Original paper

Safety and efficacy of percutaneous atrial appendage closure followed by antiplatelet therapy in a high-risk population: single-center experience with a WATCHMAN device

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Abstract

Introduction: In our everyday practice we encounter many patients with non-valvular atrial fibrillation with either a contraindication to oral anticoagulation or with its inefficiency.

Aim: To investigate whether left atrial appendage closure (LAAC) followed by post-procedure antiplatelet therapy is safe and efficient in a high-risk population.

Material and methods: Ninety-one (48 males) consecutive patients with non-valvular atrial fibrillation (NVAF) underwent an LAAC procedure using a first-generation WATCHMAN 2.5 device followed by antiplatelet therapy. Clinical and transesophageal echocardiography data were collected at baseline and at the follow-up visit.

Results: The median (IQR) CHA_2DS_2-VASc score was 5 (4.0–6.0) and the HAS-BLED score was 3 (3.0–4.0); the mean (SD) age was 74.4 (8.4). A bleeding history was observed in 89% of patients and 24.2% of patients had a history of stroke or transient ischemic attack (TIA). The procedure was successful in 98.9%. Post-procedure therapy was dual antiplatelet therapy in 85 patients; 3 patients received single antiplatelet therapy and the therapy was maintained until the follow-up visit. Peri-procedural complications were tamponade (3.3%), pericardial effusion (2.2%) and two deaths (2.2%) with no bleeding or vascular complications. The median follow-up was 67 (52.75–84.75) days. Primary safety endpoint (bleeding BARC type 3 or more, tamponade, pericardial effusion, and device embolization) and primary efficacy endpoint (stroke or TIA, hemorrhagic stroke, peripheral embolism, cardiovascular (CV) and non-CV death) were observed in 2 and 4 patients, respectively.

Conclusions: The LAAC procedure followed by antiplatelet therapy seems to be safe and efficient in the high-risk population. Further studies in this field are required.

Key words: antiplatelet therapy, atrial fibrillation, stroke prevention, left atrial appendage closure.

Summary

Nowadays left atrial appendage closure is a vigorously developing method of stroke prevention in patient with non-valvular atrial fibrillation. The most challenging group consists of high-risk patients. In this population, on the one hand we must cope with the high bleeding risk but on the other hand we have high risk of thromboembolic complication. Moreover, we do not have exact recommendations regarding the optimal post-procedure treatment. Our study suggests that the left atrial appendage closure procedure followed by antiplatelet therapy is safe and efficient in a high-risk population.

Introduction

Atrial fibrillation (AF) is the most commonly diagnosed arrhythmia, and its prevalence increases with the population's age [1]. It is proved that AF is responsible for up to 20% of ischemic strokes, which are associated with worse prognosis compared to those due to other etiologies [2]. Oral anticoagulation (OAC) therapy, with vitamin-K antagonist (VKA) or with new oral anticoagu-

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lants (NOACs), remains the standard strategy to reduce the risk of ischemic events [3]. However, the application of OAC therapy carries increased risk of bleeding complications. Data show that about 40% of patients who require OAC do not receive the treatment despite the introduction of potentially safe drug therapies [4].

Left atrial appendage closure (LAAC) is the non-pharmacological option for stroke prevention in patients with non-valvular AF who are not good candidates for long-term OAC therapy. The development of the procedure was based on finding that approximately 90% of cardioembolic strokes in AF originate from a thrombus that developed in the left atrial appendage (LAA) [5]. Two randomized trials, PROTECT-AF and PREVAIL, have shown the non-inferiority of LAAC with a WATCHMAN device (Boston Scientific, Marlborough, MA, USA) to warfarin therapy in AF patients [6, 7]. The 5-year outcomes of the trials demonstrated that LAAC with the WATCHMAN provides stroke prevention comparable to warfarin, with additional reduction in major bleeding [8]. These trials included patients without an absolute contraindication to OAC, so warfarin was used after successful device deployment. Current European guidelines recommended LAAC in patients with AF and contraindications to long-term anticoagulant treatment (class IIb indication, level of evidence B) [9]. The same guidelines also recommend antiplatelet therapy after the procedure in patients with high bleeding risk, and this antithrombotic management has never been assessed in a randomized trial [9].

