Incidence of acute thermal esophageal injury after atrial fibrillation ablation guided by prespecified ablation index

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Abstract

Introduction: Ablation index (AI), a novel parameter defining energy application at single ablation lesions, calculated by integration of ablation time, energy, catheter stability, and contact force, has been documented to be associated with effective lesions and higher ablation efficacy. Using a prespecified target AI in addition to acute lesion efficacy may affect local collateral damage like esophageal thermal injury when used for guiding radiofrequency (RF) ablation at the posterior left atrial (LA) wall.

Methods and Results: Consecutive patients undergoing first AF ablations using AI were included. Ablation energy was reduced to 25 W when ablating at posterior LA wall. Two different individually defined AI target values were used (300 and 350 for posterior wall ablation). Esophageal endoscopy (EE) was performed 1 to 3 days after ablation procedure to document and categorize endoscopically detected esophageal thermal lesion (EDEL).

Two-hundred and eleven consecutive patients with postprocedural EE were included. Incidence of EDEL was 14% (29 of 211 patients; mild category 1 lesions in 22 of 29 patients (76%) and severe category 2 lesions (ulcers > 5 mm) in 7 of 29 patients (24% of EDEL group, 3% of total group). Ablation time at posterior LA wall (9.5 vs 9.0 minutes \( P = .67 \)) was comparable in patients with and without EDEL.

Conclusion: LA posterior wall RF ablation adopting AI \( \leq 350 \) was associated with 14% esophageal thermal injury including 3% of severe esophageal thermal ulcers. This incidence is comparable to historic control groups with non AI-guided AF ablation.

KEYWORDS
ablation index, atrial fibrillation, endoscopically detected esophageal thermal lesion, esophageal thermal injury

1 INTRODUCTION

Adequate catheter contact, ablation power, and ablation duration are important parameters influencing lesion formation in radiofrequency (RF) ablation procedures and may affect the efficacy of atrial fibrillation (AF) ablation procedures. These parameters might also predict the risk of postprocedural esophageal thermal lesions (EDELs) induced by RF ablation at posterior left atrial (LA) wall. In a recent study, improved acute and 12-month efficacy were documented using ablation index (AI)—a novel parameter defining energy application at single ablation sites, calculated by integration of catheter stability, ablation time, ablation energy, and contact force—to guide local RF applications.1

Ablation-induced EDELs have been documented in up to 56% of AF ablation patients and may be precursors of perforating severe
esophageal complications like atrioesophageal fistula.\textsuperscript{2,3} The incidence of perforating esophageal complications reported may be lower than the true incidence because of underdetection and underreporting. According to a worldwide survey and a registry study, the incidence of atrioesophageal fistula after AF ablation was below 0.2\%, whereas a recently published study with rigid postablation endoscopy found an incidence of atrioesophageal fistula and esophageal perforation of up to 0.6\% in patients.\textsuperscript{2,4,5}

Limiting ablation time, contact force, and ablation energy at the LA posterior wall has been recommended in all AF ablations to decrease the risk of esophageal complications.

Whereas AI-guided ablation was designed to optimize individual ablation lesion quality (efficacy) to target prespecified values may be associated with thermal collateral damage (safety).

The purpose of this single-center study was to evaluate the incidence of esophageal thermal injury related to AI-guided ablations using postablation endoscopy in patients undergoing their first AF ablation.

## 2 | METHODS

All patients gave informed consent before entering the study. The study was approved by the local institutional review board.

### 2.1 | Study population

From July 2017 to November 2018, consecutive patients undergoing first-time AF ablation including pulmonary vein isolation using single-tip RF force-sensing ablation catheters in conjunction with the AI module at our institution were included. All patients underwent esophageal endoscopy (EE) 1 to 3 days after ablation to document esophageal thermal damage (EDEL).

