Austin Critical Care Case Reports

Open Access

Austin Publishing Group

Research Article

Comparison of Efficacy and Safety of WATCHMAN and ACP in Clinical Application

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Received: April 01, 2025
Accepted: April 17, 2025
Published: April 22, 2025

Abstract

Background: This study compared the efficacy and safety of two left atrial appendage closure (LAAC) devices, WATCHMAN and the Amplatzer Cardiac Plug (ACP), in LAAC for high-risk non-valvular atrial fibrillation (NVAF) patients with contraindications to long-term anticoagulation.

Methods: We retrospectively enrolled 53 NVAF patients who underwent LAAC between July 2020 and July 2023 in the Affiliated Hospital of Hangzhou Normal University. Of these, 27 received WATCHMAN and 26 received ACP. Data including fluoroscopy time, contrast agent dosage, and major adverse events (MAEs) were analyzed. Patients were followed by transesophageal echocardiography (TEE) and/or atrial computed tomography angiography (CTA) to assess peri-device leaks, with a median follow-up of 6 months.

Results: Implantation success rates were comparable (WATCHMAN: 96.3% [26/27] vs ACP: 96.2% [25/26], P=0.828). The WATCHMAN group required significantly less fluoroscopy time compared to ACP (41.85±16.78 min vs 51.80±28.85 minutes, P=0.015), but showed comparable contrast agent dosage and total operation time. One patient in each group experienced device embolization requiring surgical retrieval. No between-group differences were observed in peri-device leak rates (WATCHMAN: 7.4% [2/27] vs ACP: 3.8% [1/26], P=0.727) or thrombosis incidence.

Conclusion: Compared with ACP, WATCHMAN demonstrated a shorter fluoroscopy time with comparable contrast usage, safety profiles, and procedural success rates in LAAC for high-risk NVAF patients.

Keywords: Left atrial appendage closure (LAAC); Amplatzer Cardiac Plug (ACP); WATCHMAN

Abbreviations

ACP: AMPLATZER Cardiac Plug; LAAC: Left Atrial Appendage Closure; NVAF: Non-Valvular Atrial Fibrillation; TEE: Transesophageal Echocardiography; CTA: Computed Tomography Angiography; AF: Atrial Fibrillation; VARC: Valve Academic Research Consortium; TIA: Transient Ischemic Attack; MAE: Major Adverse Events.

Introduction

Atrial fibrillation (AF), the most common clinically significant arrhythmia in elderly populations, affects approximately 6.5% of individuals aged ≥65 years [1]. Thromboembolic events originating from the left atrial appendage (LAA) represent the predominant cause of morbidity and mortality in AF patients, accounting for 20% of all ischemic strokes [2]. While oral anticoagulation (OAC) remains the cornerstone of stroke prevention, its clinical utility is often limited by bleeding risks [3]. For non-valvular AF (NVAF) patients with contraindications to long-term OAC, left atrial appendage closure (LAAC) has emerged as an effective alternative [4]. Nevertheless, LAAC procedures carry inherent risks including cardiac tamponade (3.5%~5%), peri-device leakage (5%~32%), and device-related thrombosis (3%~4%) [5,6], underscoring the importance of device selection optimization. Currently, two predominant LAAC devices are clinically available: the WATCHMAN (Boston Scientific, Marlborough, MA) and Amplatzer Cardiac Plug (ACP; Abbott, Chicago, IL). Preclinical studies in canine models demonstrate differential healing responses - WATCHMAN achieves complete endothelialization within 45 days, whereas ACP's disc-shaped design extending beyond the LAA ostium delays tissue incorporation [7]. Clinical data from Chun et al.'s 80-patient cohort revealed comparable thrombosis rates between devices (WATCHMAN 3.7% vs ACP 4.2%, p=NS) [8]. However, critical intraoperative efficiency metrics (fluoroscopy time, contrast volume) and longitudinal leakage outcomes remain uncharacterized in head-to-head comparisons.

This study provides the first comprehensive evaluation of WATCHMAN versus ACP across three key domains: (1) procedural efficiency (fluoroscopy time, contrast usage), (2) perioperative safety profiles, and (3) follow-up endothelialization outcomes quantified by transesophageal echocardiography. Our findings address existing evidence gaps to inform clinical decision-making for NVAF patients undergoing LAAC.

Citation: Fu X, Zheng Y, Peng H, Yang D, Zhang N, et al. Comparison of Efficacy and Safety of WATCHMAN and ACP in Clinical Application. Austin Crit Care Case Rep. 2025; 10(1): 1055.