The choice of the antithrombotic regimen after the LAAC procedure seems to be a crucial issue. On the one hand, we must consider the bleeding risk of the patient, but on the other hand, we cannot forget about the possible thromboembolic complications. Nowadays, we have limited data on optimal treatment after the LAAC procedure in a high-risk population.

Aim

The aim of this study was to evaluate the safety and efficacy of the LAAC procedure with the first-generation WATCHMAN 2.5 device followed by an antiplatelet regimen in a high-risk population.

Material and methods

Study population

In our retrospective analysis we included 91 consecutive patients who were scheduled for the LAAC procedure with a WATCHMAN device from March 2015 to September 2019 in a single center (First Department of Cardiology, University Clinical Center, Warsaw, Poland). All patients were diagnosed with non-valvular AF and were at high thromboembolic risk assessed by the CHA_2DS_2-VASc score. Furthermore, all patients who underwent the procedure had one of the following: a contraindication for oral anticoagulation, history of bleeding complication while using oral anticoagulation, inability to maintain INR level within the therapeutic range, history of stroke while using oral anticoagulation. Exclusion criteria included presence of thrombus in the left atrial appendage, inappropriate size of the left atrial appendage in preprocedural transesophageal echocardiography (TEE), and lack of patients' consent.

At admission, all patients underwent medical evaluation with laboratory testing, and calculation of the CHA_2DS_2-VASc score and bleeding scores such as HAS-BLED, ORBITA and ATRIA. At baseline, in all patients the TEE was performed to exclude the presence of thrombus in the LAA, to assess the feasibility of the procedure and to determine the size of the device.

LAAC procedure

All procedures were performed under general anesthesia with TEE and fluoroscopic guidance. The transcatheter access was the right femoral vein in all patients and then under TEE guidance the transseptal puncture was made to access the left atrium. Each patient received intravenously unfractionated heparin (UFH) at a dose of 1000 U/10 kg to continue the procedure with prolonged activated clotting time (ACT) to at least 250 s. Half of the dosage was given before transseptal puncture and the rest after crossing the intraatrial septum. Following introduction of the sheath into the LAA, the angiographic projection with contrast injection was obtained to evaluate the shape of the LAA. The assessment of LAA anatomy and landing zone was based on acquired angiographic planes and TEE visualization, so the most suitable size of the device could be chosen. When the proper position of the WATCHMAN introduction system was obtained, the first-generation WATCHMAN 2.5 device (Boston Scientific, St. Paul, Minnesota) was deployed under TEE and angiographic guidance. After device implantation, a stability test was performed before its final release. Contrast angiography and color Doppler in TEE were used to eliminate peri-device leaks. Peri-device jet size of 5 mm or more was classified as a significant leak. If needed, recapturing and reimplantation were done. Within 24 h all patients underwent transthoracic echocardiography (TTE) to exclude peri-procedural complications, such as pericardial effusion, as well as to confirm WATCHMAN device position.

Antithrombotic regimen and follow-up

All patients were treated with dual antiplatelet therapy (DAPT) (aspirin 75 mg and clopidogrel 75 mg once a day) or with single antiplatelet therapy (SAPT) (aspirin 75 mg or clopidogrel 75 mg once a day). The treatment regimen was at the discretion of the implanting physician and was maintained until follow-up examination. The treatment regimen choice was guided by patients' medical history, risk scores, and operators' experience.

All patients were clinically evaluated approximately 3 months after the procedure, preferably by in-hospital visit. We excluded from follow-up visits patients who had unsuccessful device implantation. The follow-up TEE was planned during the same visit. If the patient refused to come, the clinical evaluation was done by telephone contact.

Clinical events

Procedural success was defined as a successful deployment of the device that fulfilled all release criteria and an absence of significant peri-device leak, i.e. less than 5 mm as assessed by intra-procedural imaging.

