Pericardial Effusion Following Drain Removal after Percutaneous Epicardial Access for an Electrophysiology Procedure

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Objectives: To determine the frequency and predictors of pericardial effusion following epicardial sheath removal.

Background: Pericardial effusion can occur following cardiac surgical or interventional procedures including percutaneous epicardial access (EpiAcc), which is increasingly used as part of electrophysiology ablation procedures.

Methods: A retrospective analysis of the Mayo Clinic comprehensive electronic medical record was performed from all patients who underwent planned EpiAcc as part of an electrophysiology ablation procedure between January 1, 2004 and June 30, 2013.

Results: Of 144 patients (mean age 51.3 ± 15.5 years, 68% male) who underwent planned EpiAcc as part of an electrophysiology ablation (95.8% pericardial access success rate), seven (4.9%) developed a postoperative pericardial effusion requiring repeat EpiAcc. Inferior access was utilized in 74 (51.4%) patients. Patients with pericardial effusion tended to be younger (41.1 years vs 51.8 years, P = 0.08) and were more likely to have undergone inferior approach access (85.7% vs 49.6%, P = 0.06) than those who did not develop postoperative pericardial effusion. Seventy-one percent of patients with postoperative pericardial effusion versus 32.1% of patients without postoperative pericardial effusion had a preprocedure ejection fraction $\geq 55\%$ (P = 0.03). There were no procedural-related deaths, and no difference in mortality between groups.

Conclusions: Postoperative pericardial effusion requiring repeat access/drainage was relatively infrequent, occurring in 4.9% of patients shortly after epicardial procedures. While the majority occur early and therefore require close observation, some patients may present in a delayed manner. (PACE 2015; 38:383–390)

epicardial, pericardial, effusion, tamponade, ejection fraction

Introduction

Pericardial effusion can occur following a wide variety of cardiac insults including surgical or interventional procedures.¹⁻⁴ Up to 6% of atrial fibrillation ablations,⁵ 4.1% of mitral valvuloplasties,⁶ 3% left atrial appendage closures,⁷ 1.2% of pacemaker implantations,⁸ and <0.5% percutaneous coronary interventions⁹ are complicated by pericardial effusion/cardiac tamponade, which may be life threatening if not

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percutaneous epicardial access (EpiAcc). When planned EpiAcc is obtained as part of an electrophysiology procedure, cardiac tamponade occurs in around 4% of procedures.^{10,11} Leaving a pericardial drain in place postablation permits management of an effusion should it develop; however, a persistent drain is associated with patient discomfort, pericardial irritation,

immediately treated. Pericardial fat irritation, vessel disruption, inadvertent right ventricular (RV)

entry, and periprocedural anticoagulation may

predispose toward pericardial effusion following

with patient discomfort, pericardial irritation, the need for more intensive nursing care and monitoring, and potentially infection. While intraprocedural pericardial fluid accumulation can be managed with the *existing* sheath, the development of pericardial effusion following drain removal requires a separate invasive procedure to drain the reaccumulated effusion with inherent

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risks. Thus, knowing which patients are at increased risk for development of postprocedural pericardial effusion is important for determining whether a pericardial drain should be removed or left in place following a percutaneous pericardial ablation procedure. We, therefore, performed a retrospective analysis of the Mayo Clinic epicardial ablation database to determine the frequency and clinical predictors of pericardial effusion following epicardial sheath removal and to assess its impact on procedural and clinical outcomes.

Methods

We retrospectively analyzed the Mayo Clinic comprehensive electronic medical record to extract data from all patients who underwent planned EpiAcc as part of an electrophysiology ventricular tachycardia (VT)/premature ventricular complex (PVC) ablation procedure between January 1, 2004 and June 30, 2013. All patients with successful access underwent placement of percutaneous pericardial sheath or drain. Patients who developed a pericardial effusion after drain removal requiring a separate pericardiocentesis were compared to those who did not develop this complication.