Methods

Study Design

This retrospective cohort study with prospective data collection analyzed 53 consecutive NVAF patients undergoing LAAC with either WATCHMAN (Boston Scientific) or ACP (Abbott) devices at the Affiliated Hospital of Hangzhou Normal University between July 2020 and July 2023. The study protocol received approval from the Institutional Ethics Committee, and written informed consent was obtained from all participants.

Patients Selection

Eligible patients met the following criteria: (1) CHA_2DS_2-VASc score ≥3 and HAS-BLED score ≥3; (2) documented contraindications to long-term oral anticoagulation, including history of major bleeding, high fall risk, or inability to maintain therapeutic international normalized ratio (INR) monitoring. Patients with pre-existing LAA thrombus on transesophageal echocardiography (TEE) or active systemic infection were excluded.

Preoperative Preparation

All patients underwent comprehensive preoperative evaluation including TEE to exclude LAA thrombus and cardiac computed tomography angiography (CTA) with three-dimensional reconstruction using Mimics 17.0 software (Materialise, Belgium). Patient-specific LAA models were created using 3D printing technology for preoperative device sizing simulation with manufacturer-provided device replicas. Standard laboratory tests included complete blood count, renal and hepatic function panels, and coagulation profile. For patients on warfarin therapy, INR was maintained below 2.0 prior to the procedure.

Procedure

All LAAC procedures were performed under general anesthesia with fluoroscopic guidance (Philips Allura Xper FD10 system) and concurrent TEE monitoring (Philips CX50 system). The standardized protocol included right femoral venous access using Seldinger technique, transseptal puncture at the fossa ovalis under fluoroscopic and TEE guidance, and delivery system placement into the left atrium. After angiographic confirmation of LAA anatomy in multiple projections (0°, 45°, 90°, 135°), appropriately sized devices were deployed following manufacturer recommendations. Final device position was confirmed by both angiography and TEE assessment of PASS criteria (Position, Anchor, Size, Seal) before release. Continuous hemodynamic monitoring was maintained for early detection of pericardial effusion.

Perioperative Adverse Events

Perioperative outcomes were adjudicated according to Valve Academic Research Consortium-2 (VARC-2) criteria. Major adverse events (MAEs) included procedure-related death, stroke, systemic embolism, device embolization requiring surgical retrieval, and major bleeding (Bleeding Academic Research Consortium [BARC] type ≥3). Device success was defined as successful implantation with ≤5 mm peri-device leak on intraoperative TEE.

Follow-up

Systematic follow-up included clinical evaluation and imaging assessment at 1-3 months and 6 months post-procedure. All patients underwent TEE and cardiac CTA during follow-up, with peri-device leaks quantified using multiplanar reconstruction (slice thickness 0.5 mm) and classified as mild (<1 mm), moderate (1-3 mm), or severe (>3 mm). Device-related thrombosis was defined as any thrombus adherent to the device or adjacent endocardial surface on TEE.

Statistical Analysis

Continuous variables are presented as mean ± standard deviation for normally distributed data or median (interquartile range) for non-normal distributions, compared using Student's t-test or Mann-Whitney U test as appropriate. Categorical variables are expressed as counts (percentages) and were compared with χ^2 test or Fisher's exact test. All statistical analyses were performed using SPSS version 20.0 (IBM Corp.), with two-tailed P-values <0.05 considered statistically significant.

Results

Patients

A total of 53 NVAF patients who underwent LAAC were included in this analysis, with 27 receiving the WATCHMAN device and 26 receiving the ACP device. Baseline clinical characteristics were well-balanced between groups, with no significant differences in demographic or clinical parameters (all P > 0.05, Table 1). The mean

Table 1: Demographic and baseline clinical characteristics of patients.

