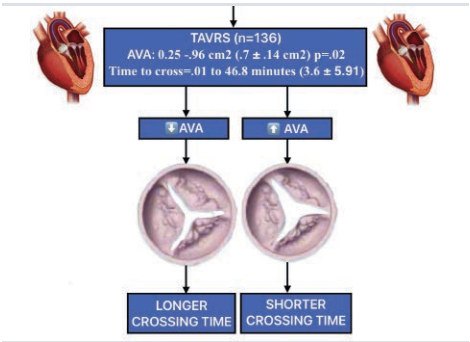
Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



TAVR

Aortic Valve Area and Time to Cross the Aortic Valve in Severe Aortic Stenosis During Transfemoral Transcatheter Aortic Valve Replacement

Richard Casazza, MAS; Joshua Fogel, PhD; Jacob Shani, MD

Abstract

Objective: Aortic valve area (AVA) may delay time to cross the aortic valve (AV) during transcatheter aortic valve replacement (TAVR). We study the association of AVA with time to cross stenotic AVs during TAVR.

Methods: We studied 136 patients at a single center with severe aortic stenosis undergoing TAVR. Time to cross the AV was defined as the amount of time the operator was on fluoroscopy from the beginning of trying to cross the AV to the actual crossing of the AV with the catheter. Covariates included age, sex, body mass index, body surface area, valve orientation, and operator specialization.

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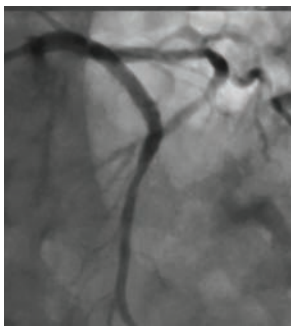
Cracking Calcium on a Cliff-Hanger: Intravascular Lithotripsy for High-Risk Left Main PCI in STEMI



CLD talks with Dr. Kalaivani Mahadevan, MD, and Prof. James C. Spratt, BSc, MB ChB, MD.

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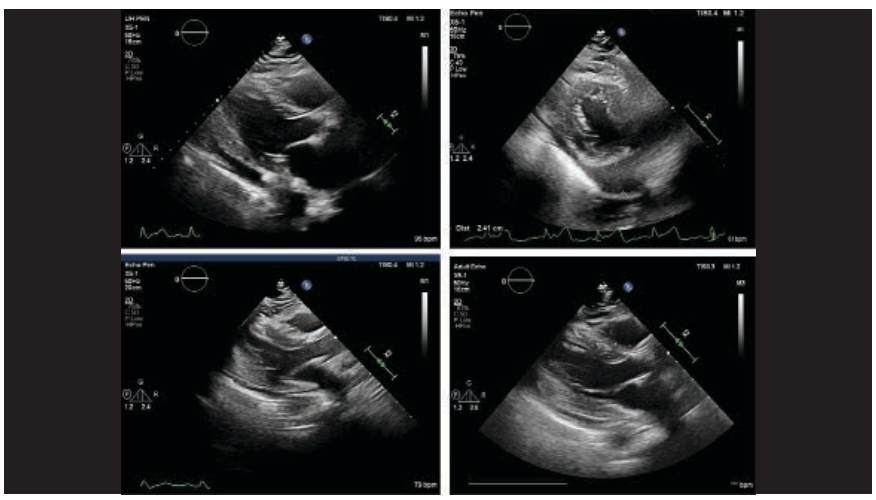
LEFT ATRIAL APPENDAGE CLOSURE

Delayed Pericardial Effusion Following Left Atrial Appendage Closure: A 5-Year Single-Center Experience

Akhil Mogalapalli, MD[1]; Sundeep Kumar, MD[2]; Tabitha Lobo, MD[1]; Joseph Reed, MD[1]; Luis Augusto Palma Dallan, MD, PhD[3]; Sung-Han Yoon, MD[3]; Steven J. Filby, MD[3]



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Delayed Pericardial Effusion Following Left Atrial Appendage Closure: A 5-Year Single-Center Experience

Akhil Mogalapalli, MD; Sundeep Kumar, MD; Tabitha Lobo, MD; Joseph Reed, MD; Luis Augusto Palma Dallan, MD, PhD; Sung-Han Yoon, MD; Steven J. Filby, MD

