catheter at the time of anesthesia induction and the secretion of the SGD tip at the end of the RFCA reflect the pH value at the oropharynx. In addition, the pH of the secretions sampled at ST probe 1 and ST probe 2 reflects the pH of the mid-esophagus and low-esophagus, respectively (Fig. 2A). The 5 ml empty syringe with a 3-way stopcock was connected to the proximal end of the ST probe and light negative pressure was applied. The stopcock was locked to fasten the secretion in the catheter. The pH was measured by removing the ST probes and squeezing the contents in each catheter and placing a drop at the tip of the pH meter (2K712, ISFETCOM Co, Ltd, Japan); pH was measured by dropping the sampled secretion onto the sensor of the pH meter. The pH meter sensor was washed with normal saline, water was removed using dry gauze, and the meter was calibrated just before each measurement. A pH of 4 was defined as having GER at the mid-esophagus, low-esophagus, or oropharynx.[10] The maximum esophageal temperature, frequency that the esophageal temperature rises, and location of the ablation catheter when the esophageal temperature rises were measured by ST probe 1. In addition, the total anesthetic time and total ablation time were measured. The GER symptom was also measured at 1 day and 1 month postoperatively.

2.3. Statistical analysis

Data are presented as the mean (standard deviation), as the median (interquartile range) or as a number (%), as appropriate. Continuous variables were compared using the *t* test or Mann-Whitney *U* test, and the Shapiro–Wilk test was used to explore normality. The change in the pH before and after the RFCA at the 3 areas was analyzed by the paired *t* test or Wilcoxon signed-rank test, as appropriate. The pH at the 3 areas was analyzed using the Kruskal-Wallis test combined with the Tukey test using ranks for post hoc testing. Categorical variables were compared using Pearson chi-square test or Fisher exact test, as appropriate. In addition, non-GER and GER groups were compared. All statistical analyses were performed with the aid of SPSS ver. 22 software (SPSS Inc, USA). A *P*-value <.05 was considered statistically significant.

3. Results

We assessed 49 patients for eligibility (Fig. 1). Of these, 19 patients were excluded: 5 because of refusal to participate, 10 had a previous GER symptom and 4 had a history of previous RFCA. Patient characteristics are shown in Table 1.

GER was observed in 13 of 30 patients (43%). In 1 patient, GER was observed in the oropharynx; in 4 patients GER was observed in the mid-esophagus; and in 13 patients, GER was observed in the low-esophagus. For patients with GER at the oropharynx and mid-esophagus, GER was also observed at the low-esophagus. The change in pH before and after the RFCA at the oropharynx, mid-esophagus, and low-esophagus is shown in Figure 3. The difference in the pH before and after the RFCA was

