

## Original Article

# Outcomes of Watchman device implantation in atrial fibrillation patients contraindicated for long-term anticoagulation: a single-center experience

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**Abstract:** Background: Left atrial appendage occlusion (LAAO) using the Watchman device is an established strategy for stroke prevention in atrial fibrillation (AF) patients at high thromboembolic risk who cannot tolerate long-term oral anticoagulation (OAC). Objectives: To evaluate short-term clinical and echocardiographic outcomes of Watchman implantation in AF patients with contraindications to long-term OAC. Methods: We conducted a retrospective single-center study of AF patients who underwent Watchman implantation between September 01, 2023, and March 01, 2025. Baseline demographics, comorbidities, procedural characteristics, complications, antithrombotic strategies, and 45-day outcomes were analyzed. Outcomes were compared between patients with and without follow-up TEE. Data were analyzed using SAS v9.4. All tests were two-tailed, and a  $p$ -value  $<0.05$  was considered statistically significant. Results: Among 10,078 AF patients, 120 underwent Watchman implantation; 105 met the inclusion criteria. The mean age was  $75.8 \pm 7.8$  years, and 46.7% were female. Implant success was 100%. Pericardial effusion occurred in 11 patients (10.5%, 95% CI 5.4-18.0%), including tamponade requiring pericardiocentesis in 2 patients (1.9%). Vascular access complications occurred in 3 patients (2.9%, 95% CI 0.6-8.1%). No device embolizations, device-related thrombi, or periprocedural strokes were observed. Most patients (88.5%) were discharged on dual antiplatelet therapy, while 3.8% received single antiplatelet therapy. At 45 days, 89 patients (84.8%) completed TEE; device position was stable in all. One patient (1.1%, 95% CI 0.03-6.1%) had a significant peridevice leak ( $>5$  mm), and none had device-related thrombus. Clinical outcomes included one hemorrhagic stroke (1.1%) and eight rehospitalizations (7.6%, 95% CI 3.4-14.5%), unrelated to the device. No ischemic strokes were observed. Conclusion: Watchman implantation achieved a 100% success rate with low complication rates and favorable short-term clinical and echocardiographic outcomes in AF patients contraindicated for long-term anticoagulation.

**Keywords:** Atrial fibrillation, left atrial appendage occlusion, Watchman device, anticoagulation intolerance, dual antiplatelet therapy, procedural outcomes

## Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, affecting over 33 million people worldwide, with a prevalence that continues to rise with aging populations [1]. AF is associated with a five-fold increased risk of ischemic stroke, largely due to thrombus formation in the left atrial appendage (LAA) [2]. Oral anticoagulation (OAC) with vitamin K antagonists or direct oral anticoagulants (DOACs) has been the standard strategy for stroke prevention in AF patients with elevated CHA<sub>2</sub>DS<sub>2</sub>-VASc scores [3]. However, many patients remain undertreated because of contraindications

such as prior intracranial hemorrhage, gastrointestinal bleeding, high fall risk, or intolerance to long-term anticoagulation [4].

The Watchman device (Boston Scientific, Marlborough, MA, USA) is the most widely studied percutaneous LAA occlusion (LAAO) device. Randomized trials such as PROTECT-AF and PREVAIL established its noninferiority to warfarin for stroke prevention, with durable protection demonstrated in long-term follow-up [5-7]. In these trials, the device was primarily evaluated in patients eligible for warfarin, and the post-implant regimen mandated temporary OAC. However, in clinical practice, the most com-

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mon indication for Watchman implantation is the inability to tolerate OAC, leaving a knowledge gap regarding safety and effectiveness in this population [8]. The ASAP study provided early evidence supporting Watchman use in OAC-ineligible patients managed with dual antiplatelet therapy (DAPT) alone [9], and subsequent registries such as EWOLUTION and the National Cardiovascular Data Registry (NCDR) LAAO Registry confirmed procedural safety and efficacy across broader patient populations [10, 11]. Nevertheless, questions remain regarding the generalizability of registry findings, the safety of DAPT-only protocols, and the spectrum of procedural and early post-procedural complications in real-world practice.

