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MULTIMEDIA REPORT

# Feasibility and safety of percutaneous epicardial access for mapping and ablation for ventricular arrhythmias in patients on oral anticoagulants

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## Abstract

**Purpose** This study aimed to assess the risk of procedure-related complications of percutaneous epicardial access (EpiAcc) for radiofrequency catheter ablation (RFA) of ventricular arrhythmias (VAs) in patients chronically treated oral anticoagulants (OACs) with warfarin compared to those not on OACs.

**Methods** We analyzed 205 patients (53 ± 16 years, 155 males) undergoing percutaneous EpiAcc as part of an RFA for VAs, and compared the outcome between patients chronically on OACs with warfarin (OAC group) and those without (non-OAC group).

**Results** Forty-seven patients (23%) were chronically treated on OACs before their procedure. EpiAcc in patients on OAC (OAC group) was not associated with an increased risk of cardiac tamponade (11% vs. 6%, $p = 0.238$) compared to non-OAC group, but a higher risk of need for blood transfusion (17% vs. 6%; $p = 0.013$). With respect to the OAC group, the international normalized ratio (INR) on the day of the RFA was ≥ 2.0 in 9 patients (19%) and < 2.0 in the remaining 38 patients (81%). The rate of all complication and blood transfusion were similar between them (11% vs. 21%; $p = 0.496$, 11% vs. 18%; $p = 0.600$).

**Conclusion** Percutaneous EpiAcc in patients on chronic OAC with warfarin did not significantly increase the risk of cardiac tamponade, but was associated with a higher risk of need for blood transfusion. EpiACC in patients with an INR > 2.0 is reasonable in experienced hands when clinical indications are strong.

**Keywords** Epicardial access · Oral anticoagulants · Ventricular arrhythmias · Radiofrequency catheter ablation · Complications

**Abbreviations**

| | |
|---|---|
| VAs | Ventricular arrhythmias |
| RFA | Radiofrequency catheter ablation |
| EpiAcc | Epicardial access |
| AF | Atrial fibrillation |
| ICM | Ischemic cardiomyopathy |
| NICM | Non-ischemic cardiomyopathy |
| OACs | Oral anticoagulants |
| LAA | Left atrial appendage |
| INR | International normalized ratio |
| FFP | Fresh frozen plasm |
| ACT | Activated clotting time |
| LV | Left ventricular |
| OR | Odds ratio |
| CI | Confidence interval |
| HR | Hazard ratio |
| CHF | Congestive heart failure |
| AAD | Antiarrhythmic drug |
| APA | Antiplatelet agents |

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## 1 Introduction

Patients with cardiomyopathy often have complex ventricular arrhythmia (VA) substrate in the endocardium, epicardium, and/or intramural mid-myocardium [1]. Combined endocardial and epicardial approaches have been used to improve the

outcomes of radiofrequency catheter ablation (RFA) of VAs in patients with cardiomyopathy. Percutaneous epicardial access (EpiAcc) is the standard and most frequently used technique for epicardial RFA [2].

The EpiAcc technique requires passage of a needle and sheath through numerous extra-cardiac structures, with an intrinsic risk of complications [3]. Patients requiring EpiAcc for RFA of VAs often have impaired cardiac function and comorbidities such as atrial fibrillation (AF) and mechanical valve prostheses, necessitating anticoagulation, which may increase the risk of bleeding complications. The discontinuation of oral anticoagulants (OACs) to permit EpiACC in patients with a chronic need for anticoagulation may lead to thrombotic complications. There are, however, few data regarding the risk of OAC discontinuation in patients chronically anticoagulated in order to permit EpiACC, or on the feasibility of EpiAcc in patients on oral anticoagulants (OACs). This study aimed to assess the risk of procedure-related complications of EpiAcc for RFA of VAs in patients chronically treated OACs with warfarin compared to those not on OACs. For patients on OACs with warfarin, we further sought to assess the risk of EpiACC performed during anticoagulation compared to that of transient discontinuation or reversal of OAC around the time of procedure.