EpiAcc Technique

Our approach to EpiAcc has previously been published.¹² Briefly, patients underwent access in the electrophysiology laboratory under heavy conscious sedation or general anesthesia. A blunttipped epidural needle (Tuohy) was directed from the left para-xiphoid space toward the cardiac silhouette under fluoroscopic guidance in the right anterior oblique (RAO)/left anterior oblique (LAO), anterior-posterior (AP), and/or lateral views. For anterior puncture, $15^{\circ}-30^{\circ}$ declination was used during access, whereas for posterior access, the needle was directed 45° from the horizontal (Fig. 1). As the needle penetrated through the fibrous pericardium a palpable "give" was appreciated and a puff of contrast demonstrated layering within the pericardial space. A guidewire was advanced into the pericardial space, and RAO/LAO imaging was used to confirm guidewire position prior to advancing a sheath over the wire.

Data Collection

Baseline clinical characteristics were recorded. The epicardial approach (anterior vs inferior) used was determined by manual review of stored cines recorded at the time of the procedure and procedure note review. The proportion of patients with postprocedural pericardial effusion requiring drainage (via a separate procedure) due to symptoms or hemodynamic compromise, the amount of fluid drained at the repeat puncture, and the duration the pericardial drain was left in place were recorded. The proportion of patients requiring blood product transfusion within 24 hours was also analyzed.

Clinical Follow-Up

All patients underwent transthoracic echocardiography to assess for pericardial effusion the day following ablation. Following hospital dismissal, patients were followed up via telephone interview at 30 days in addition to the follow-up recommended by their primary cardiologist. Procedural and clinical outcomes were determined and defined as follows:

• Procedural success: elimination/termination of the clinical PVC/VT, rendering it noninducible (protocol determined at operator's discretion). If a nonclinical PVC/VT was induced, the procedure was still classified as successful.

• Procedural failure: Inability to eliminate the clinical PVC/VT, or persistent inducibility of the clinical arrhythmia with isoproterenol or programmed stimulation.

• Clinical success: Elimination of symptoms at last follow-up with or without use of antiar-rhythmic drugs.

• Clinical failure: Persistence of symptoms or clinical PVC/VT despite antiarrhythmic drug, and/ or requiring a repeat procedure. The number of procedures required to obtain clinical success was also determined.

Statistical Analysis

Continuous variables were expressed as means \pm standard deviations, while categorical variables were expressed as percentages. Categorical variables were compared between groups using the χ^2 test for independence. Comparisons of continuous variables were completed using Wilcoxon rank-sum tests. Values with P < 0.05 were considered statistically significant.

Results

Baseline Clinical and Procedural Characteristics

There were 144 patients (mean age 51.3 \pm 15.5 years, 68% male) who underwent a planned EpiAcc procedure as part of an electrophysiology ablation (Table I). Seven (4.9%) patients had PVC/tachycardia-induced cardiomyopathy, 20 (13.9%) had ischemic cardiomyopathy, 69 (47.9%) had nonischemic cardiomyopathy, while 11 (7.6%) had arrhythmogenic right ventricular cardiomyopathy (ARVC). The remaining 37 (25.7%) either had an idiopathic/unknown cause

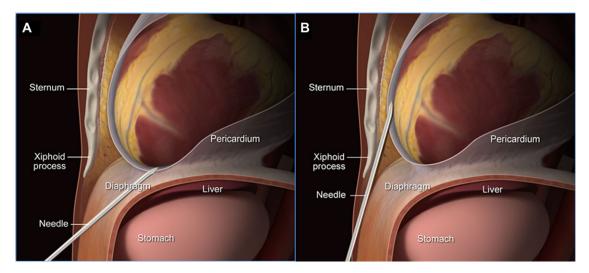


Figure 1. Diagrammatic representation of needle entry utilized in inferior (A) and anterior (B) approach epicardial access, respectively. Note the "bevel-out" needle tip position.

