Safety and efficacy of transcatheter left atrial appendage closure using the Watchman device in Egyptian patients with nonvalvular atrial fibrillation

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KEYWORDS
Transcatheter; Left atrial appendage closure; Atrial fibrillation

Abstract  Background: Atrial fibrillation (AF) is considered the major cause of stroke in the elderly. Alternative therapies to the anticoagulant therapy are warranted, particularly in patients who are ineligible or at high risk of bleeding. The left atrial appendage (LAA) is a prominent source of thrombi in nonvalvular AF, accounting for 90% of thrombi. As a result, surgical and transcatheter techniques have been explored to reduce the risk of stroke in patients with AF by occluding the LAA.

Objectives: To assess the safety and efficacy of LAA closure in patients with nonvalvular atrial fibrillation (AF) ineligible for warfarin therapy.

Methods: A prospective study that evaluated LAA closure with the Watchman device (Boston Scientific, Natick, MA; group A) in fifteen patients with nonvalvular AF and CHADS2 (congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, and prior stroke or transient ischemic attack) score ≥1, who were considered ineligible for warfarin therapy. The primary efficacy endpoint was the combined events of ischemic/hemorrhagic stroke, systemic embolism and cardiovascular/unexplained death during a period of six months follow-up.

Results: Successful closure of the LAA using the Watchman device was achieved in 15 patients (100%). The mean age was found to be 67.9 ± 9 years with 40% of them being males. No device or procedure related adverse events were detected. The mean CHADS2 score was 2.4 ± 0.8, while the mean CHA2DS2-VASC score was 4.4 ± 1.0. After a mean period of 8 ± 2 months of follow-up, no device dislodgement or device-related thrombi were documented. The all-cause stroke (ischemic and hemorrhagic) and systemic embolism were 0%. The device and procedure related mortality was found to be 0%. Only one patient died after 8 months of device implantation from pneumonia.

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1. Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia, and increases the risk of ischemic stroke 5-fold. AF-related ischemic stroke is associated with significant morbidity, mortality, and healthcare expenditures. Thus, prevention of cardioembolic stroke has a paramount clinical and economical importance.1–5

The left atrial appendage (LAA) has found considerable attention as a cause of cardioembolic stroke and echocardiographic studies have long documented spontaneous echo contrast or ‘smoke’ that indicates intracavitary blood stasis. Blackshear and Odel reviewed 23 studies that included patients with rheumatic and nonrheumatic atrial fibrillation. Distinct differences were noted in the frequency and distribution of LAA thrombus. In non-rheumatic atrial fibrillation, 91% of left atrial thrombi were isolated to or had originated in the LAA.6

This pathophysiology led to the widespread use of anticoagulant therapy, initially with warfarin, which has been proven to be superior to aspirin for stroke prevention.7 Multiple problems with warfarin have been identified, including bleeding, contraindications to its application, patient compliance, and the need for routine monitoring. Thus, it is estimated that anticoagulation is not currently used in up to 50% of eligible AF patients, which led to the development of new oral anticoagulants (NOACs), whose efficacy has been established in randomized clinical trials.

The risk of bleeding with approved doses of NOACs is either similar to warfarin, or, in the case of apixaban, lower, but rivaroxaban and dabigatran had an increased risk of gastrointestinal bleeding. In older patients or those with renal dysfunction, the bleeding risks associated with dabigatran were equal or greater than warfarin. This bleeding risk, combined with the perceived absolute or relative contraindications by the patient or physician, as well as issues with long-term compliance, cost, and the lack of widely available antidotes, represents substantial challenges for the management of stroke prevention in patients with AF.8–10

As an alternative to systemic anticoagulant therapy, the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients With AF) clinical trial examined the hypothesis that the “local” therapy of left atrial appendage (LAA) closure could achieve the benefits in stroke prevention observed with warfarin.11

The Watchman device proved to be noninferior to warfarin in preventing stroke in nonvalvular AF patients with a CHADS2 (congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, and prior stroke or transient ischemic attack) score ≥ 1. However, PROTECT AF only included patients who were candidates for either therapy, and in patients randomized to the LAA closure arm, patients received concomitant warfarin after Watchman implantation for 6 weeks.11,12

2. Aim of the study

The aim of this study was to evaluate the feasibility, safety and efficacy of transcatheter left atrial appendage (LAA) closure using the Watchman device in patients with nonvalvular atrial fibrillation (AF) especially those who were considered ineligible for anticoagulant therapy or had high bleeding risk.