## 2 Methods

### 2.1 Study population

We retrospectively analyzed all patients undergoing percutaneous EpiAcc as part of an RFA for VAs between June 1, 2004 and November 30, 2016 at Mayo Clinic, Rochester, MN. EpiAcc was performed when an epicardial origin of the VA was assumed based on the characteristics of the surface 12-lead electrocardiogram and/or if prior endocardial RFA had failed. The study was approved by the institutional review board, and written informed consent was obtained from all patients before the procedure. Patients who underwent an EpiAcc for other reasons, such as for supraventricular tachycardia ablation or left atrial appendage (LAA) ligation, and who were on direct OAC were excluded.

We divided study patients into two groups based on the chronic use (OAC group) or absence (non-OAC group) of OAC before the procedure. We compared the clinical characteristics, procedural success, complications, and clinical success between the OAC group and Non-OAC group. We further divided patients in the OAC group into two subgroups according to whether the international normalized ratio (INR) was $\geq 2.0$ or $< 2.0$ on the day of the procedure, and also compared the clinical characteristics, procedural success, complications, and clinical success.

### 2.2 Percutaneous EpiAcc technique

Our approach to the EpiAcc has been described previously [4–6]. Briefly, the EpiAcc was performed under general anesthesia or heavy conscious sedation in the electrophysiology laboratory. Following the administration of local anesthesia, a blunt-tipped epidural Tuohy needle was advanced to the pericardial space by puncturing the left subxiphoid space and directing the needle toward the cardiac silhouette. The Tuohy needle was advanced gently under fluoroscopic guidance in the right anterior oblique/left anterior oblique, or anterior–posterior, and lateral views. After the needle reached the cardiac silhouette, it was further advanced until we felt an increase then abrupt loss of resistance at the needle tip or layering of contrast was seen, indicating entry into the epicardial space. A guidewire was then advanced into the pericardial space through the needle, and we confirmed that the guidewire wrapped around the left and the right heart borders in the left anterior oblique and right anterior oblique views. A sheath was then advanced into the pericardial space over the guidewire to deliver a mapping or ablation catheter into the epicardial space. Intracardiac echocardiography was used as standard mainly to check the pericardial space during the procedure. A micropuncture needle was used in a few of the more recent cases.

### 2.3 OAC management

All the patients on warfarin were anticoagulated before the procedure to achieve 3 to 4 weeks of INR. Periprocedural OAC management in patients in the OAC group was determined by the ablation operator. In general, patients who discontinued OACs stopped taking them 1–5 days before the procedure, occasionally with heparin bridging. The use of vitamin K and/or fresh frozen plasma (FFP) pre-procedurally was determined by the operator. Unfractionated heparin was administered after epicardial access in patients in whom access was planned at the beginning of the procedure. In patients in whom heparin was already administered when the need for epicardial access was recognized, protamine was administered to reverse heparin prior to access. After successful access to the epicardium, the activated clotting time (ACT) was maintained between 200 and 300 s during the procedure. After loading with unfractionated heparin, the ACT was checked every 30 min, with additional boluses given to maintain an ACT of > 200 s during the procedure. The OAC was usually restarted on post-procedural day 0 or 1. We sometimes held off restarting the OAC, such as when a bleeding complication occurred.

### 2.4 Definitions of procedure-related complications

Complications were defined as follows [5, 6]:

1. Any event causing permanent harm or disability
2. Any event requiring a separate procedure (outside of the index ablation procedure, e.g., re-tapping for pericardial effusion, laparotomy)
3. Blood transfusion related to ablation procedure

### 2.5 Definitions of procedural and clinical outcomes

Procedural and clinical outcomes were defined as follows [5, 6]:

1. Procedural outcome: defined as successful if there was elimination and non-inducibility of the clinical VA. A procedure was deemed as failed if the clinical VA was not eliminated, or if it was inducible with isoproterenol or programmed stimulation. Non-clinical VA was excluded from the definition of procedural outcome.
2. Clinical outcome: success was defined as absence of arrhythmia symptoms at the last follow-up, either on or off antiarrhythmic drugs. Clinical failure was defined as the presence of symptoms or clinical VA despite antiarrhythmic drug, and/or requiring a repeat procedure. If a repeat procedure was required and was successful, the patient was said to be successfully ablated, but requiring multiple procedures.

### 2.6 Follow-up

Patients were admitted to the coronary care unit after the procedure. Patients underwent serial physical examinations, complete blood counts, and transthoracic echocardiography, which were usually performed the day following the procedure to assess for pericardial effusion. The duration of hospitalization depended on the individual patient's condition, and was usually 1 to 5 days after the procedure. After hospital discharge, patients were followed via telephone interviews at 30 days in addition to the follow-up recommended by their primary cardiologist.

