CLINICAL STUDY

Low Incidence of Esophageal Lesions After Pulmonary Vein Isolation Using Contact-Force Sensing Catheter Without Esophageal Temperature Probe

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Summary

Pulmonary vein isolation (PVI) is a cornerstone therapy for atrial fibrillation (AF). Although severe complications are rather rare, the development of an atrio-esophageal fistula (AEF) is a fatal complication with a very high mortality even after surgical treatment. The use of esophageal temperature probes (ETP) during PVI may protect the esophagus but it is still under debate since the ETP may also lead to esophageal lesions. The aim of this study was to evaluate the clinical safety of PVI using contact-force (CF) sensing catheter without esophageal temperature monitoring.

We investigated 70 consecutive patients who underwent point-by-point PVI without usage of ETP and who underwent esophago-gastro-duodenoscopy (EGD) with detailed evaluation of the esophagus after the index PVI procedure. The operator attempted to keep CF within the 10-40 g range. The incidences of esophageal lesions (EDEL) detected by endoscopy were then analyzed.

Two of 70 patients (2.9%) showed EDEL consisting of one longitudinal ulcer-like erythematous lesion with fibrin and a different one consisting of a round-shaped lesion surrounded by erythema and petechial hemorrhage. All EDEL healed within two weeks under high proton-pump inhibitor therapy without developing AEF as proven by a second EGD of the esophagus.

Point-by-point PVI without usage of ETP showed a low incidence of EDEL (2.9%); atrio-esophageal fistula was absent. Further studies on the necessity of ETP under CF control are necessary.

(Int Heart J 2017; 58: 880-884)

Key words: Atrial fibrillation, Atrio-esophageal fistula, Radiofrequency ablation, Complications

The prevalence of atrial fibrillation (AF) is constantly increasing due to the growth of the elderly population.1) Since the establishment of catheter ablation as a cornerstone therapy, the number of pulmonary vein isolations (PVI) as treatment in drug refractory AF is also increasing rapidly. Atrio-esophageal fistula (AEF) is the most devastating complication after left atrial catheter ablation. The incidence of AEF is rather low as has been described in the literature to be between 0.016 and 0.05%,2,3) but its mortality is very high even after surgical intervention.4)

Nevertheless, several investigators reported asymptomatic, endoscopically detected esophageal lesions (EDEL) after left atrial ablation. The incidence ranged between 0% to almost 50%.5,6) Zellerhoff, et al. showed a structural change of the esophagus in 56% of the patients after PVI by endosonography.6)

To prevent esophageal complications, different approaches are being employed. The 2012 HRS/EHRA/ECAS Expert Consensus Statement states to reduce the power while ablating at the posterior wall of LA, visualization of the esophagus and temperature control.7) However, only two-thirds of the task force members employ an esophageal temperature probe (ETP).8)

Moreover, several centers mentioned that currently use of ETP may contribute to the development of esophageal injury.9,10)

The aim of this study was to analyse the incidence of esophageal injury in patients after PVI without esophageal temperature monitoring and who underwent esophago-gastro-duodenoscopy (EGD) with detailed evaluation of the esophagus.

Methods

Study population: The study population consisted of 70
We used a multipolar diagnostic catheter (Lasso, Biosense Webster) for mapping and proving both the entry and exit block. All PVI procedures were performed by one experienced physician (>500 PVI procedures in the last 3 years). The endpoint of the PVI procedure was defined as a bidirectional block (entrance and exit block) proven by the absence of any PV spike recorded on the Lasso catheter when placed within the ipsilateral PVs at least 20 minutes after PVI and by the absence of LA capture under pacing from the Lasso catheter placed within the ipsilateral PVs (8 mV, 2 ms output).

Pulmonary vein isolation: All PVIs were performed without complications. There was one case of pericardial effusion (1.4%), which had to be punctured. We observed one inguinal arteriovenous fistula without the need for surgical treatment, which spontaneously disappeared during follow-up. The other PVIs showed no major or minor complications, such as major bleeding, stroke, or phrenic nerve palsy.

Thoracic symptoms after PVI such as burning sensation and chest pain with respiratory variation were noted in 18/70 patients (26%, 10 males). Gender, age and total burning time showed no significant differences according to the presence of these thoracic symptoms (62 ± 10 versus 66 ± 9 years, 46.7 ± 40.3 versus 49.3 ± 35.5 minutes, respectively for symptom [+] and symptom [-]). No patient suffered from symptoms triggered by swallowing.

Esophageal endoscopic findings: In 2 out of 70 patients (2.9%) a thermal lesion of the esophagus was found (Figure). One patient showed a longitudinal ulcer-like lesion with fibrin and erythema at 30 cm from the incisors (60 hours after PVI). The size of this lesion was about 4 × 1 mm and 1 mm in depth. The second patient showed a round-shaped lesion 20 cm from the incisors (68 hours after PVI) surrounded by erythema and petechial hemorrhage. This lesion had a size of 2 × 2 mm with a depth of <0.5 mm. The relatively short distance of 20 cm from the incisors was confirmed by an experienced gastroenterologist (SvD) as the distance from the upper incisors to the gastroesophageal junction was also relatively short (34 cm). Both lesions had disappeared after 14 and 12 days of follow-up, respectively under high proton-pump inhibitor therapy. Patients’ characteristics are shown in Table II.