Baseline characteristics	WATCHMAN (*n*=27)	ACP (*n*=26)	*P* value
Age (years)	69.22±9.29	67.95±10.58	0.430
Male	19 (70.37%)	14 (70%)	0.978
CHA_2DS_2-VASc score	3.44±1.45	3.25±4.55	0.951
HAS-BLED score	3.11±0.97	2.15±1.04	0.501
Paroxysmal AF	10 (37%)	5 (25%)	0.381
Clinical features			
Coronary artery disease	14 (51.85%)	6 (30%)	0.134
Hypertension	23 (85.16%)	11 (40.74%)	0.22
Diabetes	7 (25.93%)	2 (10%)	0.170
Hyperlipidemia	1 (3.70%)	3 (15%)	0.170
Creatinine (mmol/L)	73.81±13.88	81.50±23.63	0.07
INR	1.25±0.52	1.61±0.81	0.06
Smoking	11 (40.74%)	6 (30%)	0.449
Drugs before the left atrial appendage is blocked			
Clopidogrel	8 (29.63%)	5 (25%)	0.726
Aspirin	12 (44.44%)	8 (40%)	0.761
Vitamin K antagonists	7 (25.93%)	7 (35%)	0.501
New oral anticoagulant drugs	0	2 (10%)	0.093
Beta blocker	16 (59.26%)	4 (20%)	0.07
Statins	10 (37.04%)	7 (35%)	0.886
Diuretics	4 (14.81%)	3 (15%)	0.986
ACEI	17 (62.96%)	11 (55%)	0.582
Factors related to bleeding risk			
Stroke / TIA	5 (18.52%)	5 (25%)	0.591
Preoperative bleeding	0	1(5%)	0.240
Kidney disease	0	1(5%)	0.240
Liver Disease	0	2(10%)	0.093
Unstable INR	2 (10%)	2 (10%)	0.753

Note: Continuous normally distributed variables are expressed as mean ± SD. Categorical variables are expressed as N (%).

Table 2: Intraoperative data.

	WATCHMAN (*n*=27)	ACP (*n*=26)	*P* value
Successful operation	26 (96.30%)	25 (96.15%)	0.828
Operation time (min)	120.44±46.63	130.70±38.53	0.094
Contrast agent dosage (ml)	270.37±91.20	360±131.39	0.221
fluoroscopy time (min)	41.85±16.78	51.80±38.85	0.015
Hospitalization time (day)	27±16	20±14.3	0.826

Note: Continuous normally distributed variables are expressed as mean ± SD. Categorical variables are expressed as N (%).

age was 69.2 ± 9.3 years in the WATCHMAN group and 68.0 ± 10.6 years in the ACP group (P = 0.430), with comparable CHA_2DS_2-VASc (3.44 ± 1.45 vs. 3.25 ± 1.04, P = 0.951) and HAS-BLED scores (3.11 ± 0.97 vs. 2.15 ± 1.04, P = 0.501).

Device Implantation and Procedural Outcomes

Successful device implantation was achieved in 96.3% (26/27) of WATCHMAN cases and 96.2% (25/26) of ACP cases (P = 0.828). The WATCHMAN group demonstrated significantly shorter fluoroscopy times compared to the ACP group (41.9 ± 16.8 vs. 51.8 ± 28.9 minutes, P = 0.015), representing a mean reduction of 9.95 minutes (95% CI: −18.2 to −1.7). Total procedure time (120.4 ± 46.6 vs. 130.7 ± 38.5 minutes, P = 0.094) and contrast volume (270.4 ± 91.2 vs. 360.0 ± 131.4 mL, P = 0.221) did not differ significantly between groups (Table 2).

Perioperative Adverse Events

MAEs occurred in one patient per group (3.7% vs. 3.8%, P = 0.828), with one device embolization requiring surgical retrieval in each cohort (Table 3). Minor complications included pericardial effusion (WATCHMAN: 25.9% [7/27] vs. ACP: 19.2% [5/26], P = 0.943) and pleural effusion (14.8% [4/27] vs. 11.5% [3/26], P = 0.986), all of which resolved spontaneously without intervention. One ACP patient developed a femoral artery pseudoaneurysm requiring surgical repair.

Follow-up Imaging Outcomes

Follow-up imaging (TEE/CTA) was completed in 74.1% (20/27) of WATCHMAN and 69.2% (18/26) of ACP patients at a mean of 55.4 ± 31.4 vs. 53.5 ± 27.1 days post-procedure (P = 0.954). Peri-device leaks were observed in 9.3% (2/27) of WATCHMAN and 3.8% (1/26) of ACP cases (P = 0.727), all classified as mild (<1 mm). No device-related thrombosis or thromboembolic events were detected in either group (Table 4).

Table 3: Perioperative adverse events.

	WATCHMAN (*n*=27)	ACP (*n*=24)	*P* value
Major adverse event			
Death	0	0	1
Stroke	0	0	1
Systemic arterial embolization	0	0	1
Myocardial infarction	0	0	1
Pericardial tamponade	0	0	1
Heavy bleeding	1	0	0.384
Surgery is required for device shedding	1	1	0.828
Other adverse events			
TIA	0	0	1
Pericardial effusion	7	5	0.943
Pleural effusion	4	3	0.986
Femoral artery pseudoaneurysm	0	1	0.240

Table 4: Follow-up results by TEE and atrial CTA.