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Complications of left atrial appendage closure (LAAC) have been significantly reduced with the development of new devices and have become infrequent in the contemporary era.[1-5] However, pericardial effusion remains a serious potential complication of this procedure.[1-11]

The National Cardiovascular Data Registry (NCDR) LAAC registry noted an effusion rate requiring intervention of 1.4% for the first-generation device.[3] Meanwhile, the PINNACLE (Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device) FLX trial, which investigated the second-generation of the Watchman device (Boston Scientific), described an effusion rate requiring intervention of 1%. In the PINNACLE FLX trial, there were no patients with pericardial effusions before day 7; all patients required pericardiocentesis after day 7.[5] Pericardial effusions are a known complication from the Amulet occluder device (Abbott Cardiovascular) as well. In a large study comparing these 2 devices, the Amulet occluder device had a higher rate of pericardial effusions compared with the Watchman device (22/903 [2.44%] vs 11/896 [1.23%]).[11] In this study, we review our experience with the Watchman Legacy and Watchman FLX devices and their complications at a large academic hospital in a cohort of 369 patients.

Methods

Study design. This study is a single-center, prospective analysis of 369 consecutive patients who underwent LAAC from December 2016 to March 2022. The study was approved by the University Hospitals Cleveland Medical Center institutional review board. These patients all had a history of non-valvular atrial fibrillation (AF) and CHA_2DS_2VASc score ≥2, in whom oral anticoagulation was indicated but had reason to consider alternative to long-term oral anticoagulation. We analyzed baseline demographic data, procedural characteristics, complications, and postprocedural anticoagulation for both groups. *Delayed effusions* were defined as effusions occurring >6 hours post procedure.

Procedural details. With developments in new techniques and devices, our procedural workflow changed over the 5-year time period, which has been previously described.[6,12-14] In brief, transesophageal echocardiography (TEE) was initially used for procedural planning and intraoperatively under general anesthesia. In 2020, we changed to cardiac computed tomography angiography (CTA) for planning, and after the appropriate device was selected, the LAAC procedure was performed under intracardiac echocardiography (ICE) guidance, using conscious sedation with midazolam and fentanyl. Intravenous heparin was given to achieve an activated clotting time (ACT) >250 seconds. Protamine was administered at the discretion of the operator. As we transitioned to a CTA + ICE strategy, we also initiated a same-day discharge protocol.[13] We obtain a limited echocardiogram prior to and 6 hours post procedure to assess for pericardial effusion. Imaging with TEE or CTA was also obtained 45 days post procedure.

Statistical analysis. Descriptive statistics were utilized for data analysis. Categorical variables were represented as numbers and percentages. Continuous variables were represented as means ± standard deviations. Unadjusted, stepwise multivariate logistic regression was performed using Stata, version 15.0.

Results

From December 2016 to March 2022, a total of 369 consecutive patients had implantation of Watchman Legacy and Watchman FLX devices. From December 2016 to September 2020, a total of 164 patients underwent LAAC using the Watchman Legacy device. From September 2020 to March 2022, a total of 205 patients received the Watchman FLX device. Five patients (1.35%) developed pericardial effusion.

Baseline demographics for patients with effusion (n = 5) and without effusion (n = 364) are shown in Table 1. Both groups were noted to be older (mean age, 78.4 ± 7.8 years vs 76.3 ± 8.5 year; *P*=.50) and white (60% vs 90.1%), with similar CHA_2DS_2VASc (4.2 ± 1.1 vs 4.5 ± 1.4; *P*=.67) and HAS-BLED (3.4 ± 0.48 vs 3.7 ± 0.9; *P*=.53) scores in the effusion group vs the non-effusion group, respectively. A majority of patients in both groups had a history of paroxysmal atrial fibrillation (80% vs 51.4%; *P*=.02) and essential hypertension was the most common comorbid condition (100% vs 88.5%; *P*=.42). Indication for placing the device was predominantly gastrointestinal bleeding for both groups (80% vs 53.6%; *P*=.23) in the effusion group vs the non-effusion group, respectively.

Procedural characteristics for both groups are shown in Table 2. Both groups had high rates of successful implantation (100% vs 98.9% in the effusion group vs the non-effusion group, respectively). The majority had success with the first device size attempted (100% vs 92%). The 27-mm sized device was the most common device size implanted. Total procedure duration was similar (67 minutes vs 75 minutes; *P*=.16). The mean ACT during the procedure in the effusion group was 250 seconds. Protamine was not administered during the procedure for any of the patients with effusion. None of the patients with effusion required repeat transseptal puncture. There were no device recaptures or size changes in the effusion group.