### 2.2 | Atrial fibrillation ablation procedure

LA thrombi were ruled out by transesophageal echocardiography performed on the day before the ablation procedure. All procedures were performed under continued oral anticoagulation. The procedures were performed using a three-dimensional electroanatomic mapping system (CARTO 3; Biosense Webster, Diamond Bar, CA) as previously published. In brief, exit and entrance block of each pulmonary vein (PV) as the procedural endpoint was confirmed by a lasso catheter (Biosense Webster). Patients were ablated using single-electrode RF ablation catheters with open catheter-tip irrigation at an irrigation flow rate of 30 mL/min (ThermoCool SmartTouch; Biosense Webster). Ablation power was limited to 25 W at the posterior wall and to 35 W at other LA ablation sites. Target contact force was between 5 and 15 g at the posterior wall and between 15 and 30 g at other ablation sites. Target ablation time was automatically defined by the AI algorithm incorporating ablation power, time, and contact force. A color change of the ablation lesion tag to dark red indicated that the targeted AI at the current ablation site was reached. The AI target value at posterior wall ablation sites was defined for each of the participating operators individually (AI at posterior wall sites between 300 and 350). Ablation procedures were performed by four experienced operators (each having performed more than 500 AF ablation procedures). According to our current standard approach, no luminal esophageal temperature probes were used.

### 2.3 | Postablation esophageal endoscopy

EE was performed by experienced operators (having performed over 1000 post AF-ablation endoscopies each) within 1 to 3 days after ablation to assess for the presence and extent of endoscopically detected esophageal lesions (EDEL). EDEL was defined as a typical endoscopical finding of the esophageal mucosa in an area neighboring the LA and was classified as either category 1 lesion (mild: erythema/erosion or small ulcers ≤5 mm diameter) or category 2 (severe) lesion (ulcer >5 mm diameter) as previously reported.\textsuperscript{2,6}

### 2.4 | Postprocedural management

All patients received proton pump inhibitors (PPI) (80 mg per day orally) for 6 weeks postprocedurally irrespective of endoscopy results. In case of any EDEL, endoscopy was repeated until confirmation of healing of the lesion as per institutional standard protocol.\textsuperscript{2} Patients with category 2 lesions received a liquid diet in addition to PPI until repeat endoscopy indicated remission of the lesion. Perforating esophageal complications were defined as air and oral contrast medium extravasate in computed tomography imaging after swallowing in the mediastinum or as esophagopericardial or esophagointestinal fistula.

### 2.5 | Follow-up

At 3 months follow-up any late-occurring esophageal complication was documented. Procedural efficacy at 3 months was evaluated by two Holter ECG recordings and clinical evaluation in relation to AF episodes.

### 2.6 | Statistical analysis

The data are expressed as mean ± SD for continuous variables or as numbers and percentages for categorical variables. For analysis of continuous variables the t test and for analysis of categorical variables contingency tables were used.

For analysis of possible risk factors for the occurrence of EDEL binary logistic regression was used. For logistic regression results were given as odds ratios and 95\% confidence intervals and P values. P values less than .05 were considered statistically significant. Statistical analyses were performed using SPSS.
Two-hundred and eleven consecutive patients (63% male, mean age 65 ± 11 years) were included. Mean LV EF was 58 ± 11%, 54% had paroxysmal AF, and 46% persistent AF. Patient characteristics are shown in Table 1.

In all 211 patients, all PV were effectively isolated (100% acute success). Procedure duration, mean duration of RF at the posterior wall in the overall group, and mean AI at the posterior wall in overall group are displayed in Table 2.

### Endoscopy and procedural results

Incidence of EDEL was 14% (EDEL in 29 of 211 patients). Category 1 lesions were found in 22 of 211 patients (10%) and category 2 lesions were documented in 7 patients (see Figures 1 and 2). A control endoscopy documented all category 2 lesions to be in remission after 7 days (Figure 2B).

Mean RF ablation time at the posterior wall was comparable between endoscopy positive and negative patients (9.5 vs 9.0 minutes [P = .67]). (Figures 3 and 4).

Two individual AI target values for ablation sites at posterior LA wall were used (300 and 350). One-hundred and twenty nine patients (61%) were ablated using a target AI value of 300 and 82 patients (39%) were ablated using a target AI value of 350. Sixteen of 129 patients (12%) treated with a target AI of 300 and 13 of 82 patients (16%) treated with a target AI of 350 demonstrated EDEL at EE after ablation (P = .54).

In univariate statistical evaluation only systolic EF (51 ± 10 in patients with EDEL vs 59 ± 9 in patients without EDEL, P < .01) was inversely associated with the incidence of EDEL (Table 1).