### 2.7 Statistical analysis

Data are expressed as means ± standard deviations or median (interquartile range) if the distribution of the variables was skewed for the continuous variables and as numbers and percentages for categorical variables. Data were analyzed by the Wilcoxon rank sum test. The chi-square test was used to analyze the independence of the two classification criteria in the qualitative data. Univariate and multivariate analyses were performed to explore predictors for procedural events and success (logistic regression model), and clinical recurrence (Cox proportional hazard model). Variables with a $p$ value < 0.2 in the univariate analysis were used in the multivariate analysis. $p$ values < 0.05 were considered statistically significant.

## 3 Results

### 3.1 Patient characteristics

The study population consisted of 212 patients who underwent attempted percutaneous EpiAcc for VAs, of which 205 resulted in a successful EpiAcc (97%) and inclusion in this study (Fig. 1 and Table 1). One-hundred fifty-five patients (76%) were men. The mean age was 53 ± 16 years. The mean left ventricular (LV) ejection fraction was 45 ± 15%, and the substrate for VAs was ischemic cardiomyopathy (ICM) in 28 patients (14%), non-ischemic cardiomyopathy (NICM) in 134

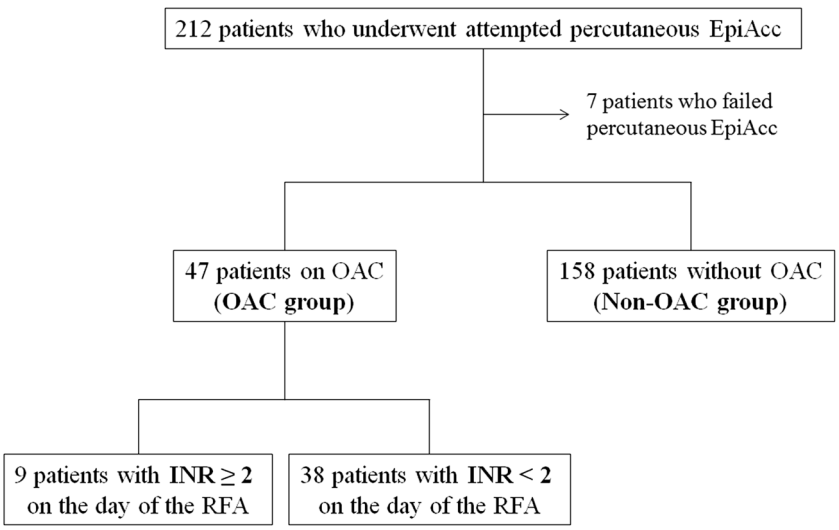


**Fig. 1** A flow chart of patient data collection. EpiAcc epicardial access, OAC oral anticoagulants, INR international normalized ratio, RFA radiofrequency catheter ablation

**Table 1** Patient characteristics in the OAC and non-OAC groups

| | Total $n = 205$ | OAC group $n = 47$ | Non-OAC group $n = 158$ | $p$ value |
|---|---|---|---|---|
| Gender, men, *n* (%) | 155 (76) | 47 (100) | 108 (68) | < 0.0001 |
| Age, years | 53 ± 16 | 60 ± 13 | 51 ± 16 | 0.0001 |
| Weight, kg | 94 ± 23 | 98 ± 18 | 93 ± 24 | 0.225 |
| Body mass index | 30 ± 7 | 30 ± 6 | 30 ± 7 | 0.695 |
| Left ventricular ejection fraction, % | 45 ± 15 | 33 ± 12 | 48 ± 14 | < 0.0001 |
| ICM/NICM/Normal | 28/134/43 | 9/37/1 | 19/97/42 | 0.001 |
| Atrial fibrillation, *n* (%) | 40 (20) | 28 (60) | 12 (8) | < 0.0001 |
| $CHADS_2$ score | 1.3 ± 1.1 | 2.1 ± 1.2 | 1.1 ± 1.0 | < 0.0001 |
| $CHA_2DS_2$-VASc score | 2.0 ± 1.4 | 2.7 ± 1.5 | 1.8 ± 1.3 | < 0.0001 |
| HAS-BLED score | 1.3 ± 1.2 | 2.3 ± 1.4 | 1.1 ± 1.1 | < 0.0001 |
| Cardiac implantable device, *n* (%) | 116 (57) | 42 (89) | 74 (47) | < 0.0001 |
| Total number of failed AADs, *n* (%) | 1.6 ± 1.2 | 2.0 ± 1.2 | 1.4 ± 1.1 | 0.003 |
| Concomitant use of APA, *n* (%) | 85 (41) | 25 (53) | 60 (38) | 0.063 |
| Previous endocardial ablation, times | 1.2 ± 1.1 | 1.0 ± 1.0 | 1.3 ± 1.1 | 0.158 |
| Previous epicardial ablation, *n* (%) | 8 (4) | 1 (2) | 7 (4) | 0.474 |
| History of cardiac surgery, *n* (%) | 13 (6) | 9 (19) | 4 (3) | < 0.0001 |