Furthermore, most published data come from multicenter registries, where variations in operator experience, device selection, and follow-up strategies can influence outcomes. Single-center analyses offer a complementary perspective by providing granular reporting of complications, device management strategies, and follow-up adherence within a consistent practice environment. Such studies can highlight practical considerations for centers performing Watchman implantation, especially in populations at the highest bleeding risk. Therefore, in this study, we conducted a retrospective analysis of all patients who underwent Watchman device implantation at our institution, Mercy Health St. Vincent Medical Center, Toledo, Ohio. Our objectives were to evaluate (i) baseline clinical characteristics of this real-world cohort of OAC-intolerant AF patients, (ii) procedural success and complication rates, (iii) antithrombotic regimens employed post-implant, and (iv) 45-day outcomes, including transesophageal echocardiographic (TEE) findings and clinical events. By reporting these results, we aim to contribute meaningful single-center real-world evidence to the literature and help inform optimal patient selection and post-procedural management in this challenging high-risk population.

### Methods

#### *Study design and population*

This was a retrospective, single-center cohort study conducted at Mercy Health St. Vincent Medical Center, Toledo, Ohio. All AF patients undergoing Watchman device implantation be-

tween September 01, 2023, and March 01, 2025 were screened. The study protocol was approved by the Institutional Review Board, and a waiver of consent was granted due to its retrospective nature.

*Inclusion criteria:* (1) Age  $\geq 18$  years. (2) Diagnosis of atrial fibrillation (paroxysmal, persistent, or unspecified). (3) Underwent Watchman device implantation. (4) Contraindication to long-term OAC as documented by the treating physician.

Contraindications to long-term oral anticoagulation included prior intracranial hemorrhage, major gastrointestinal bleeding, chronic bleeding tendency or anemia, recurrent falls or frailty, and documented intolerance or hypersensitivity to anticoagulants.

*Exclusion criteria:* (1) Patients without adequate records for baseline or follow-up assessment. (2) Valvular AF or significant mitral stenosis. (3) Patients not meeting institutional or FDA criteria for LAAO.

#### *Data collection*

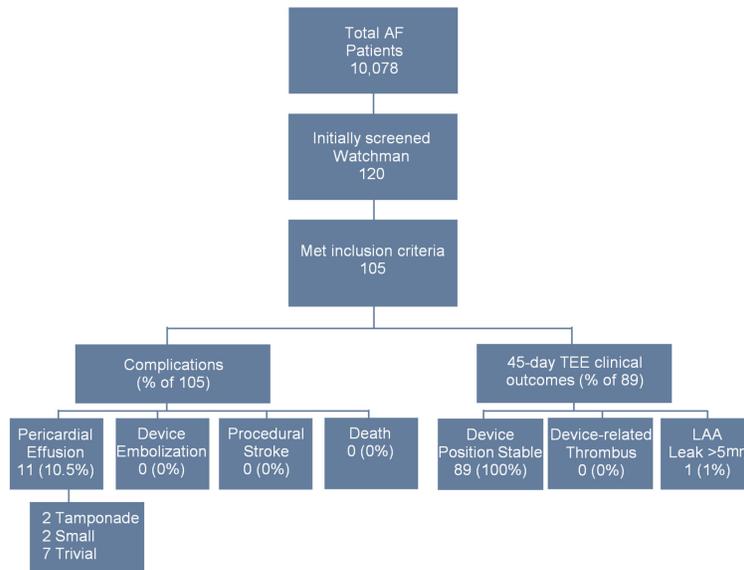
Electronic medical records were reviewed for: Patient characteristics: Baseline indicators included age, sex, CHA<sub>2</sub>DS<sub>2</sub>-VASc score, and comorbidities such as hypertension, diabetes, heart failure, coronary artery disease, chronic kidney disease, prior stroke/TIA, and liver disease.

Procedural indicators: Procedural indicators included device size, implantation success, pericardial effusion (categorized by severity), vascular access complications, antithrombotic therapy, and other adverse events.

Echocardiographic outcomes: Echocardiographic outcomes included device position stability, presence of device-related thrombus, and significant peridevice leak (PDL)  $>5$  mm. These outcomes were systematically assessed using transesophageal echocardiography (TEE) performed at approximately 45 days post-implantation. Device evaluation was conducted using standardized multiplanar TEE imaging at 0°, 45°, 90°, and 135° views.