of cardiomyopathy, abnormal right ventricle not meeting ARVC criteria, or accessory pathway. Successful access was obtained in 138 patients (95.8% pericardial access success rate). Inferior access was utilized in 74 (51.4%) patients; two patients had missing cines and therefore access could not be determined. Seven (4.9%) patients developed significant pericardial effusion requiring repeat access/drainage (Table II), a median of 1.5 days (range 0-15) postablation in which bloody fluid was returned. There were no identifiable predictors, although patients with pericardial effusion tended to be younger (41.1 years vs 51.8 years, P = 0.08), have a higher ejection fraction (EF; 54.9% vs 44.2% P = 0.08; Fig. 2) and were more likely to have undergone inferior approach access (85.7% vs 49.6%, P =0.06) than those who did not develop significant pericardial effusion. There was no difference in gender (71.4% vs 67.9% male), body mass index (BMI; 30.3 vs 29.4), aspirin, clopidogrel, or perioperative heparin use, and epicardial mapping only versus epicardial mapping/ablation (100% vs 95.6%) in patients with and without postoperative pericardial effusion, respectively (P > 0.05). Of 144 patients, 61 had ablation involving the right ventricle and 106 had ablation involving the left ventricle (24 had ablation involving both the right and left ventricles). Endocardial-only ablation was performed in 48 patients, epicardialonly ablation was performed in 11 patients, while both endocardial and epicardial ablation was performed in 85 patients. Patients with need for repeat drain placement had a shorter VT cycle length (252.8 vs 405.8 ms, P = 0.05). Otherwise, there was no difference in other procedural

characteristics between groups (Table III). Thirtyfive patients had a pericardial drain left in situ at the end of the procedure; there was no difference in any characteristic between this group and those without a drain left in place (data not shown). In patients requiring repeat EpiAcc, the mean amount of fluid drained was 271 mL (range 30-761 mL). The total duration that the pericardial drain was left in situ was longer in patients who developed postprocedure pericardial effusion requiring repeat access compared to those who had a drain left in empirically at the end of their ablation procedure (2.6 \pm 0.8 days vs 0.5 ± 1.0 days, P < 0.001). However, there was no increased requirement for blood product transfusion among these patients (14.3% vs 8.1%, P = 0.56). The hemoglobin in patients receiving blood transfusion compared to those who did not was significantly lower at baseline (12.3 g/dL vs 13.6 g/dL, respectively, P = 0.01), as would be expected. The average length of hospitalization was 8.5 days among the entire cohort. While patients who developed a postoperative pericardial effusion had longer hospitalization times than those who did not develop this complication, the difference was not statistically significant (10.6 days vs 6.6 days, P = 0.09).

Predictors of Pericardial Effusion

Patients with need for repeat drain placement had a shorter VT cycle length than those who did not require repeat drain placement (252.8 ms vs 405.8 ms, P = 0.05). Otherwise, no other predictors were identified. Specifically, gender, BMI, anticoagulation status, and epicardial ablation versus mapping only were not predictors for the

Table I.

Baseline Characteristics of Patients with and Without Postoperative Pericardial Ef	fusion
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Postoperative Pericardial Effusion					
	No (N = 137)	Yes (N = 7)	Total (N = 144)	P Value	
Age, mean (SD)	51.8 (15.5)	41.1 (13.4)	51.3 (15.5)	0.08	
Gender, male	93(67.9%)	5(71.4%)	98(68.1%)	0.84	
BMI, mean (SD)	29.4 (6.3)	30.3 (7.0)	29.5 (6.3)	0.69	
Ejection fraction, mean (SD) ($N = 144$)	44.2 (15.5)	54.9 (9.6)	44.7 (15.4)	0.08	
Atrial fibrillation	37 (27.0%)	0 (0.0%)	37 (25.7%)	0.11	
COPD	12 (8.8%)	0 (0.0%)	12 (8.3%)	0.41	
Coronary artery disease	25 (18.2%)	0 (0.0%)	25 (17.4%)	0.21	
Hypertension	71 (51.8%)	4 (57.1%)	75 (52.1%)	0.78	
Diabetes mellitus	23 (16.8%)	0 (0.0%)	23 (16.0%)	0.24	
Renal disease	20 (14.6%)	0 (0.0%)	20 (13.9%)	0.28	
Baseline creatinine (mg/dL), mean (SD)	1.2 (1.4)	1.1 (0.2)	1.2 (1.3)	0.93	
Obstructive sleep apnea	27 (19.9%)	2 (33.3%)	29 (20.4%)	0.43	
Previous cardiac surgery	7 (5.1%)	0 (0.0%)	7 (4.9%)	0.54	
Previous endocardial ablations, mean (SD)	1.5 (1.0)	1.6 (1.0)	1.5 (1.0)	0.60	
Number of antiarrhythmic drugs failed, mean (SD)	1.7 (1.2)	1.6 (1.4)	1.7 (1.2)	0.85	
Clinical follow-up (days), mean (SD)	456.1 (521.3)	756.9 (913.0)	476.0 (554.0)	0.60	
Aspirin	79 (57.7%)	2 (28.6%)	81 (56.3%)	0.13	
Clopidogrel	3 (2.2%)	0 (0.0%)	3 (2.1%)	0.69	
INR	1.31 (0.32)	1.00 (0.10)	1.30 (0.32)	0.02	
	(n = 63)	(n = 3)			
Hemoglobin, mean (SD)	13.5 (1.9)	14.1 (1.1)	13.5 (1.9)	0.40	
Patients requiring transfusion	11 (8.1%)	1 (14.3%)	12 (8.4%)	0.56	