Antithrombotic regimen at discharge was similar in both groups, with dual-antiplatelet therapy (DAPT) being most common (40% vs 44.1% in the effusion group vs the non-effusion group, respectively). Other discharge regimens for patients with pericardial effusion included novel oral anticoagulation (NOAC) only, single-antiplatelet agent (SAPT) with NOAC, and SAPT with warfarin.

Among patients who received the Watchman Legacy device, 2 patients developed acute perdicardial effusion (AE) and none developed delayed pericardial effusion (DE). One of the effusions happened intraoperatively due to cardiac perforation and required surgical repair. Of those receiving the Watchman FLX device, 1 patient developed AE and 2 patients developed DE. One patient presented 24 hours after

Named a *Journal of Invasive Cardiology* Top 10 Article of 2023 by Dr. Deepak Bhatt, Editor-in-Chief

"This is a very interesting analysis of 369 patients who underwent left atrial appendage closure at the Cleveland Medical Center," comments Dr. Bhatt. "The authors compared patients who developed effusion to patients who did not to determine if there was any factor that might predispose them to developing acute or delayed pericardial effusion. It was, I think, very insightful given the large number of left atrial appendage closures that are starting to occur."

Listen to Dr. Bhatt's "Top 10 in 2023" podcast at InvasiveCardiology.com

TABLE 1. Baseline patient characteristics.

	Pericardial Effusion (n = 5)	No Pericardial Effusion (n = 364)	*P*-Value
Age (years)	78.4 + 7.8	76.3 ± 8.5	.50
Gender			
Male	2 (40%)	219 (60.2%)	.30
Female	3 (60%)	145 (39.8%)	.30
Ethnicity			
White	3 (60%)	328 (90.1%)	
African American	2 (40%)	16 (4.4%)	
Other	0 (0%)	20 (5.5%)	
Body mass index (kg/m^2)	25.8 ± 4.535	30.4 ± 8.1	.13
CHA_2DS_2-VASc score	4.2 ±1.1	4.5 ± 1.4	.67
HAS-BLED score	3.4 ±0.48	3.7 ± 0.9	.53
Atrial fibrillation pattern			
Paroxysmal	4 (80%)	187 (51.4%)	.02
Persistent	1 (20%)	69 (19%)	.28
Permanent	0 (0%)	70 (19.2%)	.27
Unknown	0 (0%)	40 (11%)	.49
Comorbidities			
Systolic heart failure	1 (20%)	105 (28.8%)	.66
Hypertension	5 (100%)	322 (88.5%)	.42
Prior myocardial infarction/coronary artery disease	1 (20%)	119 (32.7%)	.54
Peripheral artery disease	1 (20%)	70 (19.2%)	.96
Diabetes mellitus	1 (20%)	123 (33.8%)	.51
Prior stroke or transient ischemic attack	1 (20%)	103 (28.3%)	.68
Prior deep vein thrombosis	1 (20%)	19 (5.2%)	.14
Prior pulmonary embolism	0 (0%)	8 (2.2%)	.73
Indication for left atrial appendage closure			
Gastrointestinal bleeding	4 (80%)	195 (53.6%)	.23
Central nervous system bleeding	0 (0%)	42 (11.5%)	.42
Genitourinary bleeding	0 (0%)	12 (3.3%)	.68
Serious epistaxis	1 (20%)	24 (6.6%)	.23
Hematologic disorder	0 (0%)	19 (5.2%)	.60
Falls	0 (0%)	75 (20.6%)	.25
Medication non-adherence	0 (0%)	8 (2.2%)	.73
Other	0 (0%)	51 (13%)	
Prior cardiac implantable device			
Permanent pacemaker	1 (20%)	60 (16.5%)	.32
Implantable cardioverter defibrillators	0 (0%)	29 (8%)	.51
Cardiac resynchronization therapy	0 (0%)	6 (1.6%)	.77
None	4 (80%)	280 (76.9%)	
Antithrombic regimen prior to procedure			
Aspirin	3 (60%)	157 (43.1%)	.45
$P2Y_{12}$ inhibitors	1 (20%)	50 (13.7%)	.97
Warfarin	1 (20%)	72 (19.8%)	.99
Direct oral anticoagulation	3 (60%)	144 (39.5%)	.78