1. Device position stability was assessed by confirming appropriate coaxial alignment within the LAA, consistent device orientation across

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**Figure 1.** Flow diagram demonstrating atrial fibrillation (AF) patient number and complications.

all TEE planes, and absence of migration or tilting. Adequate device compression (target range 10-25%) was evaluated by comparing the measured device diameter to the nominal size. A satisfactory seal was defined by stable device position with no or minimal (<5 mm) peridevice leak across multiplanar views.

2. Device-related thrombosis: Device-related thrombosis (DRT) was defined as the presence of a thick, dense, multilobulated, or pedunculated mass attached to the atrial surface of the device, distinct from flat, homogeneous tissue consistent with expected endothelialization. Particular attention was paid to mass mobility, as mobile echodensities were considered to confer higher embolic risk.

3. Peridevice leak (PDL) was evaluated in all imaging planes using color doppler, with a significant leak defined as a jet width >5 mm. Smaller leaks (<5 mm) were documented but considered acceptable based on contemporary criteria. Device embolization was excluded by confirming device visualization within the left atrial appendage (LAA) and correlating echocardiographic findings with clinical assessment for embolic events.

Clinical outcomes: Clinical outcomes included stroke/TIA, major bleeding, all-cause death, and rehospitalization within 45 days post-implantation.

### Outcomes

**Primary outcome:** The primary outcomes included clinical and echocardiographic indicators of therapeutic success at 45 days, defined by the absence of stroke or transient ischemic attack (TIA), absence of device-related thrombus or embolization, and maintenance of stable device position on transesophageal echocardiography (TEE).

**Secondary outcomes:** Secondary outcomes included procedural success, complications (pericardial effusion, vascular access events, and peridevice leak >5 mm), and 45-day rehospitalization rates.

### Statistical analysis

Continuous variables were summarized as mean  $\pm$  standard deviation (SD) or median (interquartile range, IQR) and compared using independent-samples t-tests or Mann-Whitney U tests. Categorical variables are presented as frequency counts and percentages and were compared using chi-square ( $\chi^2$ ) or Fisher's exact tests as appropriate. TEE completers and non-completers were compared using Fisher's exact test for categorical variables, Student's t-test for continuous variables, and Mann-Whitney U test for non-normally distributed data (such as CHA<sub>2</sub>DS<sub>2</sub>-VASc scores). Exact binomial 95% confidence intervals were calculated for complication rates. All statistical tests were two-tailed, and P<0.05 was considered statistically significant. Analyses were performed with SAS v9.4.

### Results

#### Study population

Of 10,078 AF patients, 120 underwent Watchman implantation. 105 patients met the inclusion criteria and were included in the final analysis (**Figure 1**). For AF patients who underwent Watchman implantation, the mean age was 75.8 $\pm$ 7.8 years, and 46.7% were females. Among the 105 patients, 100 (95.2%) had hypertension, 23 (21.9%) had heart failure, and

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**Table 1.** Baseline Characteristics and Co-morbidities of All Atrial Fibrillation (AF) Patients (n = 10,078)

Variables	N = 10,078
Age at hospital admission, <i>mean years (SD)</i>	71.2 (13.9)
Female, <i>n (%)</i>	5588 (55.5)
Missing	1
Race, <i>n (%)</i>	
White (non-Hispanic)	8673 (87.6)
Black/African American	894 (9.0)
Hispanic/Latino	119 (1.2)
All Others	220 (2.2)
Missing, Declined	172
Hypertension, <i>n (%)</i>	6964 (69.1)
Type 2 Diabetes, <i>n (%)</i>	0 (0)
Heart Failure, <i>n (%)</i>	1766 (17.5)
CAD, <i>n (%)</i>	0 (0)
CKD, <i>n (%)</i>	268 (2.7)
Prior Stroke/TIA, <i>n (%)</i>	702 (7.0)
Liver Disease, <i>n (%)</i>	122 (1.2)
Length of Stay, <i>median days (IQR)</i>	0 (0, 1)

SD = standard deviation, CAD = coronary artery disease, CKD = chronic kidney disease, TIA = transient ischemic attack, IQR = interquartile range.