BMI = body mass index; COPD = chronic obstructive pulmonary disease; INR = international normalized ratio; SD = standard deviation.

Table II.

Characteristics of Patients Who Developed Postoperative Pericardial Effusion Requiring Repeat Access

Patient Number	Age	Gender	Day of Re-access	Amount Drained at Re-access (mL)	Number of Days Drain Left <i>in situ</i>
8	25	Female	0	30	2
10	56	Male	1	150	2
17	49	Male	1	51	2
37	38	Female	15	41	2
92	23	Male	2	209	4
97	42	Male	2	761	3
98	55	Male	0	657	3

Day of re-access 0 equates to the day of the procedure.

development of postoperative pericardial effusion. Patients with a higher EF (\geq 55%) and those of younger age had a trend to developing pericardial effusion following sheath removal than those with a reduced EF—the two variables likely to correlate with one another. When grouped according to baseline EF, the incidence of postoperative pericardial effusion was 0% vs 4.3% vs 10.4% in patients with EF \leq 35%, 36–54% and \geq 55%, respectively (P = 0.06). Of

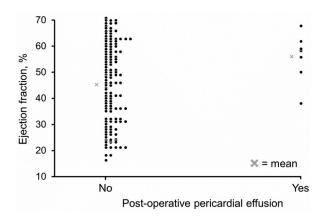


Figure 2. Scatter diagram highlighting the difference in ejection fraction between patients with and without postprocedural pericardial effusion ("x" denotes the mean for each group).

the seven patients with postoperative pericardial effusion, five had an EF $\geq 55\%$ (median 62%) [interquartile range (IQR) 58, 65]); the two with EF <55% (median 36%, [IQR 26, 46]) both underwent inferior approach access. There was no difference in the incidence of postoperative pericardial effusion requiring repeat access between cases performed in 2004-2007, 2008-2010, and 2011–2013, arguing against a learning curve risk for the complication. Additionally, after logistic regression (adjusting for the fact that inferior access was used more often early on in the experience, and operator experience), the higher rate of postprocedural pericardial effusion remained with inferior access. In patients with postprocedural pericardial effusion, 85.7% underwent inferior approach as opposed to only 49.6% in those who did not develop postprocedural pericardial effusion (P = 0.06). We also analyzed the effect of intrapericardial (IP) steroid administration between the two groups (14.3% in the postoperative pericardial effusion group received IP steroids vs 18.3% in the group without, P > 0.05); there was no difference in the rate of development of postprocedural pericardial effusion in those with or without IP steroid administration (4% vs 5%, P = 0.79).

Outcomes

There was no difference in the number of subsequent electrophysiology ablations required between groups (P = 0.71). Procedural and clinical success was similar between patients who developed pericardial effusion and those who did not (85.7% vs 93.4% and 85.7% vs 71.5% [P > 0.05], respectively). The rate of postprocedural atrial fibrillation within 7 days postablation was

similar between the two groups (0% in the postoperative pericardial effusion group, 2.9% in no effusion group, P = 0.64). There were no procedural-related deaths.