*ICM* ischemic cardiomyopathy, *NICM* non-ischemic cardiomyopathy, *AAD* antiarrhythmic drugs, *APA* antiplatelet agent

$p = 0.0004$ for both ICM vs. normal and NICM vs. normal

patients (65%), and normal/equivocal in the remaining 43 patients (21%). One patient had undergone a computed tomography-guided intercostal approach due to the presence of bowel throughout the subdiaphragmatic space in the upper abdomen [7].

### 3.2 Clinical characteristics of the OAC and non-OAC groups

Forty-seven patients (23%) were chronically treated on OACs (OAC group) before their procedure (Table 1). The patients in the OAC group were older than those in the non-OAC group (60 ± 13 years vs. 51 ± 16 years; $p = 0.0001$). LV dysfunction was more severe in the OAC group than the non-OAC group (LV ejection fraction; 33 ± 12% vs. 48 ± 14%; $p < 0.0001$). The prevalence of AF was greater in the OAC group than in the non-OAC group (60% vs. 8%; $p < 0.0001$).

### 3.3 Procedural and clinical outcomes in the OAC and non-OAC groups

The procedural outcomes in both groups are shown in Table 2 and Fig. 2. Anterior access was predominantly used for EpiAcc in both groups (61% in the OAC group vs. 55% in the non-OAC group; $p = 0.581$). The total number of VAs during the procedure was significantly greater in the OAC group than non-OAC group (3.4 ± 2.3 vs. 2.4 ± 2.1; $p = 0.005$). A micropuncture needle was used in 2 patients in the non-OAC group.

Procedural (79% vs. 91%; $p = 0.036$) and clinical success (51% vs. 75%; $p = 0.003$) rates with an average follow-up of 14 ± 22 months were lower in the OAC group than in the non-OAC group. However, the complication rate was similar between groups (19% vs. 14%, $p = 0.380$). EpiAcc in patients chronically on OAC (OAC group) was not associated with an increased risk of cardiac tamponade (11% vs. 6%, $p = 0.238$) compared to non-OAC group, but a higher risk of need for blood transfusion (17% vs. 6%; $p = 0.013$). The need for blood transfusion was not related to the INR at the time of EpiAcc (Fig. 3). As seen in Supplemental Table 1, there was no significant difference in the timing of complications relative to the procedure between the OAC and non-OAC groups (1.0 ± 1.2 days vs. 1.9 ± 3.8 days; $p = 0.519$). The complication occurred in 9 patients in OAC group. Six of 9 patients restarted OACs after the complication occurred and it was resolved. The OAC was continued throughout the perioperative period in another patient, who required a blood transfusion due to a reduction in the hemoglobin level from an unknown cause on post-procedure day 2. Another patient restarted the OAC on post-procedural day and required a blood transfusion due to hemoperitoneum on post-procedure day 3. The remaining 1 patient developed cardiac tamponade and required a surgical drainage and blood transfusion on post-procedure day 2. The OAC was not restarted in this patient because of a planned heart transplantation, and the patient was bridged with heparin.

