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CLINICAL RESEARCH
Ablation for atrial fibrillation

Combining Watchman left atrial appendage closure and catheter ablation for atrial fibrillation: multicentre registry results of feasibility and safety during implant and 30 days follow-up

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Aims Long-term results from catheter ablation therapy for atrial fibrillation (AF) remain uncertain and clinical practice guidelines recommend continuation of long-term oral anticoagulation in patients with a high stroke risk. Left atrial appendage closure (LAAC) with Watchman has emerged as an alternative to long-term anticoagulation for patients accepting of the procedural risks. We report on the initial results of combining catheter ablation procedures for AF and LAAC in a multicentre registry.

Methods and results Data were pooled from two prospective, real-world Watchman LAAC registries running in parallel in Europe/Middle-East/Russia (EWOLUTION) and Asia/Australia (WASP) between 2013 and 2015. Of the 1140 patients, 139 subjects at 10 centres underwent a concomitant AF ablation and LAAC procedure. The mean CHA_2DS_2-VASc score was 3.4 ± 1.4 and HAS-BLED score 1.5 ± 0.9. Successful Watchman implantation was achieved in 100% of patients. The overall 30-day serious adverse event (SAE) rate was 8.7%, with the device and/or procedure-related SAE rate of 1.4%. One pericardial effusion required percutaneous drainage, but there were no strokes, device embolization, or deaths at 30 days. The 30-day bleeding SAE rate was 2.9% with 55% of patients prescribed NOAC and 38% taking warfarin post-procedure.

Conclusion The outcomes from these international, multicentre registries support the feasibility and safety of performing combined procedures of ablation and Watchman LAAC for patients with non-valvular AF and high stroke risk. Further data are needed on long-term outcomes for the hybrid technique on all-cause stroke and mortality.

Keywords Left atrial appendage • Device occlusion • Catheter ablation • Atrial fibrillation • Stroke • Watchman

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What's new?

- This is the first international multicentre series to date demonstrating the feasibility and safety of combined procedures of catheter ablation for AF and left atrial appendage device occlusion
- This multicentre experience points to similar complication rates for the combined procedure as for catheter ablation alone in the hands of experienced AF ablation operators

Introduction

Long-term results from catheter ablation therapy for atrial fibrillation (AF) remain uncertain with significant rates of arrhythmia recurrence over time, especially in the persistent AF population.[1] The CHA_2DS_2-VASc risk score has been demonstrated to correlate with both risk of AF recurrence and risk of thromboembolic events post-ablation,[2,3] suggesting a need for on-going stroke protection in high risk patients. As a result, clinical practice guidelines recommend continuation of long-term oral anticoagulation in these patients following catheter ablation therapy.[4]

Left atrial appendage (LAA) occlusion has emerged as an alternative to long-term anticoagulation with warfarin with similar demonstrated efficacy for all- cause stroke prevention.[5,6] Patients with non-valvular AF who elect to undergo catheter ablation therapy (and are therefore accepting of the procedural risks) may consider this non-pharmacologic approach for long-term stroke prevention. It has been suggested that combining the two left atrial interventions may be a valuable and practical approach because of the common aspects of transseptal puncture, general anaesthesia and requirement for post-procedural anticoagulation.[7] We report on the feasibility and safety of combining catheter ablation procedures for AF and left atrial appendage closure (LAAC) in prospective international multicentre registries.

Methods

This study was approved by the respective institutional review boards for human research and complies with the Declaration of Helsinki. Informed consent was obtained from all those participating in either the prospective, multicentre EWOLUTION[8] or WASP registries. Both trials were registered on ClinicalTrials.gov (NCT01972282 and NCT01972295, respectively). The trials were designed to collect real-world usage and outcomes data for patients implanted with the Watchman LAAC device (Boston Scientific Corporation; Natick, MA). Both registries had identical inclusion/exclusion criteria, used appropriate guidelines to determine device eligibility, and were performed by trained implanters. A contract research organization monitored both studies, and conducted at least one centre visit to verify accuracy and completeness of 30-day follow-up data.

Procedural planning

Pre-procedural transoesophageal echocardiogram (TOE) was generally advised to exclude LAA thrombus and to assess suitability of the ostial dimensions of the appendage.[5]

Procedure

Procedures were performed according to the device's Directions for Use, and periprocedural oral anticoagulation, pre-ablation intravenous (IV) heparin, and target activated clotting time (ACT) were managed at the Physician's discretion.

Per Physician discretion, ablation energy modality, use of cardiac navigational system and ancillary catheters to guide electrophysiological mapping and ablation was individualized. The ablation endpoint was left and right-sided pulmonary vein electrical isolation, as well as any additional left or right atrial ablation deemed necessary by the operator. The majority of operators reported performing a deliberately more posterior approach transseptal puncture for the ablation catheter that was subsequently exchanged for the Watchman access sheath. One centre reported using intracardiac echocardiography during the ablation phase of the procedure, however, all centres reported use of TOE to guide LAA device closure. After completion of the ablation phase a mean left atrial pressure measurement of ≥10 mmHg was obtained, and the LAA was assessed using TOE imaging at angles of approximately 0°, 45°, 90°, and 135°. Implant of the LAA closure device was then performed as previously described.[5] Post-procedural oral anticoagulation was at the Physician's discretion.