Bleeding events were assessed according to the Bleeding Academic Research Consortium (BARC) definitions [10]. Major bleeding, i.e. that classified as BARC type 3 or more, was overt bleeding requiring blood transfusion or bleeding with hemoglobin drop of ≥ 3 g/dl, cardiac tamponade, bleeding requiring surgical intervention or use of vasoactive agents, intracranial or intraocular bleeding and fatal bleeding.

Peri-procedural adverse events were defined as events that occurred within 7 days after the procedure or before patients' discharge.

Primary safety and efficacy endpoints at follow-up were defined following the Valve Academic Research Consortium consensus [11]. For a more accurate assessment of events related to the postoperative treatment regimen, the peri-procedural events were excluded.

The primary safety endpoint at follow-up was a composite of bleeding BARC type 3 or more, tamponade, pericardial effusion, and device embolization.

The primary efficacy endpoint at follow-up was a composite of stroke or TIA, hemorrhagic stroke, peripheral embolism, cardiovascular (CV) and non-CV death.

The TEE-guided secondary endpoint was the device-related thrombus (DRT).

Table I. Baseline characteristics

Parameter	Value
Age [years]	74.4 ±8.4
Male	53% (48/91)
BMI [kg/m^2]	27.4 ±4.4
Atrial fibrillation:	
Paroxysmal/persistent	60% (55/91)
Permanent	40% (36/91)
Hypertension	87.9% (80/91)
Congestive heart failure	52.7% (48/91)
Diabetes mellitus	39.6% (36/91)
COPD	13.2% (12/91)
Chronic kidney disease:	64.8% (59/91)
Stage 3a	31.9% (29/91)
Stage 3b	23.1% (21/91)
Stage 4	9.9% (9/91)
Stage 5	0% (0/91)
History of ischemic stroke/TIA	24.2% (22/91)
History of hemorrhagic stroke	9.9% (9/91)
Vascular disease	40.7% (37/91)
History of bleeding	89% (81/91)
CHA_2DS_2-VASc score	4.7 ±1.6
HAS-BLED score	3.2 ±0.9
ORBITA score	4.4 ±2
ATRIA score	4.4 ±2.6
OAC before procedure:	
VKA	9.9% (9/91)
NOAC	15.4% (14/91)
LMWH	25.3% (23/91)
SAPT	9.9% (9/91)
DAPT	7.7% (7/91)
None	31.9% (29/91)

Unless indicated otherwise, data are given as the mean (standard deviation), median (interquartile range) or as n (%). BMI – body mass index, COPD – chronic obstructive pulmonary disease, DAPT – dual antiplatelet therapy, LMWH – low molecular weight heparin, NOAC – new oral anticoagulation, OAC – oral anticoagulation, SAPT – single antiplatelet therapy, TIA – transient ischemic attack, VKA – vitamin K antagonist.

Statistical analysis

Categorical variables are presented as counts and percentages. Continuous variables are presented as mean with standard deviation (SD) if normally distributed or otherwise by median and interquartile range. All statistical analyses were conducted with SPSS Statistics, version 22 (IBM SPSS Statistics, New York, US).

Results

Patient characteristics

A total of 91 patients were included in the analysis. Baseline demographics and risk factors are summarized in Table I. Fifty-three percent of the patients were male, and the mean (SD) age was 74.4 (8.4). Most patients (87.9%) had a history of hypertension, and more than a half (52.7%) were diagnosed with heart failure. Chronic kidney disease with glomerular filtration rate (GFR) < 60 ml/min/1.73 m^2 was observed in almost 65% of our patients. Type II diabetes mellitus and vascular disease were present in 39.6% and 40.7% of subjects, respectively. Based on the CHA_2DS_2-VASc risk score, patients enrolled in the study were at high risk of thromboembolic complication with a median (IQR) CHA_2DS_2-VASc score of 5 (4.0–6.0). Almost one fourth (24.2%) of the subjects had a history of stroke or TIA. Moreover, most of the patients (89%) had a history of bleeding and 86.8% of patients had a HAS-BLED score of 3 or more. At baseline, half of the subjects (50.5%) were on OAC therapy with either VKA, NOAC or low molecular weight heparin (LMWH), 9.9% were on single antiplatelet therapy (SAPT), 7.7% were on dual antiplatelet therapy, and 31.9% were not on any form of antithrombotic regimen.