We performed univariate and multivariate analyses to explore predictors of procedural success (logistic

**Table 2** Procedural outcomes in the OAC and non-OAC groups

| | Total $n = 205$ | OAC group $n = 47$ | Non-OAC group $n = 158$ | $p$ value |
|---|---|---|---|---|
| General anesthesia/Conscious sedation, $n$ | 83/122 | 21/26 | 62/96 | 0.505 |
| Access route, anterior access/inferior access, $n$* | 111/85 | 27/17 | 84/68 | 0.581 |
| Total number of VAs during the procedure, $n$ | 2.7 ± 2.2 | 3.4 ± 2.3 | 2.4 ± 2.1 | 0.005 |
| Activated clotting time during the procedure, s | 252 ± 39 | 268 ± 33 | 246 ± 39 | 0.001 |
| Heparin dose, U | 17,548 ± 8730 | 18,149 ± 7145 | 17,371 ± 9158 | 0.597 |
| Procedure time, min | 404 ± 124 | 439 ± 127 | 394 ± 121 | 0.029 |
| Fluoroscopic time, min | 77 ± 33 | 89 ± 44 | 74 ± 29 | 0.007 |
| Radiation exposure, mGy | 2129 ± 1409 | 2326 ± 1080 | 2070 ± 1491 | 0.308 |
| Procedural success, $n$ (%) † | 180 (89) | 37 (79) | 143 (91) | 0.036 |
| Patient number with repeat procedures, $n$ (%) | 26 (13) | 9 (19) | 17 (11) | 0.129 |
| Follow-up period, months | 14 ± 22 | 13 ± 18 | 14 ± 23 | 0.816 |
| Clinical success, $n$ (%) † | 143 (70) | 24 (51) | 119 (75) | 0.003 |

*Access route could not be determined because there were no sufficient cine views in 9 patients

†Two patients who did not undergo ablation were excluded from the analysis

regression model), and clinical recurrence (Cox proportional hazard model) because patient characteristics differed between groups (Supplemental Table 2). A multivariate analysis revealed that OAC use (OAC group) was not associated with procedural outcome (Supplemental Table 2A. OR 0.574, 95% CI 0.208–1.620, $p = 0.289$ by logistic regression model). Similarly, OAC use was not predictive of clinical recurrence in the multivariate analysis (Supplemental Table 2B. Hazard ratio [HR] 0.944, 95% CI 0.513–1.732, $p = 0.853$ by Cox proportional hazard model). Older age, NICM, and lower LV ejection fraction were associated with clinical recurrence (Supplemental Table 2B. HR 1.031, 95% CI 1.011–1.053, $p = 0.002$, HR 2.730, 95% CI 1.479–5.449, $p = 0.001$, HR 0.958 per % increase, 95% CI 0.937–0.980, $p = 0.0001$, respectively). There was no predictive factor for cardiac tamponade (Supplemental Table 2C). The HAS-BLED score, concomitant use of antiplatelet agent, and OAC use (OAC group) were predictive of blood transfusion in the univariate analysis; however, these were not predictive in the multivariate analysis (Supplemental Table 2D).

Pericardial effusions and/or cardiac tamponade were the most common reasons for blood transfusion requirement in both groups; 5 of 8 patients (63%) in the OAC group and 5 of 9 patients (56%) in the non-OAC group. The remaining three reasons for transfusion in the OAC group were a hemoperitoneum in 1 patient, a hematuria in 1 patient, and a reduction in the hemoglobin level from an unknown cause in another patient. Other reasons for blood transfusion in the non-OAC group included hemoperitoneum in 3 patients, and a left groin hematoma in 1 patient. There were no periprocedural ischemic strokes, transient ischemic attacks, or peripheral embolisms in the OAC group (Fig. 2). A 69-year-old patient in the non-OAC group died of a cerebral hemorrhage 28 days