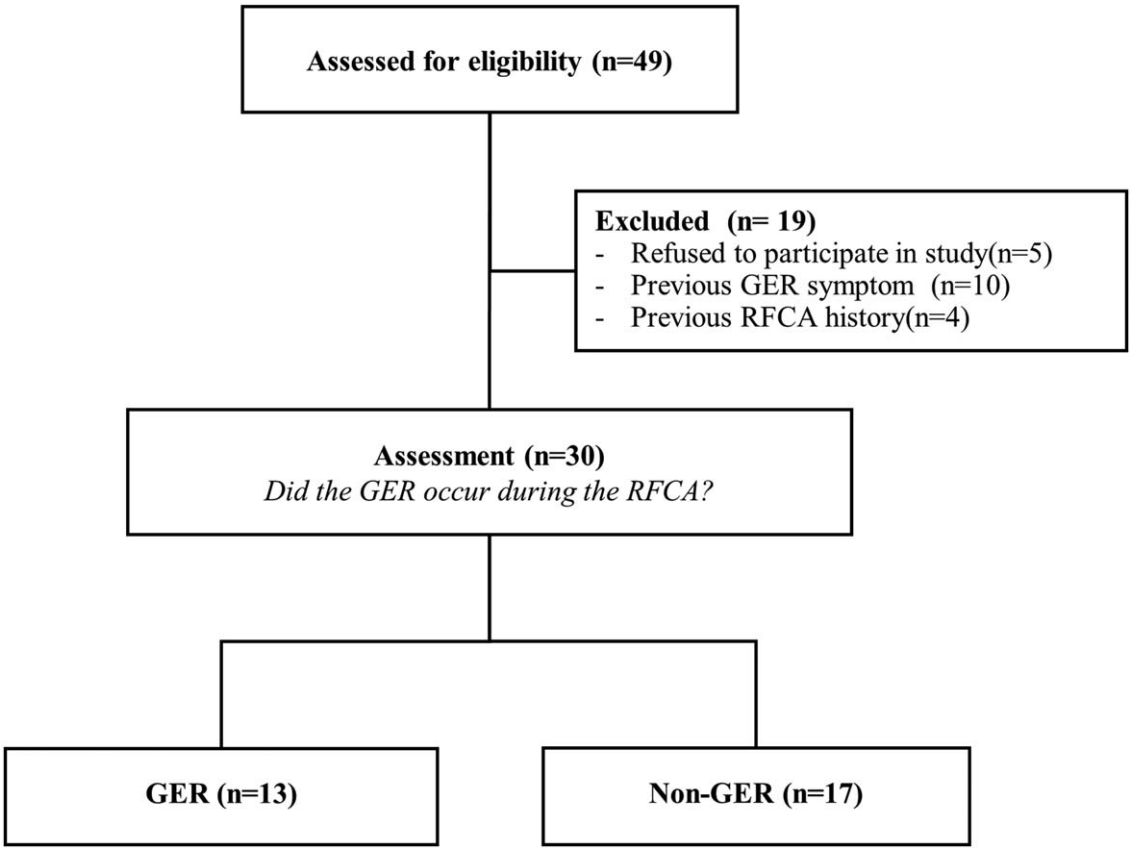

Figure 1. Flow diagram. GER = gastroesophageal reflux, RFCA = radiofrequency catheter ablation.

not significant at the oropharynx and mid-esophagus ($P = .726$ and $P = .424$, respectively), but the pH was significantly different at the low-esophagus ($P < .001$). The pH of the low-esophagus was significantly lower before and after the RFCA than the other two areas ($P < .001$ and $P < .001$, respectively). No patient was diagnosed with postoperative aspiration pneumonia.

The non-GER and GER groups after RFCA were compared. The total ablation time was 75 (62–94) minutes in the non-GER group and 103 (87–115) minutes in the GER group (median difference, 27 minutes; 95% confidence interval 4 to 42 min; $P = .021$). However, the total anesthetic time, maximum esophageal temperature, and the frequency that the esophageal temperature rose were not statistically significant between the 2 groups ($P = .187$, $P = .051$, and $P = .103$, respectively) (Table 2).

Table 1

Patient characteristics.

	(n = 30)
Sex (female/male)	4/26
Age, yr	56.7 (11)
Weight, kg	70.8 (7.8)
Height, cm	169.0 (7.8)
BMI	24.7 (2.0)
ASA PS (I/II/III)	0/28/2
Alcohol/Smoking	15/5

Data are presented as the median (IQR), mean (SD), or number.
ASA = American Society of Anesthesiologists, ASA PS = American Society of Anesthesiologists physical status, BMI = body mass index, IQR = interquartile range, SD = standard deviation.

At 1 day postoperative, 2 patients in the non-GER group and 5 patients in the GER group experienced a GER symptom ($P = .087$). In addition, at 1 month postoperative, 1 patient in the non-GER group and 2 patients in the GER group experienced a GER symptom ($P = .390$).

4. Discussion

In this study, GER was observed in 43% of patients who underwent RFCA. However, GER at the oropharynx was observed in only 1 patient and aspiration pneumonia was not observed. Moreover, the total ablation time was increased in patients with GER. To our knowledge, this study is the first study to confirm the safety of SGD use in RFCA.

Previous studies showed that ablation-induced upper gastrointestinal (GI) tract injury was observed in 11% to 17% of patients who underwent RFCA for atrial fibrillation.[11,12] Zhang et al demonstrated that postoperative endoscopic ultrasonography showed esophageal injury in 31% in RFCA and 13% in cryoablation, respectively.[13] Thermal injury was described as a key mechanism of a pathologic upper gastrointestinal finding that can be divided into 2 categories. The first is direct thermal injuries including gastric erosions, esophageal erythema, and atrioesophageal fistula caused by the ablation catheter.[14] A thermal injury to the esophageal muscular layer by heating reduces the esophageal elasticity and reduces the tone of the esophageal sphincter.[15] Furthermore, esophageal thermal lesions occurred when the inter-luminal temperature reached 41°C.[16] Second,