	WATCHMAN (*n*=20)	ACP (*n*=18)	*P* value
Occluder-related thrombosis	0	0	1
Occluder embolism	0	0	1
Leakage around the occluder			
Severe	0	0	1
Moderate	0	0	1
Mild	2	1	0.727

Discussion

In the present study, we conducted a comprehensive comparison between the ACP and WATCHMAN occludes regarding their efficacy and safety profiles in LAAC procedures. Our analysis yielded several clinically relevant findings: First, the WATCHMAN device demonstrated a statistically significant reduction in fluoroscopy time compared to ACP (41.85±16.78 vs. 51.80±28.85 minutes, P=0.015), which directly translates to decreased radiation exposure for both patients and medical staff. This novel observation, not previously reported in the literature, may be attributed to the WATCHMAN's integrated delivery system design. Second, both devices showed comparable safety outcomes, with similar rates of perioperative adverse events (3.7% vs 3.8%, P=0.828) and major adverse events. Third, the occluder-related postoperative complications, including device thrombosis and peri-device leakage, were not significantly different between the two groups during follow-up.

The high implantation success rates observed in our study (WATCHMAN 96.30% vs ACP 96.15%) are consistent with previous large-scale clinical trials [8-10]. These findings reinforce the technical feasibility of both devices in clinical practice. Our findings also support earlier observations from a prospective comparative study showing no significant difference in device-related thrombosis between WATCHMAN and ACP [8].

A particularly noteworthy aspect of our findings relates to the procedural efficiency metrics. While total operation times were comparable between groups (120.44±46.63 vs 130.70±38.53 minutes, P=0.094), the significant reduction in fluoroscopy time with WATCHMAN use represents a meaningful clinical advantage. Each minute of reduced fluoroscopy time corresponds to approximately 0.1 mSv decrease in radiation exposure [11], suggesting that WATCHMAN may reduce cumulative radiation dose by nearly 1 mSv per procedure compared to ACP.

The safety profiles of both devices were reassuring in our study population. The incidence of pericardial effusion (WATCHMAN: 25.9%; ACP: 19.2%) and pleural effusion (14.8% vs 11.5%) were consistent with previous reports, and importantly, all cases resolved spontaneously without requiring invasive interventions. The absence of pericardial tamponade in our series compares favorably with some registry data, possibly reflecting improved procedural techniques or patient selection.

Interestingly, our study found lower rates of peri-device leakage (6.67% for ACP) compared to the 11.6% reported in the multicenter EUROPACE registry [5]. This discrepancy may be attributed to our more rigorous preprocedural planning using 3D reconstruction and the standardized application of PASS criteria during device deployment. The complete absence of device-related thrombosis

in our cohort, compared to the 3.7-4.4% rates reported in previous studies, may reflect differences in follow-up duration, imaging protocols, or antithrombotic regimens. These variations underscore the importance of standardized assessment methods in future comparative studies of LAAC devices [12,13].

Limitations

Several limitations should be considered when interpreting our findings. First, the nonrandomized, retrospective design may introduce selection bias despite our efforts to match baseline characteristics. Second, the relatively small sample size (n=53) limits the statistical power to detect differences in rare but clinically important endpoints such as stroke or mortality. Third, the single-center nature of this study may affect the generalizability of results to other practice settings. Fourth, the intermediate-term follow-up duration precludes assessment of long-term device performance and late complications. Finally, the lack of core laboratory adjudication for imaging endpoints may introduce variability in outcome assessment. These limitations highlight the need for larger, prospective multicenter studies with longer follow-up to confirm our observations.

Conclusions

This comparative study demonstrates that the WATCHMAN device significantly reduces fluoroscopy time during LAAC procedures compared to ACP, offering the practical advantage of decreased radiation exposure for both patients and operators. Importantly, both devices showed comparable safety profiles and procedural success rates in the short-term follow-up period. Our findings support the use of either WATCHMAN or ACP as effective options for stroke prevention in NVAF patients unsuitable for long-term anticoagulation. Future research should focus on multicenter randomized comparisons to validate these results across diverse populations, investigate long-term device performance, and evaluate newer generation occluders to further optimize LAAC outcomes. The choice between devices may ultimately depend on operator experience, institutional protocols, and individual patient characteristics.

Acknowledgments

This study was supported by the Hangzhou Health Science and Technology Plan (Major) Project (2017ZD02), Hospital Fund of Affiliated Hospital of Hangzhou Normal University (No.2021YN2021112), and Hangzhou Agricultural and Social Development Scientific Research Guidance Project (No.20220919Y021).

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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