Table II. Transesophageal echocardiography parameters

Parameter	Value
Rhythm:	
Sinus	49.5% (45/91)
Atrial fibrillation	50.5% (46/91)
Thrombus in LAA	0% (0/91)
SEC	16.5% (15/91)
LAA flow velocity [cm/s]	53.2 ±32.3
Ostium diameter [mm]:	
0°	20.1 ±3.2
45°	19.6 ±2.6
90°	19.3 ±3.2
135°	20.2 ±3.1
Depth of LAA [mm]	29.5 ±5.6

Unless indicated otherwise, data are given as the mean (standard deviation), median (interquartile range) or as n (%). LAA – left atrial appendage, SEC – spontaneous echo contrast.

A history of bleeding during OAC therapy occurred in 81 patients, and it was the most common indication for the LAAC procedure. Three patients had a history of stroke during OAC therapy, 2 patients were diagnosed with vascular pathologies (one cavernous hemangioma in the occipital lobe and one cerebral arteriovenous malformation), which were contraindications to initiate OAC therapy. The other indications were labile INR (n = 3), recurrent thrombus in the left atrial appendage (LAA) despite different OAC regimen (n = 1) and intolerance of OAC therapy (n = 1).

All patients had TEE before the procedure. No thrombus in the LAA was found and the spontaneous echo contrast (SEC) was observed in 15 patients. Detailed data of LAA are presented in Table II.

Procedural and peri-procedural details

The procedural data are shown in Table III. All procedures were performed under general anesthesia and in 98.9% of the cases the device was implanted successfully, comparing favorably with rates reported in the previously published first-generation WATCHMAN trial (Figure 1). In 1 patient the device could not be implanted due to unfavorable LAA anatomy. In 26 cases the device had to be partially recaptured because of its unstable position, and in only 3 patients the full recapture was necessary. In all 3 cases the device size was changed to a bigger size. Complete sealing of the LAA was achieved in 81% of cases. Peri-device leaks were observed in 17 cases, and in all cases the residual flow was < 5 mm assessed with peri-procedural TEE. The median size of the device and its compression after deployment were 27 mm (24.0–20.0) and 16.67% (14.81–20.21), respectively.

All peri-procedural serious adverse events (SAEs) are summarized in Table IV. Major bleeding assessed as BARC ≥ 3 was observed in 3 cases excluding tamponade. In the peri-procedural period 3 tamponade occurred, out of which one was during the procedure and was treated successfully by pericardiocentesis after the device deployment. Another 2 were observed several hours after the procedure. One was treated with pericardiocentesis, and the other one required surgical drainage of the pericardial sac. Moreover, 2 cases of mild pericardial effusion were observed and were treated conservatively. A day after the procedure one device embolization was observed during follow-up TTE, which required cardiac surgery and resulted in death. One more death occurred 1 week after

Table III. Procedural data

Variable	Value
Successful deployment	98.9% (90/91)
Rhythm during procedure:	
Sinus	46.2% (42/91)
Atrial fibrillation	53.8% (49/91)
General anesthesia	100% (91/91)
Procedure time [min]	77.6 ±19.3
Fluoroscopy time [min]	17.5 ±7.9
Fluoroscopy dose [mGy]	669.3 ±458.2
Contrast agent [ml]	124 ±49.3
Size of device [mm]	29.5 ±5.6
Partial recapture:	28.6% (26/91)
One	69% (18/26)
Two	27% (7/26)
Three	4% (1/26)
Full recapture	3.3% (3/91)
Change in size of the device	3.3% (3/91)
Compression (%)	17.6 ±4.8
LAA seal:	
Complete seal	81% (73/90)
Jet size 1–2 mm	14.5% (13/90)
Jet size 3–4 mm	4.5% (4/90)
Jet size 5 and more	0% (0/90)

Unless indicated otherwise, data are given as the mean (standard deviation), median (interquartile range) or as n (%). Abbreviations: see Table II.