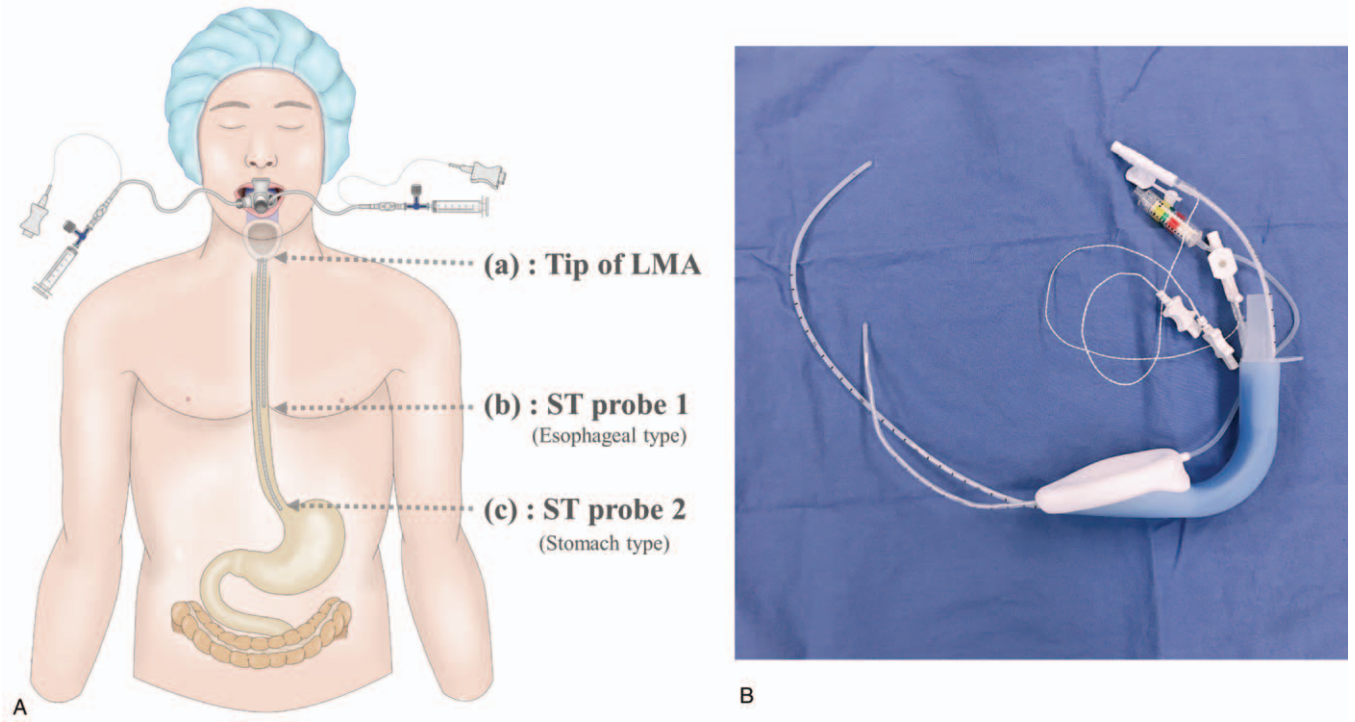

Figure 2. (A) Schematic diagram for pH measurement at 3 areas: (a) Tip of SGD or oropharynx, (b) ST probe 1 is placed at mid-esophagus, the secretion sampled from ST probe 1 reflects the pH value at mid-esophagus. (c) ST probe 2 is placed at low-esophagus, the secretion sampled from ST probe 2 reflects the pH value at low-esophagus. (B) Two ST probes were inserted through the suction port of the SGD. SGD = Supraglottic device.

there is a secondary complication such as gastroparesis, reflux esophagitis, or Jackhammer esophagus by vagal nerve injury.[7,11,17] Transient damage to the efferent vagal neurons by heat conduction relaxes the lower esophageal sphincter and reduces the motility of the upper gastrointestinal tract.[18]

Conscious sedation, in which esophageal peristalsis is maintained, compared to general anesthesia, results in a temperature lowering effect and reduces heat transfer to the esophageal wall.[19] Therefore, the incidence of GER during RFCA may decrease under conscious sedation compared to general anesthesia. On the other hand, general anesthesia has the advantage of reducing the prevalence of pulmonary reconnection and the recurrence of atrial fibrillation compared to conscious sedation.[3] However, the possibility of GER and esophageal damage may increase due to increased heat conduction resulting from a decrease in esophageal peristalsis. In our results using general anesthesia, GER occurred in 13 of 30 patients (43%). Therefore, in the RFCA procedure, the possibility of GER should be considered when general anesthesia is selected for the convenience of the procedure and the advantage of improving the outcome.