3. Methodology

3.1. Study design and patients

A prospective registry included fifteen patients with nonvalvular atrial fibrillation ineligible for long term anticoagulant therapy or with high bleeding risk. LAA closure using the Watchman device was performed for all enrolled patients followed by at least 6 months follow-up.

- **Inclusion criteria:**
  - Patients with nonvalvular AF (paroxysmal, persistent or permanent).
  - Age > 18 years.
  - CHADS2 score ≥ 1
  - Patients with a contraindication for long term oral anticoagulant therapy or with a high risk of bleeding as indicated by the presence of at least one of the following criteria:
    - HAS-BLED score ≥ 3
    - Prior bleeding complication while using warfarin.
    - Major bleeding prior to using warfarin leading to markedly elevated risk of recurrence.
    - Walking instability with recurrent falls.
    - Inability to maintain INR levels within the therapeutic range with warfarin.
  - Patients who were able to verbally confirm understanding of risks, benefits and treatment alternatives of receiving left atrial appendage closure with the Watchman device and he/she or his/her legally authorized representative provided written informed consent prior to any related procedure.
  - Patients must agree to undergo all investigation plan.

- **Exclusion criteria:**
  - Intracardiac thrombus detected by transesophageal echocardiography (TEE).
  - An existing pericardial effusion > 3 mm.
3.2. Study device

The WATCHMAN device (Boston Scientific, Natick, Massachusetts) has a self expanding, open-ended, nitinol cage with tines to anchor the device in place. The body of the device, specifically the aspect exposed to the left atrium, is covered in a permeable polytetrafluoroethylene (PET). It comes in sizes of 21, 24, 27, 30, and 33 mm, and the appropriate device is chosen to be 2-4 mm greater than the maximum LAA ostium diameter.11

3.3. Study procedure

– Baseline transoesophageal echocardiography (TEE) was performed to assess the shape, size, and location of the appendage. LAA thrombus and pericardial effusion had to be excluded. The LAA length and ostial diameter were measured (must be between 17 and 31 mm).
– Under sedation anesthesia, TEE and fluoroscopic guidance, Watchman implantation was performed through traditional transseptal puncture and the Amplatz superstiff guidewire (Boston scientific) was positioned in the left upper pulmonary vein to be used as a rail. Anticoagulation was started immediately after transseptal puncture using heparin to achieve active clotting time (ACT) between 200 s and 300 s.11
– The device had to meet all four of the device release criteria, abbreviated as PASS:
  (1) Position: the plane of maximum diameter of the device should be at or just distal to the LAA ostium and span it completely. The position is confirmed via TEE and fluoroscopy. (2) Anchor or stability: the AS/DC assembly is withdrawn a few centimeters from the device. Gently pull back and then release deployment knob. The device and LAA should move in unison. Stability is confirmed via TEE and fluoroscopy. (3) Size: the plane of maximum diameter of the device is measured and should be 80–92% of the original size measured under TEE. (4) Seal: all lobes must be distal to the device and sealed under TEE. If any of the release criteria were not met, the device could always be recaptured partially or completely.11
– After the procedure, patients had to remain on warfarin (INR 2.0–3.0) and 81 mg aspirin for a minimum of 45 days (except those with absolute contraindication for anticoagulant therapy). Then, device placement was confirmed with TEE, patients discontinued warfarin and began clopidogrel 75 mg and aspirin daily for 6 months after implantation and remained on daily aspirin indefinitely.11 This regimen might change according to the clinical situation as assessed by the physician.
– Short term follow-up was done during hospitalization after the procedure and included clinical examination, electrocardiography, transthoracic echocardiography (TTE) and other needed investigations to detect any possible complication.
– Long term follow-up was done for 6 months through monthly visits. On each visit, the patient was subjected to full clinical examination, TTE and any other investigation needed based on history and physical examination. A TEE was performed at 45 days and 6 months to assess device position, peri-device LAA flow, and device related thrombus. Neurological consultation was done on each visit and any requested investigations were performed. The National Institutes of Health stroke scale was administered by a neurologist at baseline, 3 and 6 months.13