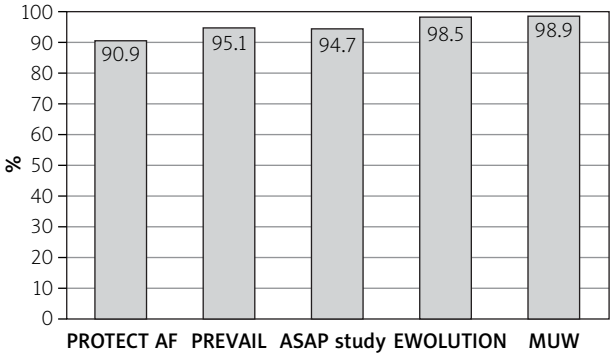

Figure 1. Device deployment success in Medical University of Warsaw (MUW) compared to previous WATCHMAN device studies

Table IV. Peri-procedural serious adverse events

Variable	Value
Serious bleeding BARC ≥ 3	3.3% (3/91)
Tamponade	3.3% (3/91)
Pericardial effusion	2.2% (2/91)
Ischemic stroke	0% (0/91)
TIA	0% (0/91)
Hemorrhagic stroke	0% (0/91)
Systemic embolization	0% (0/91)
Air embolization	0% (0/91)
CV death	1.1% (1/91)
Non-CV death	1.1% (1/91)

*Unless indicated otherwise, data are given as the mean (standard deviation), median (interquartile range) or as n (%). BARC – Bleeding Academy Research Consortium, CV – cardiovascular, non-CV – non-cardiovascular. *excluding tamponade.*

Table V. Primary safety and efficacy outcomes at follow-up

Variable	Value
Primary safety endpoints:	2.2% (2/88)
Serious bleeding BARC ≥ 3	2.2% (2/88)
Tamponade	0% (0/88)
Pericardial effusion	0% (0/88)
Device embolization	0% (0/88)
Primary efficacy endpoints:	4.5% (4/88)
Ischemic stroke	1.1% (1/88)
Hemorrhagic stroke	0% (0/88)
Systemic embolization	0% (0/88)
CV death	1.1% (1/88)
Non-CV death	2.2% (2/88)

Unless indicated otherwise, data are given as the mean (standard deviation), median (interquartile range) or as n (%). BARC – Bleeding Academy Research Consortium, CV – cardiovascular, non-CV – non-cardiovascular.

the procedure at the cardiac intensive care unit due to a septic shock.

The median (IQR) in-hospital period lasted 3 (2.0–5.0) days. Eighty-five patients were discharged on DAPT with aspirin and clopidogrel, and 3 patients on SAPT – two on clopidogrel and one on aspirin alone. All patients with a history of unsuccessful OAC treatment received DAPT.

Clinical follow-up

The median follow-up was 67 (52.75–84.75) days. At this time, an in-clinic visit with TEE was performed in 78 (88.6%) cases. Seven (8%) patients refused to undergo the TEE examination; thus, the clinical assessment was done over the phone. Three (3.4%) deaths occurred. The TEE was performed to confirm or exclude thrombus on the device and confirm complete sealing of the LAA.

The primary safety and efficacy endpoints are presented in Table V.

The primary safety endpoints were observed in 2 patients, and all were serious bleeding. None of these patients required hospitalization or blood transfusion. Neither tamponade, pericardial effusion nor device embolization was observed within this period.

The primary efficacy endpoints were observed in 4 patients. Three (3.4%) deaths occurred, of which one was due to worsening of heart failure and the other two were non-cardiovascular deaths. One ischemic stroke occurred 1 month after the procedure. At discharge, the patient was prescribed with DAPT, but after 3 weeks the patient abandoned clopidogrel and continued aspirin alone. One week later the patient was admitted with ischemic stroke, resulting in complete recovery after a few days, and no thrombus was detected in follow-up TEE.