Data presented as mean ± standard deviation or count (percentage).

the procedure with chest tightness and was found to have an increase in effusion size compared with preprocedure echocardiogram. The effusion gradually increased over the ensuing 48 hours and she underwent a pericardial window due to the posterior location (Figure 1). The second patient complained of lightheadedness 8 hours after the procedure and was found to be hypotensive, requiring urgent pericardial drainage. The remaining patients were also successfully treated by pericardiocentesis. All 5 patients with effusion underwent imaging with CT scan or TEE 45 days after their procedure and did not have a significant peridevice leak, thrombus, or device embolization. None were readmitted after pericardial intervention. One patient with DE had persisting small anterior pericardial effusion on follow-up CT scan. The remaining 4 patients had trivial or no effusion on follow-up imaging.

Discussion

Pericardial effusion is one of the most serious complications of LAAC. We examined patients with and without effusion over a 5-year span. We were not able to identify any major differences between the 2 groups. Patients in the overall cohort were older, female, and white, with average CHA_2DS_2VASc score of 4.4 and HAS-BLED score of 3.6. Gastrointestinal bleeding was the most common procedural indication. There were no differences in regard to procedural characteristics. Both groups had successful device implantation, with the majority receiving only 1 device and 27 mm the most common device size used.

TABLE 2. Procedural characteristics.

	Pericardial Effusion (n = 5)	No Pericardial Effusion (n = 364)	*P*-Value
Successful implantation	5 (100%)	360 (98.9%)	—
Failed implantation	0 (0%)	4 (1.1%)	—
Number of devices attempted			—
1 device	5 (100%)	334 (92%)	—
2 devices	0 (0%)	26 (7.2%)	—
3 devices	0 (0%)	3 (0.8%)	—
Final device size			
20 mm	1 (20%)	20 (5.6%)	
21 mm	0 (0%)	17 (4.7%)	
24 mm	1 (20%)	72 (20%)	
27 mm	3 (60%)	107 (29.7%)	—
30 mm	0 (0%)	31 (8.6%)	
31 mm	0 (0%)	45 (12.5%)	
33 mm	0 (0%)	33 (9.2%)	
35 mm	0 (0%)	35 (9.7%)	
Total procedural duration (min)	67.6 ± 16.8	75 ± 19.3	.16

Data presented as mean ± standard deviation or count (percentage).

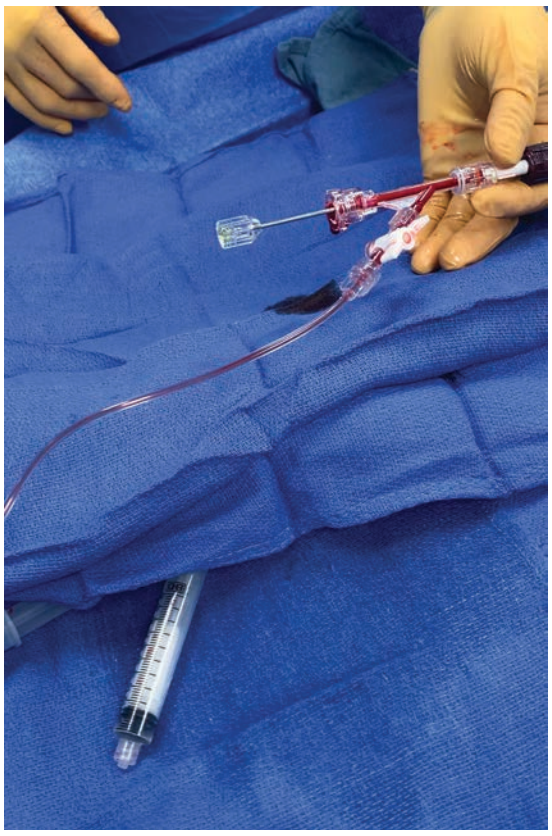
Both groups had similar procedural duration of approximately 1 hour.

AEs may result from injury at various points in the procedure, typically related to transseptal puncture or manipulation of wires, catheters, and device in the left atrium or LAA.[7] DEs are less common following LAA closure.[9,10] However, in the PINNACLE FLX trial, all of the patients with significant pericardial effusions presented after day 7.[5] In this experience, there were more DEs with the FLX device compared with the Watchman Legacy device. Two out of 3 patients had DEs after implantation of the Watchman FLX device while zero patients had DEs with the Legacy device. Both patients with DEs had imaging done shortly after the procedure, with no new pericardial effusion visualized. Still, concern for DE should not be a barrier to same-day discharge following LAAC. In fact, outcomes in patients with same-day discharge after LAA have been shown similar to those admitted overnight.[15,16] In our analysis, the rate of DE was very low, suggesting that same-day discharge of patients who undergo LAAC is still safe and feasible.