Logistic regression analysis of parameters possibly influencing the incidence of EDEL (category 1 and category 2) did not identify any of the included variables to significantly influence the occurrence of EDEL (Table 2).

### Follow-up

At 3 months follow-up, 180 of 211 patients (85.3%) were in stable sinus rhythms. No late esophageal complications were documented.

### DISCUSSION

As the main findings, the incidence of EDEL in AI-guided AF ablation was low with 14% EDEL including only 3% category 2 lesions. All patients with EDEL including seven patients with category 2 lesions demonstrated healing of the lesion in a control endoscopy within 7 days and no progression to esophageal fistula or perforation was documented.

| TABLE 1  | Patient characteristics |
|-----------|--------------------------|
| Patients with EDEL in postprocedural endoscopy n = 29; 14% | Patients without EDEL in postprocedural endoscopy n = 182; 86% | All patients n = 211 | P |
| Age in years | 64.7 ± 10.7 | 65.0 ± 10.9 | 64.9 ± 10.6 | .90 |
| Sex: male n (%) | 20 (69) | 112 (62) | 132 (63) | .54 |
| BMI | 30.0 ± 5.8 | 29.4 ± 5.9 | 29.5 ± 5.7 | .73 |
| Paroxysmal AF n (%) | 12 (41) | 101 (56) | 113 (54) | .17 |
| LVEF (%) | 51 ± 10 | 59 ± 9 | 58 ± 11 | <.01 |
| CHA²DS²-VASc Score | 2.8 ± 1.6 | 2.5 ± 1.6 | 2.5 ± 1.5 | .83 |
| Hypertension n (%) | 26 (90) | 157 (86) | 183 (87) | .77 |
| CAD n (%) | 11 (38) | 65 (36) | 76 (36) | .84 |
| Diabetes n (%) | 2 (7) | 17 (9) | 19 (9) | 1.0 |
| Prior stroke/TIA n (%) | 3 (10) | 7 (4) | 10 (5) | .14 |

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CAD, coronary artery disease; LVEF, left ventricular ejection fraction; TIA, transient ischemic attack.

| TABLE 2  | Patient-specific and procedural risk factors for occurrence of EDEL |
|-----------|--------------------------|
| Odds ratio (95% CI) | P |
| Male sex | 1.114 (0.301-4.123) | .871 |
| Age | 0.993 (0.936-1.053) | .812 |
| BMI | 0.941 (0.853-1.038) | .224 |
| Paroxysmal AF | 1.057 (0.378-2.951) | .916 |
| CHA²DS²-VASc score | 0.734 (0.415-1.299) | .289 |
| LVEF | 0.945 (0.905-0.987) | .011 |
| CAD | 1.156 (0.363-3.676) | .806 |
| Arterial hypertension | 2.930 (0.571-15.018) | .197 |
| Ablation time | 0.975 (0.936-1.015) | .214 |
| Target AI | 1.517 (0.540-4.264) | .430 |

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CAD, coronary artery disease; CI, confidence interval; LVEF, left ventricular ejection fraction; AI, ablation index.
documented. AI aiming at optimizing local ablation lesion quality seems to be safe in regard to clinically relevant collateral esophageal damage if AI target values ≤350 are used. New ablation technologies and strategies targeting posterior LA wall sites have to be evaluated regarding their potential impact on the incidence of EDEL.

4.1 | Incidence of esophageal thermal injury

EDEL have been identified in between 0% and up to 40% of patients after AF ablation depending on ablation energy, type of ablation catheter, use of catheter-tip irrigation, use of temperature probes, and depending on the indication and timing of postprocedural endoscopy. Endoscopy is considered the gold standard for detecting thermal esophageal damage and category 2 EDEL are the endoscopic findings in patients with increased risk of perforating esophageal injury like atrioesophageal fistula. A recently published study found an incidence of atrioesophageal fistula and esophageal perforation of 0.6% in patients undergoing rigid postablation surveillance. Of note, esophageal thermal injury can be identified...
using endoscopy already during the ablation procedure and most EDEL heal off within 7 days after the initial thermal injury. Timing of postablation endoscopy may be crucial for accurate documentation of esophageal thermal injury and for practical reasons endoscopy is usually done within the first 3 days after the procedure (days EE performed after ablation procedure: mean 2.4 ± 4.5).