11 (10.5%) had prior stroke/TIA. Baseline demographics and co-morbidities of all AF patients and AF patients who underwent Watchman implantation are summarized in **Tables 1** and **2**, respectively.

### Procedural outcomes

Device implantation was successful in 100% (105/105) of patients without any mortality. Device sizes used ranged from 20-40 mm, and among those, the most frequently used device sizes were 24 mm and 27 mm (30.5% each).

Pericardial effusion occurred in 11 patients (10.5%, 95% CI 5.4-18.0%), and among those, 2 patients (1.9%) developed tamponade requiring pericardiocentesis while the effusion was trivial/small and clinically insignificant in the other 9 patients. Vascular access complications occurred in 3 patients (2.9%, 95% CI 0.6-8.1%), which was not significant and didn't need any intervention. No device embolization, device thrombus, or periprocedural stroke occurred (**Table 3**).

### Antithrombotic therapy

Most patients (88.5%) were discharged on dual antiplatelet therapy (aspirin + clopidogrel),

while 3.8% were discharged on single antiplatelet (clopidogrel) therapy. A minority received anticoagulation-based regimens (**Table 3**).

### 45-day outcomes

At 45 days, 89 patients (84.8%) followed up and completed TEE. Device position was stable in all patients. One patient (1.1%, 95% CI 0.03-6.1%) had a significant peridevice leak (>5 mm), while no device-related thrombi or embolizations were observed. No ischemic strokes had occurred at the time of follow-up TEE (one patient had hemorrhagic stroke which occurred 3 weeks after the Watchman implantation and was unrelated to the procedure).

Rehospitalization occurred in 8 patients (7.6%, 95% CI 3.4-14.5%), with causes including heart failure exacerbation, pneumonia, urinary tract infection, angina requiring percutaneous coronary intervention (PCI), non-ST-elevation myocardial infarction (NSTEMI), pulmonary embolism, and hypertensive urgency (**Table 4**). No readmission was attributed to device complications.

### TEE completers vs non-completers

Baseline characteristics of TEE completers vs non-completers are shown in **Table 5**. There were no statistically significant differences between the groups regarding age, sex, or comorbidities.

### Discussion

In this single-center retrospective analysis of 105 atrial fibrillation patients who underwent left atrial appendage occlusion (LAAO) with Watchman, we observed a 100% device implantation success rate with low complication rates and favorable short-term clinical and echocardiographic outcomes at 45-day follow-up. These results are consistent with and extend findings from prior randomized trials and large real-world registries, while specifically addressing outcomes in patients who were contraindicated for long-term oral anticoagula-

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**Table 2.** Baseline Characteristics and Co-morbidities of Atrial Fibrillation (AF) Patients who Underwent Watchman Device Implantation (n = 105)

Variables	N = 105
Age at hospital admission, <i>mean years (SD)</i>	75.8 (7.8)
Female, <i>n (%)</i>	49 (46.7)
Race, <i>n (%)</i>	
White (non-Hispanic)	95 (91.4)
Black/African American	6 (5.8)
Hispanic/Latino	3 (2.9)
All Others	0
Missing, Declined	1
Hypertension, <i>n (%)</i>	100 (95.2)
Type 2 Diabetes, <i>n (%)</i>	0 (0)
Heart Failure, <i>n (%)</i>	23 (21.9)
CAD, <i>n (%)</i>	0 (0)
CKD, <i>n (%)</i>	10 (9.5)
Prior Stroke/TIA, <i>n (%)</i>	11 (10.5)
Liver Disease, <i>n (%)</i>	0 (0)
CHA <sub>2</sub> DS <sub>2</sub> -VASc Score, <i>n (%)</i>	
2	2 (1.9)
3	18 (17.1)
4	42 (40.0)
5	27 (25.7)
6	14 (13.3)
7	1 (1.0)
8	1 (1.0)
Length of Stay, <i>median days (IQR)</i>	0 (0, 0)

SD = standard deviation, CAD = coronary artery disease, CKD = chronic kidney disease, TIA = transient ischemic attack, IQR = interquartile range.

tion (OAC) and largely managed with dual antiplatelet therapy (DAPT) alone.