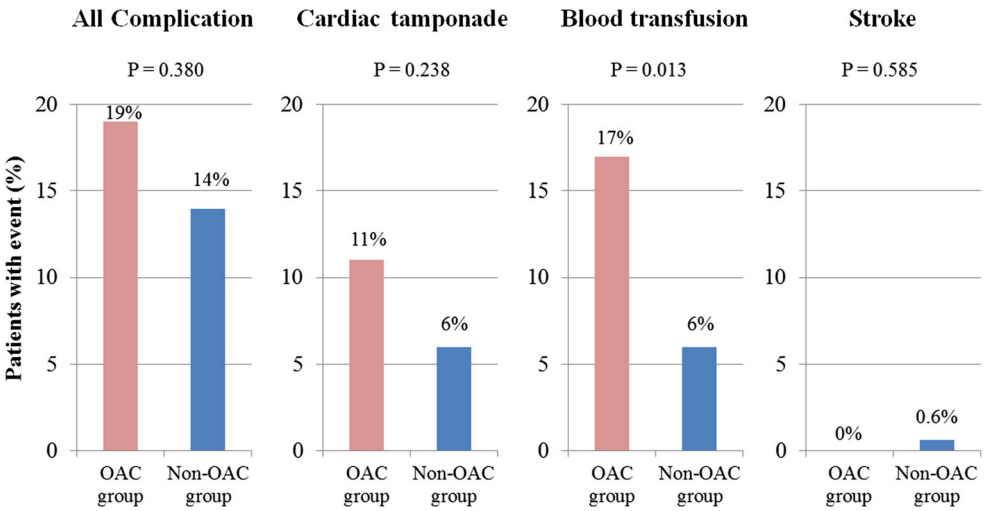


**Fig. 2** The frequency of the complication, cardiac tamponade, and blood transfusion in both OAC group and non-OAC group

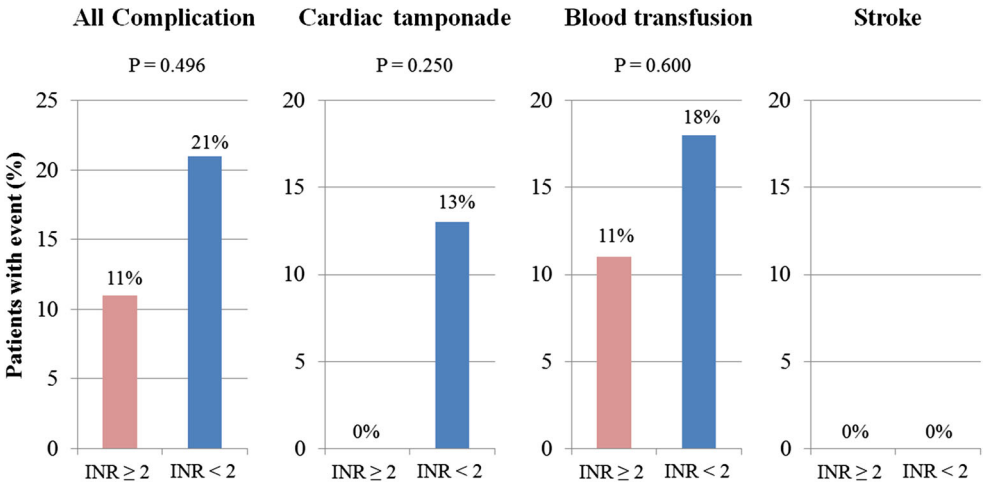


**Fig. 3** The frequency of the complication, cardiac tamponade, and blood transfusion in patients with INR ≥ 2 and those with INR < 2 on the day of the RFA. INR international normalized ratio, RFA radiofrequency catheter ablation

after RFA. He had arrhythmogenic right ventricular cardiomyopathy, and was taking aspirin but no OACs.

### 3.4 Clinical characteristics and procedural/clinical outcome based on the anticoagulation status on the day of the RFA

Within the OAC group, we subdivided patients based on treatment strategy according to whether the INR was ≥ 2.0 or < 2.0 on the day of the RFA. The INR on the day of the RFA was ≥ 2.0 or more in 9 of 47 patients (19%) in the OAC group and INR was less than 2.0 in the other 38 patients (81%). There were no significant differences in patient characteristics between patients with INR ≥ 2.0 and those with INR < 2.0 on the day of the RFA with regard to gender, age, body weight, LV function, prevalence of AF, $CHADS_2$ score, $CHA_2DS_2$-VASc score, and HAS-BLED score (Table 3).

There were no significant differences in procedural outcomes, intraoperative ACT, heparin dose, and procedure time between patients with INR ≥ 2 and those with INR < 2 on the day of the RFA (Supplemental Table 3). Anterior access was predominantly used for EpiAcc in both groups (71% vs. 59%). Figure 3 shows the rate of all complication, cardiac tamponade, blood transfusion, and stroke. Complications occurred in 1 patient with INR ≥ 2, who required a blood transfusion due to a reduction in the hemoglobin level from an unknown cause. Eight patients (21%) with INR < 2 on the day of the RFA had complications; blood transfusion due to