Discussion

Percutaneous pericardial access is increasingly performed to ablate epicardial arrhythmogenic substrates, permit percutaneous left atrial appendage ligation, and to place device leads.^{11,13-18} We found that a significant postoperative pericardial effusion after pericardial drain removal requiring repeat puncture was relatively uncommon, occurring in 4.9% of procedures. No clinical factors could reliably predict the occurrence. Therefore, physicians need to be aware of this potentially life-threatening problem in order to expeditiously recognize and manage it, should it develop. It may not be desirable to leave a pericardial drain *in situ* postprocedure in many patients since this is associated with significant pericarditis and pain. However, consideration should be given to leaving the pericardial drain in postprocedurally, especially in certain highrisk individuals such as those on anticoagulation or with a history of bleeding problems. While statistical significance was not achieved, there was a trend toward a higher risk in younger patients with a preserved EF; it may be reasonable to carefully observe this group.

The clinical manifestations of pericardial effusion are dependent on several factors, including the size of the perforating device, which cardiac structure is perforated, the properties of the pericardium, and the hemodynamic state of the patient.¹⁹ In addition, the anticoagulation status plays a fundamental role. Importantly, all patients with postoperative effusion underwent left-sided endocardial and epicardial ablation and were therefore treated with postoperative pericardial effusion rates may be significantly lower following procedures that do not require continuous anticoagulation, such as some forms of left atrial appendage closure and device placement.

VT cycle length was shorter in patients with postoperative pericardial effusion, which may suggest that rapid VT can lead to catheter-/sheathassociated injury. The mechanism for this is not clear. Although not statistically significant, an inferior approach was associated with a trend toward a higher rate of postoperative pericardial effusion requiring re-access. The inferior approach necessitates a more perpendicular angle relative to the myocardium than the anterior approach, perhaps accounting for greater trauma and effusion cardiac motion on a perpendicularly oriented

Table III.

Procedural Characteristics of Patients with and Without Postoperative Pericardial Effusion

Postoperative Pericardial Effusion	No (N = 137)	Yes (N = 7)	Total (N = 144)	P Value
Access, inferior	68 (49.6%)	6 (85.7%)	74 (51.4%)	0.06
Successful access	131 (95.6%)	7 (100.00%)	138 (95.8%)	0.50
Heparin	134 (97.8%)	7 (100.0%)	141 (97.9%)	0.69
Concomitant endocardial and epicardial ablation, mean (SD)	1.0 (0.2)	1.0 (0.0)	1.0 (0.2)	0.57
Number of PVCs/VT morphologies found, mean (SD)	2.6 (2.3)	1.6 (1.1)	2.6 (2.3)	0.15
Number of PVCs/VTs ablated, mean (SD)	1.7 (1.2)	1.4 (0.8)	1.7 (1.1)	0.59
Average cycle length of PVC/VT (ms), mean (SD)	405.8 (126.1)	252.8 (102.8)	397.9 (128.9)	0.05
Total ablation lesions, mean (SD)	21.1 (12.9)	27.7 (16.1)	21.4 (13.1)	0.27
Epicardial	4.8 (7.6)	3.8 (4.5)	4.7 (7.5)	0.94
Endocardial	14.4 (12.7)	19.3 (13.0)	14.7 (12.7)	0.37
Fluoro time (minutes), mean (SD)	82.8 (54.4)	90.2 (43.4)	83.2 (53.8)	0.59
Study time (minutes), mean (SD)	392.1 (132.2)	435.3 (160.1)	394.2 (133.4)	0.59
Radiation dose (rads), mean (SD)	2,137.2 (1,437.7)	2,507.3 (2,218.0)	2,149.8 (1,458.4)	0.89
Time pericardial drain left in (days), mean (SD)	0.5 (1.0)	2.6 (0.8)	0.6 (1.1)	<0.0001
Procedural success	128 (93.4%)	6 (85.7%)	134 (93.1%)	0.43
Clinical success	98 (71.5%)	6 (85.7%)	104 (72.2%)	0.44
Number of Subsequent Ablations	. ,	. ,	· · ·	
0	122 (89.1%)	6 (85.7%)	128 (88.9%)	0.71
1	10 (7.3%)	1 (14.3%)	11 (7.6%)	
2	5 (3.6%)	0	5 (3.5%)	

PVC = premature ventricular complex; SD = standard deviation; VT = ventricular tachyarrhythmia.

sharp needle can lead to tissue trauma and potential laceration of arteries and veins.