### Procedural success and complications

Our study demonstrated a 100% successful device implantation rate, which exceeds the early pivotal trials such as PROTECT-AF (91%) [5] and PREVAIL (~95%) [6] and is consistent with contemporary registries (NCDR LAAO Registry, EWOLUTION) data [8, 10], as well as with the more recent newer generation trial (PINNACLE FLX) [12], reporting success rates between 95% and 99%. From the authors' perspective, this exceptionally high success rate likely reflects a combination of factors, including growing operator experience, improved patient selection, meticulous preprocedural imaging, adherence to a standardized contemporary sizing protocol, and refinements in

implantation technique. Additionally, the use of second-generation devices during the study period may have contributed to procedural ease and reproducibility.

The most notable procedural complication was pericardial effusion, occurring in 10.5% of patients; however, only 1.9% required pericardiocentesis for tamponade, while the remaining cases had asymptomatic small/trivial pericardial effusions. When contextualized with prior studies, the rate of clinically significant effusion in our cohort is comparable to PREVAIL (1.9%) [6] and PINNACLE FLX (1.0%) [12], suggesting that most effusions in our series were clinically insignificant and detected due to meticulous post-procedural imaging. This observation highlights how comprehensive echocardiographic surveillance may increase detection of trivial effusions without altering clinical outcomes.

Vascular access complications occurred in 2.9% of patients consistent with rates reported in large registries such as the NCDR LAAO registry [8]. The absence of procedural device embolization, device-related thrombus, or periprocedural stroke in our cohort reinforces procedural safety in an experienced center.

### Post-procedural antithrombotic management

Device-related thrombus (DRT) remains a clinically important concern following LAAO due to its association with increased ischemic stroke risk [13]. Optimal post-implant antithrombotic therapy remains a key area of ongoing investigation. In contrast to the registry data, where the vast majority received OAC [14] and pivotal trials (PROTECT-AF and PREVAIL) that mandated post-implant oral anticoagulation [5, 6], the majority of patients in our cohort were managed with single or dual antiplatelet therapy (DAPT) alone due to formal contraindications to anticoagulation. Despite this, we observed no DRT and no ischemic strokes at 45-day follow-up. These findings align with the ASAP trial, which demonstrated acceptable stroke prevention using DAPT alone in anticoagulation-ineligible patients [9]. The absence of DRT in

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**Table 3.** Procedural and device-related characteristics/complications (n = 105)

Variables	N = 105
Device Size, n (%)	
20 mm	13 (12.4)
24 mm	32 (30.5)
27 mm	32 (30.5)
31 mm	24 (22.9)
35 mm	3 (2.9)
40 mm	1 (1.0)
Successful Implant, n (%)	105 (100)
Pericardial Effusion, n (%)	
No	94 (89.5)
Yes (tamponade + pericardiocentesis)	2 (1.9)
Yes (small)	2 (1.9)
Yes (trivial)	7 (6.7)
Total of 11/105 yes, or 10.5% with 95% CI: (5.4%, 18.0%)	
Device Embolization, n (%)	0 (0)
Procedural Stroke/TIA, n (%)	0 (0)
Device Thrombus, n (%)	0 (0)
Vascular Access Complications, n (%)	
None	102 (97.1)
N + H83	1 (1.0)
R groin hematoma (no pseudoaneurysm): no intervention	1 (1.0)
Groin hematoma with small pseudoaneurysm: no intervention	1 (1.0)
Total of 3 complications, or 2.9% with 95% CI: (0.6%, 8.1%)	
AP/AC Post Procedure, n (%)	
Aspirin + clopidogrel for 6 months followed by asp only	93 (88.5)
Eliquis + aspirin for 6 weeks followed by aspirin + clopidogrel for 6 months and then asp only	6 (5.7)
Only clopidogrel	4 (3.8)
Warfarin for 6 weeks followed by aspirin + clopidogrel for 6 months and then asp only	1 (1.0)
Aspirin + clopidogrel but changed to Eliquis + aspirin after Dx of PE within 3 weeks	1 (1.0)
Death, n (%)	0 (0)
Procedure Aborted, n (%)	
No	104 (99.1)
PEA arrest. Procedure completed but had PEA arrest during procedure d/t tamponade which was drained. Aortic wall hematoma but patient survived	1 (1.0)