All patients who refused to have follow-up TEE were recommended to continue DAPT after the follow-up period. If the follow-up TEE revealed complete sealing of the LAA and no thrombus was detected, lifelong SAPT was recommend. In 7 cases DAPT was continued because of previous percutaneous coronary intervention with stent deployment and 1 patient, who experienced an ischemic event, was discharged on NOAC therapy.

Device-related thrombus (DRT) was observed in 5 patients and all were treated successfully with OAC therapy.

Discussion

Two randomized trials, PROTECT AF and PREVAIL, were conducted to assess the LAAC with a WATCHMAN device. In those studies, OAC therapy with warfarin was continued for 45 days after device implantation, followed by DAPT up to 6 months and aspirin lifelong [7, 12]. Post-LAAC warfarin treatment is feasible in patients without contraindications to anticoagulation therapy. There are also several trials assessing the post-procedure NOAC regimen with favorable outcomes, but until we get the results of ongoing randomized trial, there is no indication for such treatment [13]. There is a growing amount of evidence for the effectiveness of post-procedure antiplatelet therapy, and our population consists of patients with either a contraindication to OAC or its failure, which is why VKA was not administered after the LAAC procedure. In 2018 Bergmann *et al.* evaluated patients treated with DAPT in the EWOLUTION trial and at 1 year they concluded that this treatment regimen after successful LAAC with the WATCHMAN device is safe and is associated with risk reduction regarding ischemic stroke and major bleeding compared to the expected base on risk scores [14]. Investigators of the PRAGUE-17 trial found that the LAAC procedure followed by DAPT for 3 months was noninferior to NOAC in preventing major AF-related cardiovascular, neurological, and bleeding events [15]. According to Glikson *et al*., DAPT is the currently recommended therapy in high bleeding risk patients during the post-procedure period, although this regimen needs further evaluation [16].

This study aimed to evaluate the safety and efficacy of the antiplatelet regimen after LAAC with the WATCHMAN device in our single-center experience. For this purpose, we evaluated consecutive, high-risk patients who were treated with LAAC. The median CHA_2DS_2-VASc score shows higher thrombo-embolic risk than either the PROTECT AF, PREVAIL or even the EWOLUTION trial. Furthermore, almost 87% of our patients had a HAS-BLED score of ≥ 3, compared with 40% of EWOLUTION participants, 20% of PROTECT AF participants and 30% of PREVAIL participants. We achieved successful device deployment in 90 out of 91 patients (98.9%), which is higher success in comparison to the 91% in PROTECT AF or 98.5% in the EWOLUTION trial.

The peri-procedural safety that consists of tamponade, pericardial effusion, stroke, major bleeding, and death was observed to be at a similar or higher level than in previously mentioned studies. To our analysis we included the very first cases performed in our department. LAAC has been shown to be a relatively safe procedure with complications related to the operator's experience, so with time fewer complications were noted. The comparison of bleeding complications in the available literature remains an issue because of different types of bleeding classifications used in different studies. We used the BARC classification, and serious bleeding was defined as at least type BARC 3. In the peri-procedural period, we observed all serious bleeding complications in 6.6% of patients, while in another 'real-life' cohort serious bleeding was observed in 5.5%, but major bleeding was defined as in-hospital need for blood transfusion, so it seems that the classification was narrower than ours [17]. On the other hand, in the EWOLUTION trial the major bleeding complications were assessed in a period of 30 days after the procedure, and they occurred in 11% of patients [18]. High bleeding risk among our patients may be a reason for such a rate of major bleeding. We did not observe procedure-related stroke in our population, while in the PROTECT AF, PREVAIL and EWOLUTION registries this complication appeared in 0.9%, 0.3%, and 0.1% of cases, respectively. One device embolization was observed 1 day after the procedure that required surgical intervention and resulted in the patient's death 7 days after surgery.