3.4. Definitions

– The CHADS2 score (scale 0–6) includes congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, and prior stroke or transient ischemic attack (TIA [2 points]). The CHA2DS2-VASc score (scale 0–9) includes the same components but with 2 points for age ≥ 75 years and the addition of 1 point for vascular disease, age 65–74 years, or female sex.14
– Contraindications for oral anticoagulant use (based on the warfarin labeling) were categorized as follows:
  • Hemorrhagic/bleeding tendencies defined as active peptic ulcer disease or history of overt bleeding of the gastrointestinal, genitourinary, or respiratory tract; central nervous system hemorrhage, cerebral aneurysms, dissection of the aorta, pericarditis/pericardial effusions or bacterial endocarditis.
  • Blood dyscrasias.
  • Unsupervised patients with senility and/or high fall risk.
  • Other documented reason (including hypersensitivity to warfarin).
– The composite primary efficacy endpoint included ischemic stroke, hemorrhagic stroke, systemic embolism, cardiovascular or unexplained death. The composite primary safety endpoint included the occurrence of death, bleeding, procedure or device-related events e.g. pericardial effusion, stroke or device embolization within 7 days of the procedure.
– A serious adverse event included any untoward medical condition that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, required major cardiovascular or endovascular intervention or resulted in persistent or significant disability/incapacity.

3.5. Statistical analysis

This is a feasibility study designed to provide preliminary information on the performance of the Watchman LAA closure device in patients with nonvalvular AF. The sample size was not defined on the basis of an end-point hypothesis but rather to provide information on device performance. For binary variables, percentages were calculated. When provided, the 95% confidence intervals were computed with the gaussian approximation, taking into account the paired analysis. Paired comparisons between post-procedural and follow-up results were done by a Wilcoxon signed-rank test.

4. Results

4.1. The baseline clinical characteristics

Demographic data, cardioembolic and bleeding risk factors of patients enrolled in this study are listed in Table 1. The age of
the study population ranged from 57 to 84 years with a mean of 67.9 ± 9 years, and 40% of them were males. The most common risk factor for stroke was hypertension (80%), and 26.6% of patients previously had an ischemic stroke/TIA. Only two patients had paroxysmal AF and all other patients had permanent AF. These patients were selected after screening of 42 patients. The excluded patients did not meet the inclusion criteria especially being ineligible for long term anticoagulant therapy or refusing device implantation (see Fig. 1).

The mean CHADS2 score was found to be 2.4 ± 0.8, and 93.2% of patients had a CHADS2 score ≥ 2. However, the mean CHA2DS2-VASC score was 4.4 ± 1.0 and all patients had a CHA2DS2-VASC score ≥ 2. High bleeding risk (HAS-BLED score ≥ 3) was estimated in 86.6% of the enrolled patients (Table 2 and Fig. 2).

High (HAS-BLED Score) was the most common reason for device implantation (86.6%). Moreover, nine patients (60%) had history of previous bleeding (2 cerebral, 3 gastrointestinal, 2 urinary tract, 1 piles and 1 subcutaneous hemorrhage). In addition, three patients had unsupervised senility and high fall risk (20%), and one patient suffered from thromboembolism despite target INR (6.7%) (Fig. 3). It should be noted that some patient had more than one indication for LAA occlusion.

4.2. The procedural details

The procedural details are listed in Table 3. The mean procedure time was 56.8 ± 10 min. Successful device implantation was done in all patients (100%). Difficult implantation occurred in only one patient due to anatomical considerations (cauliflower LAA with a large oval ostium), and the device was introduced but did not meet the device release criteria. Therefore, partial recapture was done and the device was repositioned and successfully deployed. The majority of implanted devices (73.3%) were either 24 mm or 27 mm in size (Table 3 and Fig. 4). No procedure or device related adverse events were noted during the procedure or during post-procedural hospitalization apart from a small inguinal hematoma in one patient related to the femoral access that resolved completely after 48 h without requiring any surgical interference.