TIA = transient ischemic stroke, AP = antiplatelet, AC = anticoagulation, PEA = pulseless electrical activity.

our study is clinically important considering estimated DRT rates of ~3-5% in multiple registry data [11, 15], particularly given that known predictors of DRT (including advanced age, chronic kidney disease, and high CHA<sub>2</sub>DS<sub>2</sub>-VASc scores) were prevalent in our population [16, 17]. Our interpretation is that careful patient selection, uniform adherence to a structured antiplatelet regimen, and experienced procedural technique all likely contributed to the absence of DRT and ischemic stroke in our cohort. These findings strengthen the growing

body of evidence with real-world data from more recent FLX devices [18], suggesting that DAPT may provide adequate protection against device thrombosis in OAC-intolerant patients, at least in the short term.

### 45-day outcomes

At 45-day follow-up, TEE was completed in 84.8% of patients, a higher rate than that reported in many real-world registries where follow-up imaging is often incomplete [8, 10].

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**Table 4.** 45-day TEE and clinical outcomes (n = 89)

Variables	N = 89
Stroke/TIA, n (%)	
No	88 (98.9)
Yes (Hemorrhagic - occurred 3 weeks after the procedure, so not related to procedure)	1 (1.1) CI: (0.03%, 6.1%)
Major Bleed, n (%)	0 (0)
Death, n (%)	0 (0)
Device Position Stable, n (%)	89 (100)
Device Related Thrombus, n (%)	0 (0)
LAA Leak >5, n (%)	
No	88 (98.9)
Yes	1 (1.1) CI: (0.03%, 6.1%)
Rehospitalization*, n (% of 105)	8 (7.6) CI: (3.4%, 14.5%)

\*Details for 8 Rehospitalizations: (1) Admitted in 2 weeks with HF and MRSA PNA; (2) Admitted after 2 weeks for HF; (3) Admitted for UTI and AMS in 5 weeks; (4) Admitted in 4 weeks for recurrent angina, +PCI OM and LAD; (5) Admitted in after 2 days for NSTEMI, COPD exacerbation; (6) Admitted with hemorrhagic stroke in 3 weeks and died; (7) From PE (aspirin + clopidogrel then changed to Eliquis + aspirin after Dx of PE within 3 weeks); (8) In 4 weeks for hypertensive urgency. TEE = Transesophageal Echocardiogram, TIA = transient ischemic attack, LAA = left atrial appendage, HF = heart failure, MRSA = methicillin-resistant staphylococcus aureus, PNA = pneumonia, UTI = urinary tract infection, AMS = altered mental status, PCI = percutaneous coronary intervention, OM = obtuse marginal artery, LAD = left anterior descending artery, NSTEMI = Non-ST-elevation myocardial infarction, COPD = chronic obstructive pulmonary disease, Dx = diagnosis, PE = pulmonary embolism.

**Table 5.** Baseline Characteristics and Co-morbidities of Atrial Fibrillation (AF) Patients who Underwent Watchman Device Implantation - Comparison TEE Completers versus Non-Completers

Variables	TEE Completers	TEE Non-Completers	p-value
No. Subjects	89	16	
Age at hospital admission, mean years (SD)	76 (8)	75 (9)	0.79
Female, n (%)	38 (43)	11 (69)	0.06
Race, n (%)			Overall P = 1.0
White (non-Hispanic)	80 (91)	15 (94)	
Black/African American	5 (6)	1 (6)	
Hispanic/Latino	3 (3)	0 (0)	
All Others	0 (0)	0 (0)	
Missing, Declined	1	0	
Hypertension, n (%)	85 (96)	15 (94)	0.57
Type 2 Diabetes, n (%)	0 (0)	0 (0)	N.A.
Heart Failure, n (%)	22 (25)	1 (6)	0.19
CAD, n (%)	0 (0)	0 (0)	N.A.
CKD, n (%)	8 (9)	2 (13)	0.65
Prior Stroke/TIA, n (%)	8 (9)	3 (19)	0.37
Liver Disease, n (%)	0 (0)	0 (0)	N.A.
CHA <sub>2</sub> DS <sub>2</sub> -VASc score, median (IQR)	4 (4, 5)	4 (3.5, 4)	0.06

Binary variables are compared between groups with Fisher's Exact two-tailed tests, age with a Student t-test, and CHA<sub>2</sub>DS<sub>2</sub>-VASc score with a Mann Whitney Wilcoxon test. TEE = Transesophageal Echocardiogram, SD = standard deviation, CAD = coronary artery disease, CKD = chronic kidney disease, TIA = transient ischemic attack, IQR = interquartile range.