**Table 3** Patient characteristics in patients with INR ≥ 2 and those with INR < 2 on the day of the RFA

| | Total $n = 47$ | Patients with INR ≥ 2 $n = 9$ | Patients with INR < 2 $n = 38$ | $p$ value |
|---|---|---|---|---|
| Gender, male, *n* (%) | 47 (100) | 9 (100) | 38 (100) | – |
| Age, years | 60 ± 13 | 59 ± 6 | 61 ± 14 | 0.728 |
| Weight, kg | 98 ± 18 | 102 ± 16 | 97 ± 19 | 0.466 |
| Body mass index | 30 ± 6 | 33 ± 6 | 29 ± 6 | 0.124 |
| Left ventricular ejection fraction, % | 33 ± 12 | 33 ± 12 | 33 ± 12 | 0.966 |
| ICM/NICM/normal | 9/37/1 | 0/9/0 | 9/28/1 | 0.222 |
| Atrial fibrillation, *n* (%) | 28 (60) | 5 (56) | 23 (61) | 0.785 |
| $CHADS_2$ score | 2.1 ± 1.2 | 2.0 ± 1.0 | 2.1 ± 1.2 | 0.858 |
| $CHA_2DS_2$-VASc score | 2.7 ± 1.5 | 2.3 ± 0.9 | 2.8 ± 1.6 | 0.410 |
| HAS-BLED score | 2.3 ± 1.4 | 1.6 ± 1.5 | 2.4 ± 1.3 | 0.077 |
| Cardiac implantable device, *n* (%) | 42 (89) | 8 (89) | 34 (89) | 0.959 |
| Total number of failed AADs, *n* (%) | 2.0 ± 1.2 | 2.0 ± 0.9 | 2.0 ± 1.2 | 0.952 |
| Concomitant use of APA, *n* (%) | 25 (53) | 3 (33) | 22 (58) | 0.184 |
| Previous endocardial ablation, times | 1.0 ± 1.0 | 0.8 ± 0.8 | 1.1 ± 1.0 | 0.372 |
| History of epicardial approach, *n* (%) | 1 (2) | 0 (0) | 1 (3) | 0.623 |
| History of cardiac surgery, *n* (%) | 9 (19) | 0 (0) | 9 (24) | 0.104 |

*ICM* ischemic cardiomyopathy, *NICM* non-ischemic cardiomyopathy, *AAD* antiarrhythmic drugs, *APA* antiplatelet agent

cardiac tamponade in 4 patients, blood transfusion due to pericardial effusion in 1 patient, cardiac tamponade in 1 patient, hematuria in 1 patient, and blood transfusion due to hemoperitoneum in 1 patient. There was no significant difference in the timing of complications relative to the procedure ($p = 0.413$) between patients with INR ≥ 2 and those with INR < 2 on the day of the RFA (Supplemental Table 1). Procedural success was similar between groups (89% vs. 76%; $p = 0.407$). Similarly, there was no significant difference in the clinical success between groups (33% vs. 55%; $p = 0.237$) with an average follow-up of 13 ± 18 months (Supplemental Table 3).

## 4 Discussion

### 4.1 Main findings

We found that (1) EpiAcc in patients chronically on OACs did not significantly increase the risk of cardiac tamponade, but was associated with a higher risk of blood transfusion irrespective of the INR level, and (2) the procedural and clinical success rates were lower in the patients on OACs than in those not treated with OACs; however, this was probably partly due to differences in patient characteristics between groups (more severe LV dysfunction and an older age in the patients on OACs).

### 4.2 A percutaneous EpiAcc for current electrophysiological procedures

The importance of epicardial substrate in treating cardiac arrhythmias has been recognized, especially for VAs in patients with NICM [1, 8]. Although percutaneous EpiAcc is an invasive approach for RFA of VAs with epicardial substrate, combined endocardial and epicardial mapping and RFA has been reported to improve clinical outcomes. [9] Percutaneous EpiAcc is therefore an increasingly common technique utilized for the treatment of VAs [6].

Other than that, percutaneous EpiAcc has become an important technique for current electrophysiological procedures. Percutaneous LAA closure procedures are increasingly performed worldwide for patients with AF, and some LAA closure devices require percutaneous EpiAcc for placement [10–13]. However, whether to discontinue OAC, which might lower EpiAcc risk at the expense of stroke or thrombotic risk, or continue, it has not been previously studied, to our knowledge. Our findings suggest that in experienced hands, epicardial access during ongoing warfarin anticoagulation is a reasonable option. We anticipate based on published reports that a micropuncture technique may further lower risks, although we had too small of a micropuncture experience to comment [14].