None of these patients suffered from any

Table I. Baseline Characteristics

| Characteristic               | Value       |
|------------------------------|-------------|
| Age (years)                  | 64 ± 9      |
| Gender (male)                | 35 (50%)    |
| Arterial hypertension        | 46 (65.7%)  |
| Dyslipidemia                 | 35 (50%)    |
| Diabetes mellitus            | 9 (12.9%)   |
| Coronary artery disease      | 22 (31.4%)  |
| History of stroke            | 4 (5.7%)    |
| Heart failure                | 13 (18.6%)  |
| NYHA (I-IV)                  | 1.6 ± 0.8   |
| Paroxysmal atrial fibrillation| 44 (63%)    |
| EFRA (I-IV)                  | 2.5 ± 0.7   |
| Ejection fraction (%)        | 58 ± 10     |
| Left atrial diameter (mm)    | 39 ± 7      |
| CHADS2 VASC-Score            | 2.5 ± 1.6   |
| Creatinine (mg/dL)           | 1.0 ± 0.4   |
| GFR (mL/minute)              | 72 ± 20     |
| Procedure duration (minute)  | 141 ± 29    |
| Fluoroscopic time (minute)   | 12 ± 5      |
| Total burning time (minute)  | 48 ± 36     |
patients did not complain of the thoracic symptoms mentioning above. No development of AEF was observed. Moreover, these 2 patients did not develop any thoracic symptoms or oropharyngeal fistula. PVI indicates pulmonary vein isolation; FU, follow-up; and EGD, esophago-gastro-duodenoscopy.

![Figure. Esophageal thermal lesions after pulmonary vein isolation. Esophageal thermal lesions are shown. Patient 1 showed a longitudinal ulcer-like lesion with fibrin and erythema at 30 cm from the incisors (60 hours after PVI). The size of this lesion was about 4 × 1 mm and 1 mm in depth. Patient 2 showed a round-shaped lesion 20 cm from the incisors (68 hours after PVI) surrounded by erythema and petechial hemorrhage. This lesion had a size of 2 × 2 mm, with a depth of < 0.5 mm. Both lesions were not noted anymore after 14 and 12 days of follow-up, respectively. Both patients did not develop any thoracic symptoms or atrio-esophageal fistula. PVI indicates pulmonary vein isolation; FU, follow-up; and EGD, esophago-gastro-duodenoscopy.](image)

**Table II.** Baseline Characteristics of Patients with EDEL

|                         | Patient 1 | Patient 2 |
|-------------------------|-----------|-----------|
| Age (years)             | 74        | 78        |
| Gender                  | Male      | Female    |
| Body mass index (BMI)   | 22        | 31        |
| Arterial hypertension   | Yes       | Yes       |
| Dyslipidemia            | Yes       | No        |
| Diabetes mellitus       | No        | No        |
| Coronary artery disease | Yes       | Yes       |
| History of stroke       | No        | No        |
| Heart failure           | Yes       | Yes       |
| Paroxysmal atrial fibrillation | Yes   | Yes       |
| EHRA (I-IV)             | 2b        | 3         |
| Ejection fraction (%)   | 26        | 60        |
| Left atrial diameter (mm) | 36  | 39        |
| CHA2DS2-VASC Score      | 4         | 5         |
| Creatinine (mg/dL)      | 3.9       | 1.5       |
| GFR (mL/minute)         | 14        | 34        |
| Procedure duration (minute) | 155 | 160        |
| Fluoroscopic time (minute) | 15.2 | 14.4     |
| Total burning time (minute) | 99.45 | 54.14   |

Odynophagia, haemoptysis, or sour stomach symptoms. No development of AEF was observed. Moreover, these 2 patients did not complain of the thoracic symptoms mentioned above.

Of note, only 15 patients (21%) showed no gastrointestinal pathologies. Gastritis, esophagitis, lesions pointing to short Barrett esophagus and esophageal varices were noted in 41, 9, 6, and 5 patients (59%, 13%, 9%, and 7%, respectively). Moreover, in 1 patient (1.4%) an oropharyngeal tumor was discovered, which was diagnosed as a benign papilloma upon further work-up by oto-rhino-laryngologists.

**Discussion**

The major findings of the present study were: 1) the incidence of EDEL was 2.9%, relatively low as compared to previous studies, 2) all these EDEL disappeared spontaneously within two weeks. We also observed a significant incidence of various gastroenterologic pathologies. To the best of our knowledge, this is a first report on EDEL after point-by-point PVI using contact-force sensing catheter without ETP.