4.3. The anti-thrombotic medication regimen

The majority of cases (87%) received warfarin prior to device implantation. Aspirin and warfarin were administered during

<table>
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<tr>
<th>Table 1 Baseline characteristics of the study population.</th>
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<tbody>
<tr>
<td>Demographic information</td>
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<tr>
<td>Age (yrs) 67.9 ± 9</td>
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<tr>
<td>Male (%) 40%</td>
</tr>
<tr>
<td>Stroke risk factors</td>
</tr>
<tr>
<td>Heart failure or reduced ejection fraction 20%</td>
</tr>
<tr>
<td>Hypertension 80%</td>
</tr>
<tr>
<td>Age ≥ 75 yrs 26.6%</td>
</tr>
<tr>
<td>Diabetes Mellitus 66.6%</td>
</tr>
<tr>
<td>Prior stroke or TIA 26.6%</td>
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<tr>
<td>Vascular disease 66.6%</td>
</tr>
<tr>
<td>Age 65–74 yrs 46.6%</td>
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<tr>
<td>Female 60%</td>
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<tr>
<td>Additional bleeding risk factors</td>
</tr>
<tr>
<td>Abnormal renal function 33.3%</td>
</tr>
<tr>
<td>Abnormal liver function 13.3%</td>
</tr>
<tr>
<td>Bleeding tendency 53.3%</td>
</tr>
<tr>
<td>Labile INR 13.3%</td>
</tr>
<tr>
<td>Drug therapy (that increases risk of bleeding) 73.3%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2 Thromboembolic and bleeding risks.</th>
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<tbody>
<tr>
<td>CHADS2 score CHA2DS2-VASC score HASBLED score</td>
</tr>
<tr>
<td>Score Patients (%) Score Patients (%) Score Patients (%)</td>
</tr>
<tr>
<td>1 6.6 1 0 1 0</td>
</tr>
<tr>
<td>2 53.3 2 0 2 13.3</td>
</tr>
<tr>
<td>3 26.6 3 13.3 3 40</td>
</tr>
<tr>
<td>4 13.3 4 46.6 4 3.33</td>
</tr>
<tr>
<td>5 0 5 26.6 5 13.3</td>
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<td>6 0 6 6.6 6 0</td>
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<tr>
<td>7 6.6 7 0</td>
</tr>
<tr>
<td>8 0 8 0</td>
</tr>
<tr>
<td>9 0 9 0</td>
</tr>
<tr>
<td>Mean CHADS2 score 2.4 ± 0.8</td>
</tr>
<tr>
<td>Mean CHA2DS2-VASC score 4.4 ± 1.0</td>
</tr>
<tr>
<td>Mean HASBLED score 3.4 ± 0.9</td>
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</table>

Figure 1 The Watchman device.12
the first 45 days after the procedure in 73% of patients. Afterward, aspirin and plavix were given till 6 months in 87% of cases and then aspirin was taken indefinitely by 80% of patients (Table 4 and Fig. 5).

4.4. Follow-up outcomes

The mean duration of follow-up was 8 ± 2 months, and the overall compliance with follow-up visits was 100%. Clinical follow-up revealed no device or procedure related adverse events. Furthermore, all-cause stroke (ischemic and hemorrhagic) and systemic embolism were not documented in any patient (0%). No device or procedure related mortality has been observed. Only one patient died 8 months after device implantation from pneumonia (he was 53 years old, had previous multiple strokes despite optimum anticoagulation and was bed ridden) (see Fig. 6).

Transesophageal echocardiographic follow-up showed well positioned device in all patients with no dislodgement or device related thrombus. A nonsignificant leak (3 mm) was observed in only one patient.

5. Discussion

This study reports, for the first time in Egyptian patients, high acute implantation success rates of Watchman LAA closure system despite variable anatomy and different device sizes in conjunction with an acceptable procedural risk. Importantly, the vast majority of the “high risk” patients included in our registry was able to switch to “stand alone” ASA therapy after 6 weeks of combined anticoagulation therapy without any increase in the incidence of stroke or systemic embolization.
5.1. Patient population and implantation success

The first prospective, randomized trial investigating Watchman LAA closure device was PROTECT AF trial in which 707 patients with NVAF were randomly assigned in a 2:1 ratio to either percutaneous LAA occlusion with the WATCHMAN device or to warfarin therapy. The study was designed to assess the non-inferiority of the device against chronic OAC therapy. Patients with paroxysmal, persistent or permanent NVAF were eligible for enrollment if they had a CHADS2 risk score ≥ 1. The trial confirmed the non-inferiority of WATCHMAN LAA occlusion compared with OAC therapy regarding the primary efficacy endpoint—a composite of stroke, systemic embolism and cardiovascular death (RR = 0.62, 95% CI 0.35–1.25). The probability of non-inferiority of the intervention was >99.9%.