Recently, SGDs have been used to minimize the sympathetic response during intubation period in RFCA.[5,20] Among these, second-generation SGDs have special features that increase safety relating to the prevention of gastric aspiration through an adequate oropharyngeal seal and aspiration of GER via a suction port of the SGD.[21,22] However, SGDs have the disadvantage of not completely preventing the aspiration of gastric contents compared to tracheal tubes. Several previous studies were conducted on GER during general anesthesia with SGDs and the incidence of GER when using an SGD varies depending on the type of surgery and the generation of the SGD.[23–26] The use of

Table 2

Comparison of non-GER and GER groups.

	Non-GER (n = 17)	GER (n = 13)	*P*-value
Total anesthetic time, min	147 (128–188)	168 (143–207)	.187
Total ablation time, min	75 (62–94)	103 (87–115)	.021
Maximum esophageal temperature, °C	38.4 (37.0–39.0]	39.4 (37.9–40.1)	.051
Frequency that esophageal temperature rises, n	1.2 (1.4)	2.0 (1.2)	.103
Location of ablation catheter when esophageal temperature rises, n (LSPV/LIPV/RSPV/RIPV)	14/6/0/1	20/6/0/0	
GER symptom on POD 1, n	2	5	.087
GER symptom at 1 mo postoperative, n	1	2	.390

Data are presented as the median (IQR) and number.

GER = gastroesophageal reflux, IQR = interquartile range, LSPV = Left superior pulmonary vein, LIPV = Left inferior pulmonary vein, POD = postoperative day, RSPV = Right superior pulmonary vein, RIPV = Right inferior pulmonary vein.