Patient follow-up

Follow-up TOE imaging was recommended at 6 weeks to reassess device position and any residual jet flow around the device. If satisfactory appearances on TOE follow-up study had been confirmed, oral anticoagulation discontinuation was recommended and patients were then recommended for antiplatelet therapy (aspirin 81–325 mg + clopidogrel 75 mg) for 6 months post-implant or at the discretion of the Physician. Left atrial appendage occlusion was defined as satisfactory positioning of the device at the ostium covering all trabeculated portions of the LAA with peri-device flow ≤5 mm.[5,7] The schedule of clinical follow-up of patients was at the discretion of the Physician.

Both trials required serious adverse events (SAEs) reporting per ISO 14155 and the MEDDEV 2.7/3 12/2010. Adjudication was performed by investigators with oversight by a Medical Safety Group, as previously described.[8] Events included procedure-related complications (e.g. serious pericardial effusion, device embolization, and procedure-related stroke) and events related to excessive bleeding (e.g. intracranial or gastrointestinal bleeding) scored according to the Bleeding Academic Research Consortium (BARC) criteria.[9] Safety events were further classified as Watchman procedure-related, device-related or related to prescribed anticoagulation regimen. Efficacy endpoints also required reporting of any occurrence of stroke (including ischaemic or haemorrhagic stroke), death, or systemic embolism.

Statistical analysis

Continuous variables are summarized using the mean, standard deviation, and range and categorical variables with counts and percentages. The Kaplan–Meier method was used to describe adverse events.

Results

Patient demographics

Enrolment in the EWOLUTION study included 1025 patients and spanned from October 2013 to May 2015 in 47 centres across 13 countries in Europe, the Middle East and Russia. Enrolment in the WASP trial commenced in January 2014 and concluded in October

Table 1 Baseline Characteristics

Characteristics	Summary statistics
Age at time of consent (years)	
Mean ± SD	64.1 ± 7.3
Range	(39.0, 85.0)
Age ≥80	0.7% (1/139)
Male	54.7% (76/139)
$CHADS_2$ Score—continuous	
Mean ± SD	2.2 ± 1.2
Range	(0.00, 5.00)
CHA_2DS_2-VASc Score—continuous	
Mean ± SD	3.4 ± 1.4
Range	(0.00, 7.00)
HAS-BLED Score—continuous	
Mean ± SD	1.5 ± 0.9
Range	(0.00, 4.00)
Components of $CHADS_2$ and CHA_2DS_2-VASc Scores	
CHF	34.5% (48/139)
Hypertension	81.3% (113/139)
Age ≥75	9.4% (13/139)
Age 65–74	41.0% (57/139)
Diabetes	13.7% (19/139)
History of TIA/stroke	41.0% (57/139)
Vascular disease	20.9% (29/139)
Female	45.3% (63/139)
Components of HAS-BLED Scores	
Uncontrolled hypertension	15.8% (22/139)
Abnormal renal function	2.2% (3/139)
Abnormal liver function	0.0% (0/139)
History of ischaemic/haemorrhagic stroke	29.5% (41/139)
Prior major bleeding or predisposition to bleeding	5.0% (7/139)
Labile INRs	18.0% (25/139)
Concomitant use of drugs	30.2% (42/139)
Alcohol abuse	5.8% (8/139)
Age >65	41.0% (57/139)
AF pattern	
Paroxysmal	68.3% (95/139)
Persistent	28.8% (40/139)
Long-standing persistent	1.4% (2/139)

Values presented are % (*N*/total) or mean ± standard deviation, range (minimum, maximum).
CHF, congestive heart failure; TIA, transient ischaemic attack; INRs, international normalized ratios; AF, atrial fibrillation; SD, standard deviation.

2015, resulting in 201 patients across 7 countries including Australia, Asia, and the Middle East.

Of the 1140 patients from both registries 139 subjects at 10 centres underwent a concomitant ablation and LAAC procedure and are included in our analysis. The majority of cases (97%) were performed by experienced AF catheter ablation proceduralists (≥50 procedures per year)[10] and all implanters were trained, certified implanters of the device.

The mean age at time of consent was 64.1 ± 7.3 years, and 54.7% patients were male. Stroke risk scores (mean ± SD) for $CHADS_2$ and CHA_2DS_2-VASc were 2.2 ± 1.2 and 3.4 ± 1.4, respectively, whereas the HAS-BLED score was 1.5 ± 0.9. Key characteristics contributing to stroke risk scores were hypertension (81.3%), age of 65–74 (41.0%), and history of TIA/Stroke (41.0%), whereas many of the same components also contributed to the HAS-BLED bleeding risk scores [uncontrolled hypertension (15.8%), history of stroke (29.5%), and age > 65 (41.0%)], as well as concomitant use of drugs (30.2%). The primary AF pattern was paroxysmal in 68.3%. The indications for LAA device occlusion included labile INRs in 25 (17.9%), requirement for concomitant drug therapy in 42 (30.2%), previous major bleeding in 14 (10.0%), recurrent anaemia due to gastrointestinal bleeding in 4 (2.8%), history of blood dyscrasia in 1 (0.7%), alcohol abuse in 8 (5.7%), senility in 1 (0.7%), job or lifestyle that prohibits warfarin use in 28 (20.1%), other contraindication e.g. HAS-BLED score ≥ 3 in 20 (14.3%), and reason not recorded in 30 (21.5%). For a complete listing of all demographics, see *Table 1*.