However, Protect AF included “nonhigh risk” stroke patients and all patients were still eligible to OAC and therefore continued warfarin for at least 45 days after the procedure.

In our registry, in contrast to Protect AF trial, the mean CHA2DS2-VASC score was 4.4 ± 1.0 and all patients had a CHA2DS2-VASC score ≥ 2. High bleeding risk (HAS-BLED score ≥ 3) was estimated in 86.6% of the enrolled patients. The expected annual risk of stroke based on the CHADS2 score in our study cohort was calculated to be

<table>
<thead>
<tr>
<th>Antithrombotic medication used</th>
<th>Number of patients</th>
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<tr>
<td></td>
<td>Baseline (n = 15)</td>
</tr>
<tr>
<td>ASA + Plavix + Marevan</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>ASA + Plavix</td>
<td>2 (13%)</td>
</tr>
<tr>
<td>ASA + Marevan</td>
<td>7 (47%)</td>
</tr>
<tr>
<td>Marevan</td>
<td>4 (27%)</td>
</tr>
<tr>
<td>ASA</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Plavix</td>
<td>0 (0%)</td>
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</table>

**Table 4** Antithrombotic medications.
Safety and efficacy of transcatheter left atrial appendage closure

4.9%/year and 2.4%/6 months. In contrast, no strokes have occurred in any of the patients in this study despite discontinuation of anticoagulation in all patients after 45 days and an average follow-up of 8 ± 2 months.

It is also of particular interest that in Protect AF, acute device implantation failed in 9% (41/449 patients) due to various reasons but Watchman device implantation has been reported to be difficult in specific LAA anatomies such as a shallow landing zones. It has also been recognized that human LAA anatomy may be highly variable. Multiple lobes and short LAA diameters may negatively impact successful LAA occluder positioning and implantation.

Contrary to Protect AF, several recent registries including those performed by Kim et al. and Swaans et al. reported 100% success rate of device implantation with better utilization of imaging modalities and careful selection of device size as well as the effect of progressive learning curve of the operators. In our registry as well, the device was implanted successfully in all of our patients. Notably, the procedure time declined gradually with the increased experience of our operators.

5.2. Procedural safety and short-term outcome

In our registry no major device or procedure related adverse events were observed. The all-cause stroke was estimated to be 0% with no reported cases of device related mortality. Only one patient died 8 months after the procedure due to pneumonia without any device related complications.

In the pivotal PROTECT AF trial, an early safety hazard was identified: an increase in peri-procedural events of pericardial effusions, which did not result in mortality but only prolonged hospital stay. A risk for peri-procedural stroke was also identified, usually the result of air embolization during catheter placement. Longer term follow-up of PROTECT AF has confirmed the efficacy of LAA occlusion. At a mean follow-up of 2.3 ± 1.1 years, the primary efficacy endpoint remained non-inferior for device (probability of non-inferiority > 0.999).11

Within the early and late PROTECT AF experience, as well as the CAP Registry, procedural/device related safety events (including pericardial effusions) declined significantly, suggesting that the procedural safety of Watchman implantation improved with increasing experience.12

The more recent PREVAIL (Prospective Randomized Evaluation of the Watchman LAA Closure Device In Patients With Atrial Fibrillation versus Long Term Warfarin Therapy) documented the following findings in patients with NVAF at risk for stroke: (1) procedural complications occurring after Watchman LAA occlusion were infrequent and significantly improved compared with the PROTECT AF trial; (2) Watchman LAA occlusion was non-inferior to chronic warfarin for the prevention of stroke and SE beginning 1 week after randomization, consistent with the hypothesis that the LAA is the nidos for embolism in AF; and (3) the primary efficacy endpoint of early and late events was similar and did not achieve non-inferiority with the Watchman device. Overall event rates were lower than expected, which may have contributed to this last finding.13

The lower rates of periprocedural major adverse events in recent trial as well as our registry can be ascribed to a better understanding of the procedure and an operator learning curve effect.