In recent reports on patients ablated using our protocol thermal esophageal lesions were documented in 18% to 19% of all patients when using postablation endoscopy as a standard procedure and category 2 lesions comprised one-third of these lesions. In a single-center registry analyzing 832 patients treated with different RF ablation catheters at our institution using prespecified ablation parameters when ablating at the posterior LA wall (maximum 25 W) resulted in an incidence of 18% EDEL. The ablation approach used in these studies performed by the same operators resulted in slightly higher incidences of EDEL compared to individual Al-guided ablation although there is no head-to-head or randomized comparison available. The concept of Al as a parameter for local ablation lesion quality integrates ablation time, power, and contact force in a weighted formula at each ablation site. Our data indicate that Al-guided ablation may also be safe in regard to creating low incidences of EDELs by potentially reducing local energy and ablation time to a minimum needed for adequate lesion formation but not more. Al-guided ablation has been documented to improve the procedural and long-term outcome of AF ablation but randomized trials documenting efficacy on the one hand and safety on the other hand are lacking.

Of note, in our study, we used lower target AI values (compared to the CLOSE-protocol studies using 400 AI at posterior wall and 550 AI at anterior wall) at posterior LA wall which may affect the incidence and extent of collateral esophageal thermal injury. The incidence of EDEL was slightly higher after ablation with a target AI value of 350 compared to ablation with a target AI value of 300 supporting the concept of higher energy applications leading to a higher risk for esophageal thermal injury. However, this difference was statistically not significant.

4.2 | Efficacy

In all 211 patients, all PVs demonstrated exit and entrance block at the end of the procedure regardless of the targeted posterior wall AI. The short-term success rate after 3 months FU was 85%. However, long-term success was not evaluated in this study protocol and future comparative studies are needed. Optimal AI values to keep the incidence of EDEL as low as possible without decreasing ablation success need to be defined.

4.3 | Incidence of category 2 lesions

EDEL is a surrogate parameter for the risk of relevant esophageal complications including perforation and atrioesophageal fistula. The incidence of EDEL overestimates the number of patients progressing to atrioesophageal fistula and esophageal perforation but category 2 lesions have been documented to identify patients at a 1-out-of-10 risk to progress to esophageal perforation. Therefore dedicated protocols for this patient cohort including repeat endoscopy and early esophageal stenting are being evaluated. In the present study, category 2 lesions (3%) were slightly lower than what has been documented for non AI-guided contact-force posterior wall ablation (5%) which may allude to a lower risk for perforating esophageal complications using posterior wall AIs ≤350. Of note, an ablation strategy resulting in an overall 3% rate of postprocedural esophageal ulcers still has to be used with caution and additional efforts to further reduce this rate of esophageal injury are required.

5 | LIMITATIONS

The major limitation of the current study is its observational noncomparative character. Patients were included consecutively and the incidence of EDEL in this study cohort was compared with the incidence of EDEL in previous studies performing postablation EE at our institution. We did not use luminal esophageal temperature probes as they seem not to be predictive for the occurrence of EDELs and have not been clearly related to reduced atrioesophageal fistula or EDEL rates. Conflicting data regarding the potential of temperature probes to reduce the risk of EDEL have been published so far. According to this study use of luminal esophageal temperature monitoring was not associated with a lower incidence of post ablation EDEL. Of note, endoscopically detected esophageal lesions are an important surrogate parameter for clinically relevant but rarely occurring esophageal complications like esophageal perforation or fistula.

Furthermore, a major limitation of currently used temperature probes is that esophageal tissue temperature rises might be detected too late to prevent thermal esophageal damage by interrupting RF energy application at LA posterior wall. A high-definition accurate temperature probe using infrared technology has been evaluated in an IDE-trial (HEAT-AF) and data in regard to identify patients at risk for EDEL are promising but further investigations are needed.

6 | CONCLUSION

In this noncomparative single-center study of patients undergoing Al-guided AF ablation (with a target AI ≤350 at the posterior wall) the incidence of EDEL was slightly lower than expected from previous published trials. Different prespecified AI target values were not associated with significantly different incidences of EDEL. Larger prospective and randomized studies should evaluate the impact of Al on the incidence of collateral thermal injury and efficacy to define
optimal AI values potentially further reducing the risk of esophageal complications.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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