**Endoscopy detected esophageal lesion:** We observed a very low incidence of EDEL (2.9%) without any persistent damage after contact-force guided PVI. None of the patients showed any symptoms and no AEF had occurred. All PVIIs where successfully undertaken with a reasonably low incidence of complications.

AEF has been described as a very rare but devastating complication with a very high mortality. Nevertheless, the occurrence of EDEL after PVI seems to be more prevalent. The incidence ranged from 0% to almost 50%. Zellerhoff, et al. discovered an even higher incidence of mucosal disorder via endosonography and concluded that the esophageal damage seen in the endoscopy resembled only the “tip of the iceberg.”

The use of ETP is currently controversial. Although the 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation mentioned temperature probes as a possible to prevent esophageal damage, less than two-third of the task force members indicated the use of such a probe. Moreover, several studies reported that the use of ETP might lead to the development of esophageal damage. On the other hand, Kiuchi, et al. demonstrated a benefit for using an ETP with decreased esophageal injury.

Keshishian, et al. reported a series of three patients with mucosal erythema and shallow and deep ulceration after PVI. The EDEL documented in our study resemble those lesions reported by other groups with all EDEL
healed in between two weeks. The two patients with EDEL in our study were older than the average patient, had a higher CHA2DS2-VASc-Score and had impaired kidney function. Furthermore, the total burning time and total procedure time were longer than the mean values of other patients, although the statistical significance was not demonstrated due to small sample size.

In the present study, the 2 patients with EDEL complained of no thoracic symptoms such as burning sensation or chest pain. This suggests that the risk of esophageal pathologies after PVI cannot reliably be estimated based on the occurrence of thoracic symptoms.

It is not yet understood if the pre-procedural use of proton-pump inhibitors (PPI) may lead to a decreased development of EDEL. In our cohort, 34.1% of the patients took PPI before PVI. Interestingly, both EDEL patients were treated with PPI before the procedure. Due to the small number of patients, the role of pre-procedural use of PPI remains unclear concerning our cohort.

Temperature probes and clinical implication: Nguyen, et al. showed in a bovine model that the use of an uninsulated ETP leads to a higher temperature below the temperature probe and consecutive damage of the underlying tissue. In contrast, the use of an insulated ETP showed a similar temperature as the control group, where no probe was used. Halfbass, et al. reported the use of insulated temperature probes in humans to be safe and feasible. Interestingly, Kumar, et al. found that the transesophageal echo probe may also lead to an increase in esophageal damage. 

After analyzing the patients with esophageal injury, we found no significant differences in patients without lesions due to the low incidence of EDEL. However a lower BMI was been shown to be a predictor for the development of esophageal injury. For ablating physicians, the prevention of EDEL and AEF is essential. Knowledge of the left atrial anatomy and thoughtful ablation at the posterior left atrial wall with reduced power setting may contribute to a safe and successful PVI. The previous data regarding esophageal injury were based on the procedures with the use of irrigation catheters but not with contact-force controlled radiofrequency ablation.

Based on the low incidence of EDEL in the present study in contrast to the previous data without CF control, our data suggests that the controlling of CF may reduce the esophageal damage. Therefore, studies examining the contact-force measurement in the development of EDEL are imperative.

Gastroesophageal disease: Beside the patients with thermal injury of the esophagus, the retrospective analysis of the endoscopic examinations showed only 15 patients without any pathologies. Macroscopic gastritis was most frequently observed followed by esophagitis, esophageal varices and lesions suspicious of short Barrett esophagus. Moreover, one tumor was discovered which had to be investigated further on. These findings are in accordance with a work of Knopp, et al. They showed that pathological findings were observed in 77% of patients, and further work-up or treatment was initiated in 25% of patients.

In our cohort, effective anticoagulation prevented bi-opsies. These are helpful for the work-up of Helicobacter pylori and mandatory for diagnosis of proven Barrett’s epithelium at the gastroesophageal junction. In the cases with overt macroscopic pathology, a further gastrointestinal diagnostic work-up was recommended. For example, stool analyses and breath tests could reliably secure Helicobacter-associated gastroduodenal pathology, even in anticoagulated patients.

Study Limitations: This study has several limitations. First, it is a retrospective single-center study. There is a lack of data concerning the ablation time at the posterior wall and detailed contact-force data. Therefore it may be possible that the CF data information during posterior wall ablation helped to reduce the incidence of esophageal thermal lesion formation. Additionally, the aim of this study was not to evaluate or seek the optimal CF value to reduce esophageal injury. Further studies focusing on these values should be undertaken.

Conclusions

In our patient cohort, esophageal thermal lesion were found only in 2.9% of patients who underwent pulmonary vein isolation via contact-force guided radiofrequency ablation without the use of an esophageal temperature probe. We observed complete remission in both cases under proton-pump inhibitor therapy. No atrio-esophageal fistula was documented and none of the patients suffered from any clinical symptoms. Further studies are needed to investigate the benefit of esophageal temperature monitoring and the potential use of insulated probes. Further gastrointestinal workup can be recommended in a majority of the cases.

Disclosures

Conflicts of interest: None.

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