Among those undergoing follow-up TEE, device position was stable in all cases, with only one patient (1.1%) demonstrating a significant pe-

ridevice leak (>5 mm), a rate lower than the 5-8% reported in prior studies [19]. No device embolization or DRT was identified.

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Clinically, no major bleeding events (except one hemorrhagic stroke) or ischemic strokes were observed, a rate lower than the reported 45-day major bleeding of ~3.1% and ischemic stroke of ~0.23% in the registry data [20, 21]. The higher proportion of major bleeding in the registry analyses was likely related to the predominant use of OAC in contrast to the predominant use of DAPT in our study.

Rehospitalization occurred in 7.6% of patients and was primarily driven by comorbid conditions such as heart failure, infection, and coronary artery disease rather than device-related complications. In the authors' view, these findings emphasize that while LAAO effectively reduces thromboembolic risk, it does not mitigate the broader systemic frailty and multimorbidity inherent in this patient population. This finding is consistent with contemporary registry data demonstrating that early rehospitalizations after LAAO are most often attributable to underlying cardiovascular or systemic illness rather than procedural failure [8].

### *Comparison with existing literature*

Our findings reinforce prior evidence that left atrial appendage occlusion (LAAO) provides effective stroke prevention with an acceptable safety profile in patients who are not candidates for long-term oral anticoagulation (OAC). Compared with previous trials and registries, our single-center study demonstrated procedural success and complication rates that are comparable to contemporary real-world experience, despite including an exclusively OAC-intolerant population. These results support the safety and efficacy of LAAO with dual antiplatelet therapy-only protocols in appropriately selected patients. Importantly, our study adds granularity by reporting the full spectrum of pericardial effusion, including clinically insignificant findings that are often underrepresented in large registries. Moreover, the high rate of transesophageal echocardiographic follow-up (85%) strengthens confidence in the reliability of our short-term outcome assessment. Finally, the predominance of DAPT-only therapy in our cohort addresses a pressing clinical question regarding post-implant antithrombotic management in high-risk patients unable to receive anticoagulation and provides additional real-world support for antiplatelet based strategies in the contemporary device era.

### *Clinical implications*

The results of this study have several implications for clinical practice: 1. High success and safety in real-world practice suggest Watchman can be confidently offered to OAC-intolerant AF patients. 2. Low rates of DRT and leak with DAPT-based regimens strengthen the case for avoiding anticoagulation in patients where it is unsafe, though individualized decision-making remains essential. 3. Readmissions highlight the frailty of this population, reminding clinicians that LAAO addresses thromboembolic risk but not the broader morbidity of AF patients with multimorbidity.

### *Strengths and limitations*

Strengths of this study include consecutive real-world enrollment, comprehensive reporting of complications (including trivial effusions), and high TEE follow-up rates. Limitations include its retrospective single-center design, modest sample size, and short-term follow-up limited to 45 days. Longer-term outcomes, including late DRT, stroke, and device durability, could not be assessed. Additionally, as all implants were performed at a single center with experienced operators, results may not be generalizable to centers with lower procedural volumes.

### **Conclusions**

In this single-center retrospective study, Watchman implantation in AF patients contraindicated for long-term anticoagulation was associated with 100% implant success, low complication rates, and favorable 45-day outcomes, even in patients predominantly managed with dual antiplatelet therapy. These findings support Watchman as a safe and effective strategy in contemporary practice for OAC-intolerant AF patients and contribute real-world evidence to the ongoing discussion of optimal post-implant antithrombotic therapy.

### **Disclosure of conflict of interest**

None.

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