We hypothesize that DE occurs due to microperforation during or just after device implantation. One possible explanation as to why DE was more common with the Watchman FLX device is the increase in the number of J-shaped fixation anchors on this device compared with the Watchman Legacy device. The Watchman FLX device contains 18 peripheral fixation anchors (2 rows of 9) compared with 10 fixation anchors in the earlier-generation device. The addition of more J-anchors was done to reduce device embolization but could have the unintended consequence of DE. The device embolization rate was 0.7% for the first-generation device but decreased to 0% for the second-generation device.[3,5] There were no device embolization events noted in our cohort. The interaction of these increased anchors could lead to microperforation of the thin-walled appendage during the procedure, leading to a slow accumulation of blood in the pericardium as opposed to a more brisk accumulation that might occur with catheter or wire injury. Interestingly, both patients with DEs were in sinus rhythm at the time of the procedure. Sinus rhythm makes the appendage and the left atrium more mobile, thus increasing the interaction of the device and the heart tissue and possibly increasing the risk of injury. A tight hemostatic valve on the core wire may add additional tension between the core wire and the appendage, causing the anchors to pull upon appendage tissue and may be observed especially in the setting of hypermobile or hyperdynamic appendage. This phenomenon—commonly referred to as "auto-tug"—is noted when the core wire automatically shifts back and forth within a loosened hemostatic valve (Video 1). Maintaining a loose hemostatic valve until device release can reduce system tension and may reduce the risk of injury in this circumstance.

In addition to anchor number, anchor length may also contribute to the development of pericardial effusions. In the Amulet IDE trial, the Amulet occluder device had a higher rate of pericardial effusion compared with the Watchman Legacy (22/903 [2.44%] vs 11/896 [1.23%]).[11] This higher rate of pericardial effusion may be related to longer fixation anchors. The Amulet anchors are 2.2 times longer compared with the effective length of the Watchman anchors (Figure 2 and Figure 3). Since total wall (LAA + pulmonary artery) thickness is approximately 1.55 mm, longer anchors could perforate with less manipulation.

Four of our patients with pericardial effusions developed cardiac tamponade. Identifying these patients early and treating them with pericardiocentesis or pericardial window to drain the effusion is crucial. All patients recovered well after drainage



Video 1 (online). The "auto-tug" phenomenon.