5.3. Post-procedural considerations and anti-coagulant regimens

Various antithrombotic regimens have been used after LAA closure. In the PROTECT AF trial, OAC was given for 45 days and patients discontinued OAC if the 45-day TEE control showed either complete closure of the LAA or if the jet width of the residual peridevice flow was < 5 mm. After stopping OAC therapy, patients were given dual antiplatelet therapy (DAPT) with acetylsalicylic acid (ASA) and clopidogrel until completion of the 6-month TEE control, after which ASA monotherapy was continued indefinitely. In 14% of patients, OAC was continued beyond 45 days, and in 8% of patients, OAC was continued beyond 6 months because of incomplete LAA closure or device thrombosis.11

Nevertheless, PROTECT AF trial did not address the safety and efficacy of LAA occlusion in patients with a high thromboembolic risk (CHA2DS2-VASc score of > 2) in whom anticoagulation is believed to be either relatively or absolutely contraindicated. Hence, our registry included this important category of the AF patients and represents the first prospective study of LAA closure with the Watchman device in the clinically important population of Egyptian patients with nonvalvular AF who are ineligible for oral anticoagulation therapy or with high risk of bleeding.

It is worth mentioning that, although 80% of our patients received warfarin for the first 45 days after the device implantation, 20% of cases received only antiplatelet therapy (13% dual antiplatelet therapy and 7% clopidogrel alone) due to contraindication to warfarin. Notably, the clinical outcome did not show a significant difference with no reported strokes or systemic embolization events, which may explicit the device efficacy even in the absence of anticoagulant therapy following implantation.

A population similar to ours was evaluated in the observational ASAP (ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology) study, a multicenter, prospective, nonrandomized study which included 150 patients with nonvalvular AF and CHADS2 score ≥ 1, who were considered ineligible for warfarin therapy. The study reported that WATCHMAN implantation can be safely performed without OAC transition and that DAPT prescribed for 6 months followed by ASA alone may be an adequate antithrombotic regimen.18

It should be noted that dual antiplatelet therapy (DAPT) when given for 6 months followed by lifelong single antiplatelet therapy, generates a major bleeding risk comparable to that of warfarin.19 However, DAPT exposure following LAA occlusion is only for short time, thus reducing the cumulative risk of major bleeding events. In our registry cohort, DAPT was abandoned after 6 months in 93% of cases, and single antiplatelet therapy was continued (aspirin or clopidogrel in 80% and 13% of cases respectively).

Although 13% of patients in our study continued DAPT for longer periods due to other indications (i.e. coronary artery disease and recent PCI using DES), this strategy (LAA closure plus DAPT) was supposed to offer less bleeding risk than using triple antithrombotic therapy (warfarin plus DAPT) and more thromboembolic protection than using DAPT alone, taking into consideration that this specific group of patients had high both thromboembolic and bleeding risks according to the CHADS2-VASc and HAS-BLED scores.20,22 Eventually, this

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strategy resulted in neither increase in ischemic events nor increase in bleeding complications.

5.4. TEE follow-up and the impact of residual perdevice leaks

Transesophageal echocardiographic follow-up in our registry showed well positioned device in all patients with no dislodgement or device related thrombus. A nonsignificant leak (3 mm) was observed in only one patient.

Perdevice leaks are typically evaluated by color Doppler (TEE) and classified as follows: (1) severe—multiple jets or free flow; (2) major—jet width > 3 mm; (3) moderate—jet width of 1–3 mm and (4) minor—jet width <1 mm. Major residual leaks have been reported in as many as 32% of the patients after WATCHMAN device implantation. Most importantly, however, the presence of residual perdevice leaks has never been associated with cardioembolic events in any of Watchman studies.

6. Study limitations

This study was a non-randomized feasibility trial primarily designed to test the safety of the implantation procedure. The study size was not intended to be of sufficient power to evaluate efficacy. The absence of a control or alternative treatment group and utilizing historical control data to predict the expected stroke rates are considered another limitation.

7. Conclusion

LAA occlusion with the WATCHMAN device appears to be safe with preliminary results suggesting low stroke risk despite discontinuation of anticoagulation. Thus, percutaneous LAA occlusion can be considered as an alternative treatment strategy to long-term anticoagulation for patients at greatest clinical need for an alternative to oral anticoagulation therapy like AF patients at high risk for stroke but with contraindications to systemic oral anticoagulation or high bleeding risk.

Conflict of interest

The authors declare that they have no conflict of interest.

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