Similarly to other cardiovascular implants, the LAAC device has potential to develop DRT on the free surface, raising the risk of thromboembolic events [19]. Some studies show that the endothelialization of the implanted device may require up to 90 days [20]. As we mentioned, antiplatelets are recommend in a specific patient population and seem to be an effective strategy to prevent thrombus formation on the surface of the WATCHMAN device until its complete endothelization. In the EWOLUTION registry 3-month results were obtained in 979 patients and the data revealed that the WATCHMAN device provides high safety and efficacy. Moreover, there was no significant influence on all SAEs, regardless of whether patients were on VKA, SAPT, DAPT, NOAC, or nothing at all [21]. Among this group, 605 patients were treated with DAPT after LAAC. Major bleeding complications were observed in a similar percentage of patients with DAPT compared to warfarin therapy, 2.4% and 2.0%, respectively. In our study, serious bleeding assessed as at least BARC 3 bleeding was noted in 2.3%.

EWOLUTION registry data showed that in the 92-day follow-up 0.5% of the patients who received DAPT experienced ischemic stroke [21]. In our study, 1 patient experienced a stroke complication 1 month after the procedure. Discontinuation of one antiplatelet drug, despite a different recommendation, could have had an impact on such complication. However, Ledwoch *et al.* in their analysis of patients in the EWOLUTION trial found that post-procedure SAPT or no therapy in high bleeding risk patients is possible. In those two groups, they observed very similar rates of thromboembolic complications in comparison to the DAPT group [22]. In the EWOLUTION registry, only patients on SAPT had a higher rate of ischemic stroke (1.4%) at 3 months compared to those on DAPT. Reddy *et al*. in their 5-year outcomes from PREVAIL and PROTECT AF trials found that there were fewer disabling/fatal strokes related to LAAC compared with those observed in the warfarin-regimen group [8]. In our case, the patient recovered completely after a few days. Moreover, our patient's indication for the procedure was recurrent thrombi in LAA despite OAC therapy, so we suspect that in this case we had to deal with higher prothrombotic propensity of the patient. Yaghi *et al*. reported that patients with AF and a history of ischemic stroke on anticoagulation may have higher ischemic risk compared with anticoagulation-naïve patients, probably because of different underlying pathomechanisms [22]. A recent trial published by Pracon *et al.* evaluated patients with OAC failure compared to those with classic indications of OAC contraindications [23]. They found that the CHA_2DS_2-VASc predicted to observed annual stroke/TIA rate was smaller in the study vs control group and concluded that long-term OAC or prolonged DAPT should be considered. Thus, this population needed further evaluation to identify the optimal post-procedural drug regimen, minimizing risk for stroke or bleeding.

Device-related thrombus was found in 6.4% of our patients who had at 3-month follow-up TEE. All patients were successfully treated within 6 weeks of LMWH administration and none of them experienced a thromboembolic event. Previously mentioned publications of Ledwoch *et al.* and Boersma *et al.* did not report any association with DRT and type of antithrombotic regimen. We assume that there are other clinical, procedural and echocardiographic factors that have an impact on DRT formation, and this field requires further evaluation [24, 25].

This is a retrospective, single-center, observational study. The follow-up was limited to the time of device endothelialization, i.e. to 3 months after device implantation. Results of the study included the first generation WATCHMAN device for the LAAC procedure, so our outcomes do not necessarily relate to other devices, such as the latest generation WATCHMAN Flex device or the Amulet device. Larger population, prospective and randomized trials are needed to provide more powerful data to confirm LAAC safety and efficacy.

Conclusions

The data from our study showed that LAA closure with the WATCHMAN device can be successfully performed with a low rate of adverse events with their reduction with operators' experience. Even using the first generation WATCHMAN device the results are convincing. Safety and efficacy when using the latest generation of the LAAC devices is significantly higher. It seems that the high-risk population requires at least antiplatelet treatment after the LAAC procedure to prevent thrombotic complications. Within the first 3 months after WATCHMAN device implantation, antiplatelet therapy seems to be a safe and effective regimen in this population. In addition, withdrawal of anticoagulation therapy after the LAAC procedure does not increase the rate of stroke, whereas the bleeding rate decreases, as compared to large clinical trials. However, further efforts are needed to define its duration and the population that benefits the most.

Conflict of interest

The authors declare no conflict of interest.

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