When access was reobtained, the drains were left *in situ* for an average of 2.6 days, with a mean drainage of 292 mL. It should be noted that repeat transthoracic echocardiography was performed the day following drain removal as standard practice to ensure that there was no meaningful re-accumulation.

In our experience, there was a wide range in the time period between the ablation procedure and the need for re-access. Patients who developed postoperative pericardial effusion all did so early (within 2 days), except for one patient who developed it after 15 days. One patient developed profound hypotension with dramatic effusion within 15 minutes of removing the drain. The difference in time course may represent the variable mechanisms by which a pericardial effusion can develop. For example, in the patient with acute hypotension, it is possible that the sheath had entered and then exited the RV or traumatized an IP vessel, which only started bleeding after the drain was removed. It is clinically important to identify myocardial laceration with through and through wall puncture in patients with profound hypotension after sheath removal as this may necessitate surgical closure. In our practice, we now pull sheaths over a wire, and observe for 15–30 minutes before pulling the wire to manage these dramatic effusions. In those with a longer delay in presentation, irritation of epicardial fat or pericarditis may be the mechanism. It is worth noting, however, that there was no difference in the rate of postoperative pericardial effusion between those who did or did not receive corticosteroids, suggesting that pericardial IP reaction is not causative to the development of pericardial effusion in such patients.

Procedural and clinical outcomes in those who developed postoperative pericardial effusion were comparable to those without pericardial effusion. While the development of significant pericardial effusion can be immediately life

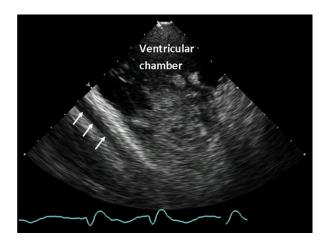


Figure 3. Intracardiac echocardiogram (ICE) image showing the intraprocedural identification of an enlarging pericardial effusion (arrows) which allowed prompt management.

threatening and may be associated with increased morbidity, our results showed no proceduralrelated deaths, suggesting that prompt treatment is key. As prevention of pericardial effusion is not always possible, early recognition is paramount. Use of intracardiac echocardiography is useful in electrophysiology procedures²⁰ to permit real-time monitoring for early diagnosis and management of pericardial effusion (Fig. 3, Video 1). As such, it has become standard in our practice. This also highlights the importance of performing percutaneous pericardial access

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procedures at a center with resources readily available.

Our study has several limitations. This is a retrospective analysis of a tertiary referral center practice with its inherent limitations. The procedural time was long, reflecting the many cases referred to us for redo procedures in which access time may be long and may have contributed to the occurrence of postprocedural pericardial effusion. As it was felt that RV puncture could not be reliably recorded retrospectively, this variable was not measured. In addition, we did not assess the effect of VT location on development of pericardial effusion, the relationship between the amount of intraprocedural bleeding and late pericardial effusion, nor did we determine the ablation application time and amount of energy used. Our operators have high procedural volume and levels of experience. Therefore, results may not be generalizable to the whole of the electrophysiology community. Furthermore, patient numbers and event rates are small; hence clinically meaningful predictors of pericardial effusion may be masked. Larger studies with prospective enrollment are needed.

Conclusion

Postoperative pericardial effusion requiring repeat access/drainage was relatively infrequent, occurring in 4.9% of patients shortly after epicardial procedures. While the majority occur early and therefore require close observation, some patients may present in a delayed manner.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Video 1. Intracardiac echocardiography (ICE) video demonstrating intraprocedural identification of the enlarging pericardial effusion seen in Figure 3.

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