### 4.3 The prevalence of CHF and AF in patients undergoing an EpiAcc

The frequency of congestive heart failure (CHF) in patients who required an EpiAcc for mapping and RFA of VAs is generally high; in fact, three fourths of the patients had the substrate of ICM or NICM with a mean LV ejection fraction of 45% in this study. On the other hand, the prevalence and incidence of AF in the general population has been increasing during the last decades [15]. In addition, AF occurs frequently in patients with CHF because CHF itself directly predisposes to AF [16]. As a result, the estimated AF prevalence in CHF patients has been reported as high as 15 to 30% [17]. In fact, one fourth of the patients in this study were on OACs, mainly to prevent stroke in AF.

With regard to thrombogenesis, CHF itself is a risk factor for both LV and LAA thrombi, and it has been reported that CHF is more highly associated with a sludge/thrombus in the left atrium/LAA in patients with AF [18, 19]. The management of anticoagulation in patients that undergo an EpiAcc is increasingly important for these reasons.

### 4.4 Bleeding complications of EpiAcc in patients on OAC

EpiAcc in patients chronically on OACs was associated with a higher risk of blood transfusion as expected, although there was not an increased risk of cardiac tamponade. Surprisingly, the risk of complications such as bleeding requiring the blood transfusion was similar between patients with INR ≥ 2.0 and those with INR < 2.0. It has been reported that the bleeding risk with an INR less than 2.0 may be similar or even higher than that of INR 2.0–3.0 [20–22]. Nelson et al. evaluated the association of INR level and clinical outcomes among nonvalvular AF patients on warfarin [20]. They reported that all adverse event rates were even higher when patients had INR < 2.0 compared to those with INR ≥ 2.0 for major bleeding (4.6 per 100 patient-years for INR < 2.0 and 1.6 per 100 patient-years for INR 2.0–3.0). Although there were some methodological limitations, they recognized that the higher bleeding risk may exist in patients with less than INR of 2.0. Their findings suggest that the bleeding risk is higher in patients on warfarin even the INR is below the therapeutic range. Our findings indicate that the risk of EpiACC in patients who are chronically anticoagulated is acceptable when epicardial ablation has a strong clinical indication as long as physicians are aware of the increased risk for bleeding complications and prepared to manage them. It has been reported that although the frequency of a puncture of the right ventricle by an EpiAcc is not low (17%), two-thirds of the cases had no significant

bleeding [23]. We believe that even if there is an inadvertent puncture of the right ventricle, the puncture site is easy to be sealed by the surrounding myocardium and epicardial fat in patients without the OAC; however, it is hard to be sealed in those with the OAC. The higher rate of bleeding in the OAC group may in part be explained by that group's higher rate of concomitant antiplatelet agent use although it did not reach statistical significance (53% OAC vs. 38% non-OAC; $p = 0.063$). Although the procedural and clinical success rates were lower in the OAC group than non-OAC group, OAC use (OAC group) was not associated with the procedural outcome and clinical outcome in the multivariate analysis. In addition, we thought that a longer procedure and fluoroscopic times were also due to the difference in the patient characteristics between the groups.

### 4.5 Limitations

This study was a retrospective analysis performed at a single center with a high procedural volume and 24-h surgical availability, and as such, the results may not be generalizable to other electrophysiology laboratories. A micropuncture needle was used only in 2 patients during the reported period. The advancing technology and technique of the EpiAcc, including the micropuncture needle, is thought to lower the risk. There was no pre-specified regimen concerning blood transfusion in this retrospective study, and the decision to perform blood transfusion was determined by the ablation operator. The number of patients was relatively small, further investigation with a larger patient population is required to confirm our results and the broader applicability.

## 5 Conclusion

Percutaneous EpiAcc in patients on chronic OAC did not significantly increase the risk of cardiac tamponade, but was associated with a higher risk of need for blood transfusion. EpiACC in patients with an INR > 2.0 is reasonable in experienced hands when clinically indications are strong.

### Compliance with ethical standards

The study was approved by the institutional review board, and written informed consent was obtained from all patients before the procedure

**Conflict of interest** The authors declare that they have no conflict of interest.

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