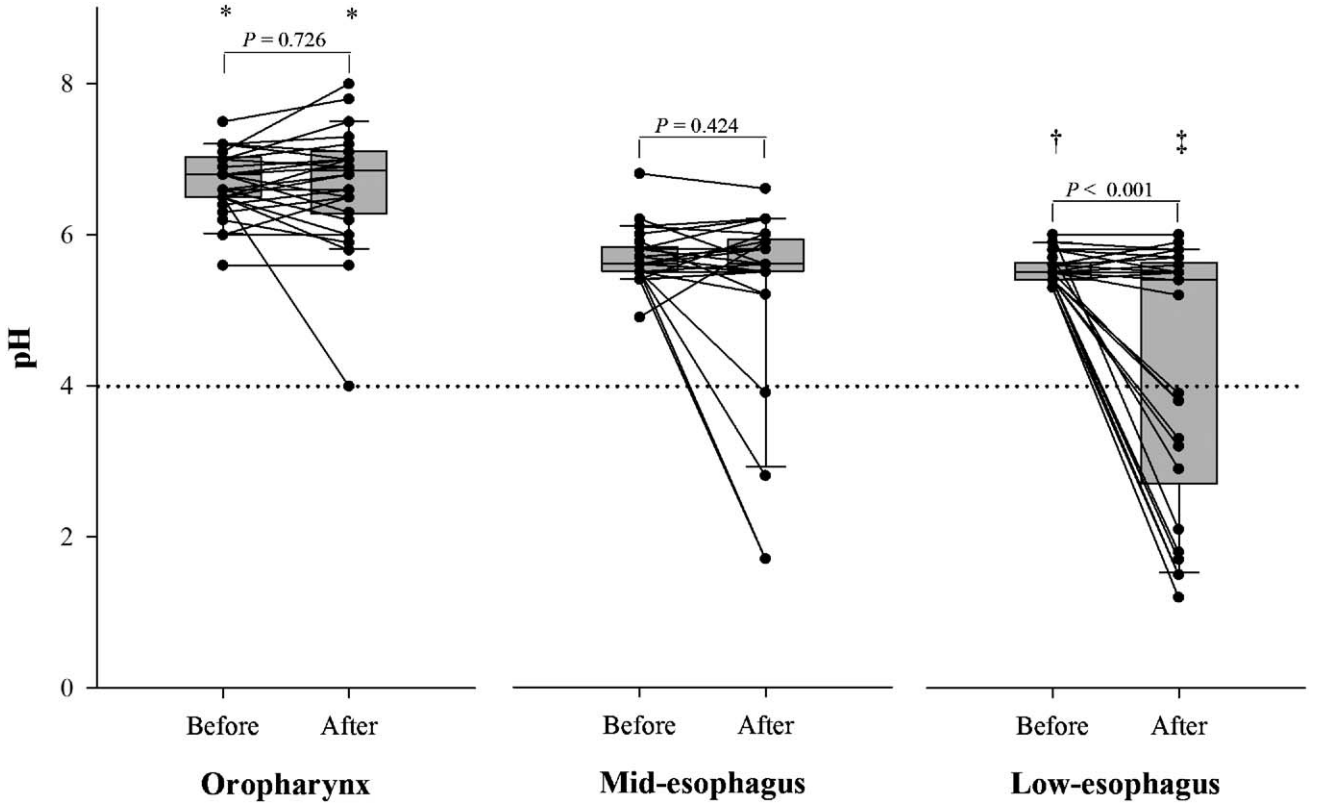

Figure 3. Change in pH before and after radiofrequency catheter ablation at the oropharynx, mid-esophagus, and low-esophagus. A patient under the dotted line (pH < 4) was defined as GER. * $P < .001$ vs mid-esophagus and low-esophagus. † $P = .021$ vs mid-esophagus. ‡ $P = .002$ vs mid-esophagus.

an SGD did not lead to a critically ill course such as aspiration pneumonia, even if GER occurred in the mid-esophagus or oropharynx.[26] Our results showed that 4 of 30 (13%) patients had GER occur at the mid-esophagus and oropharynx, but aspiration pneumonia did not occur. Therefore, SGDs can be safely used in RFCA under general anesthesia. However, considering the possibility of GER occurring during RFCA procedures with long ablation times, it is recommended to use 2nd generation SGD capable of esophageal suction.

RFCA related gastrointestinal tract injuries are related to several factors such as ablation power, duration, and kind of procedure. Esophageal complications are known to increase the risk if the ablation power is greater than 15 to 20 W and the single ablation time is greater than 20 seconds.[27] Previous studies demonstrated that higher-power and shorter duration ablations were safer than lower power and long duration.[28] In our results, the total ablation time was longer in the GER group, it suggests that ablation time is also one of the major factors that cause GER. In addition, the maximum esophageal temperature and frequency of the esophageal temperature rises were not statistically different between the non-GER group and the GER group. The reason for this is that esophageal temperature does not reflect the actual degree of thermal stimulation reaching the esophageal wall because the degree of heat energy is different, such as the power and impedance, depending on the patient.[29,30] GER is associated with an increase in the total ablation time but is not related to an elevated esophageal temperature. Therefore, if there is an increase in the total ablation time during RFCA, care must be taken to prevent pulmonary aspiration during extubation.

Our study had several limitations. First, we did not measure the pH continuously. GER occurs during SGD removal or after administration of the reversal agent for the neuromuscular blocking agent.[23,31] The aim of our study was to confirm the incidence of GER during RFCA by measuring the pH in three areas after SGD removal. Therefore, in our study, we measured the pH before the procedure and after SGD removal. Second, patients with an asymptomatic GI pathology may have been included because GI symptoms were not evaluated preoperatively with endoscopy. Third, each duration of a single ablation was not measured separately. Several studies demonstrated that the duration of a single ablation is also an important factor to affect esophageal damage. Fourth, the results of our study cannot be generalized because of the small sample pilot study. However, these results may provide a basis for further large studies. In conclusion, GER after RFCA occurred in 43% of patients, only 1 patient in the oropharynx. And critical complications such as aspiration pneumonia after extubation did not occur. Therefore, the use of an SGD in RFCA can be relatively safe, but care should be taken as SGDs do not completely eliminate the possibility of aspiration. therefore, an additional study is needed in the future.

Author contributions

Conceptualization: Jin Hee Ahn, Jiyeon Park, Ji Seon Jeong.
Data curation: Jin Hee Ahn.
Formal analysis: Young Keun On.
Investigation: Jin Hee Ahn, Jiyeon Park, Kyoung-Min Park.
Methodology: Jin Hee Ahn, Ji Seon Jeong.

Project administration: Eun Jeong Oh.
Resources: Jae Seong Jo, Eun Jeong Oh.
Software: Jae Seong Jo.
Supervision: Sung Hyun Lee, Young Keun On, Kyoung-Min Park, Justin Sangwook Ko.
Validation: Sung Hyun Lee, Eun Jeong Oh.
Visualization: Sung Hyun Lee, Eun Jeong Oh, Justin Sangwook Ko.
Writing – original draft: Jin Hee Ahn, Kyoung-Min Park.
Writing – review & editing: Ji Seon Jeong.

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