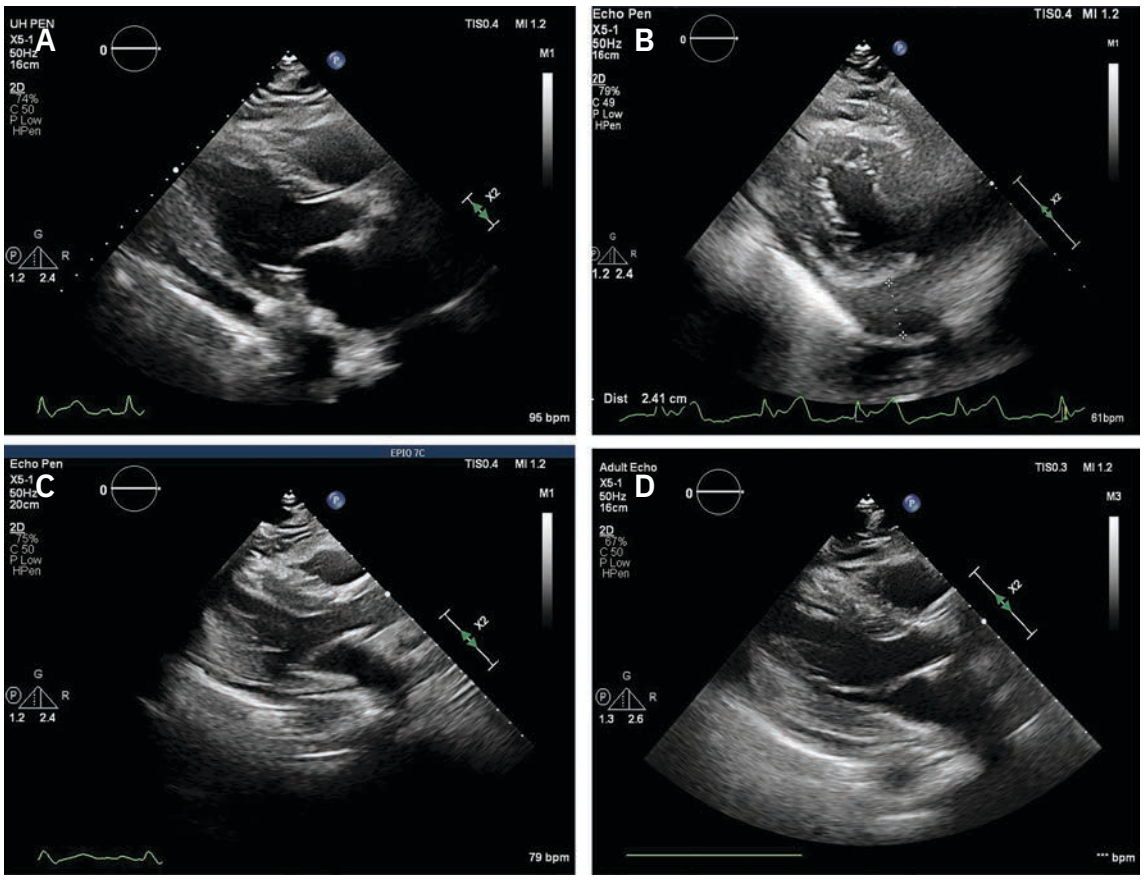


Figure 1. **Transthoracic echocardiogram images showing slow accumulation of a posterior pericardial effusion. (A) Small effusion noted preprocedure. (B) No change at 6 hours post procedure. (C) Moderate effusion at 24 hours post procedure. (D) Moderately large posterior effusion at 48 hours post procedure.**

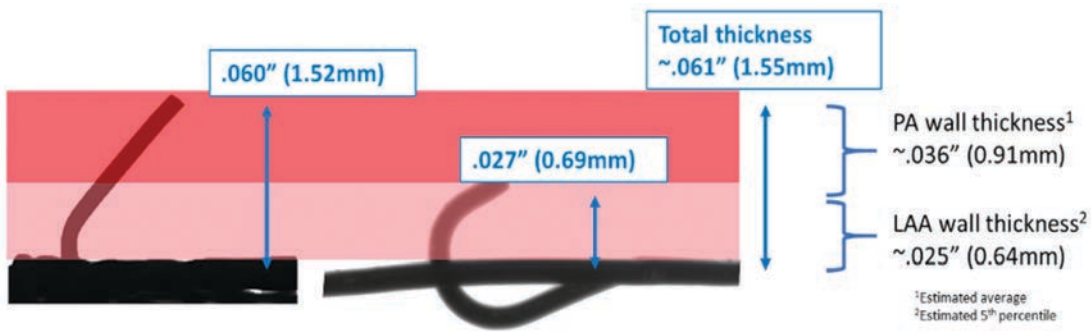


Figure 2. **Graphic comparing J-anchor length of Amulet occluder device (left) and Watchman device (right) in relation to pulmonary artery (PA) and left atrial appendage (LAA) wall thickness.**

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Figure 3. **Graphic comparing J-anchor length of Amulet occluder device (left) and Watchman device (right) in relation to pulmonary artery (PA) and left atri**

of the effusion. As with all of our patients, we obtained imaging after 45 days and these patients had no significant peridevice leak, thrombus, or device embolization, with stable position of the device. We recommend obtaining imaging on all the patients prior to discharge.

Study limitations. A few limitations should be noted. Because so few patients developed effusions, the study was not sufficiently powered to identify statistically significant risk factors between the 2 groups. There was a change in our procedural workflow over the 5-year span period. Finally, our project required extraction of data from the electronic medical record and there could have been inaccuracy in the data recorded in this record.

Conclusion

In this 5-year, single-center experience, DEs were uncommon and potentially related to LAA device anchor microperforation. No statistically significant risk factors predisposing patients to pericardial effusions were identified in our analysis. ■

Acknowledgments

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Reader Note:

The article references, video, and abstract are available with the article online. Scan the QR code:

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The authors report that patient consent was provided for publication of the images used herein.

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