Procedural success

All procedures were successful and all implants achieved a satisfactory seal (residual leak ≤5 mm) per device release specifications previously described.[5] The mean procedural time was 177 ± 44 min and mean fluoroscopy time 31 ± 9 min. Complete occlusion was achieved in 97.1% of the implants, while 2.9% of patients had a residual leak ≤5 mm. The majority of devices were released without recapture or device resizing (71.9 and 97.1%, respectively). The mean LAA diameter was 20.8 ± 2.8 mm, resulting in final device size of primarily 24 or 27 mm (34.5 and 29.5%, respectively) with an oversizing of 10–30% for the majority of patients (80.6%) and a mean achieved device compression of 14.0 ± 6.0 %. See *Table 2* for additional information. The ablation modality used by the different operators included irrigated radiofrequency ablation in 105 patients, cryoballoon in 1 patient, non-irrigated phased radiofrequency energy multielectrode applications in 29 patients and modality not recorded in 4 patients. Ablation endpoints were not recorded in the registry dataset.

Oral anticoagulant regimen

Post-implant, 92.8% of patients were prescribed an oral anticoagulant (54.7% novel oral anticoagulant (NOAC) 38.1% warfarin), 5.8% were given anti-platelet (3.6% dual, 2.2% single), and the remainder received no therapy (1.4%). Of the 76 patients prescribed a NOAC post-procedure 40 were taking Dabigatran, 31 were on Rivaroxaban, and 5 were prescribed Apixaban.

Adverse events

The 7-day device and/or procedure related SAE rate was 0.7% (0.1%, 3.6%). The overall 30-day SAE rate was 8.7% (4.7%, 14.1%) with 14 events in 12 patients, while the device and/or procedure-related SAE rate was 1.4% (0.3%, 4.7%). There were four significant bleeding events including progressive anaemia due to recurrent gastrointestinal bleeding on NOAC (known gastric vascular ectasia) requiring transfusion Day 1 post-procedure, frank haematuria on warfarin Day 5 post-procedure, secondary bleed from groin (vascular access) on warfarin requiring transfusion on Day 13 post-procedure and traumatic knee haematoma on NOAC on Day 28 post-procedure. The bleeding SAE rate at 30-days was 2.9% (0.9%, 6.7%) (*Figure 1*). One

Table 2 Procedural results

Procedure	Summary statistics
Successful implant	100.0% (139)
LAA Seal—implant	
Complete seal	97.1% (135/139)
Jet Size ≤5 mm	2.9% (4/139)
Jet Size >5 mm	0.0% (0/139)
LAA Seal >28 days post-implant	
Complete seal	61.0% (64/105)
Jet size ≤5 mm	37.1% (39/105)
Jet size >5 mm	1.9% (2/105)
Number of recaptures	
0	71.9% (100/139)
1–2	18.7% (26/139)
≥3	9.4% (13/139)
Number of device size changes per implant—categorical	
0	97.1% (135/139)
1	2.9% (4/139)
2	0.0% (0/139)
LAA diameter	
Mean ± SD	20.8 ± 2.8
Range	(14.0, 28.0)
Device compression	
Mean ± SD	14.0% ± 6.0%
Device oversizing	
<10%	8.6% (12/139)
10–30%	80.6% (112/139)
>30%	10.8% (15/139)

Values presented are % (*N*/total) or mean ± SD, range (minimum, maximum).
mm, millimetres; LAA, left atrial appendage; SD, standard deviation.

pericardial effusion with tamponade occurred on day 12 post-procedure, which resolved with pericardiocentesis; another patient was noted to have an increase in size of pre-existing pericardial effusion on the day of the procedure but did not require intervention. There were no strokes, TIAs, device embolization or deaths over the initial follow-up for this cohort (*Table 3*).

Transoesophageal echocardiogram follow-up

A first follow-up TOE was performed at least 28 days post-procedure in 105/139 patients and demonstrated proper seal (residual leak ≤5 mm) in almost all of the patients studied (98.1%). Two patients had a jet size >5 mm determined to be due to device migration and were continued on OAC. The complete LAA occlusion rate was noted to decline to 61.0% at initial TOE follow-up. Comparison between achieved device compression for patients with a new or persisting peri-device leak at TOE follow-up and patients with complete occlusion maintained showed no statistically significant difference (14.0 ± 6.0% vs. 16.0 ± 6.0%, $P = 0.15$). Comparisons could not be made based on ablation modality due to only one centre performing cryoablation, leading to insufficient numbers for analysis. Device associated thrombus was detected on follow-up TOE in 3 patients (2.1%) resolving without clinical sequelae on continued oral anticoagulation.

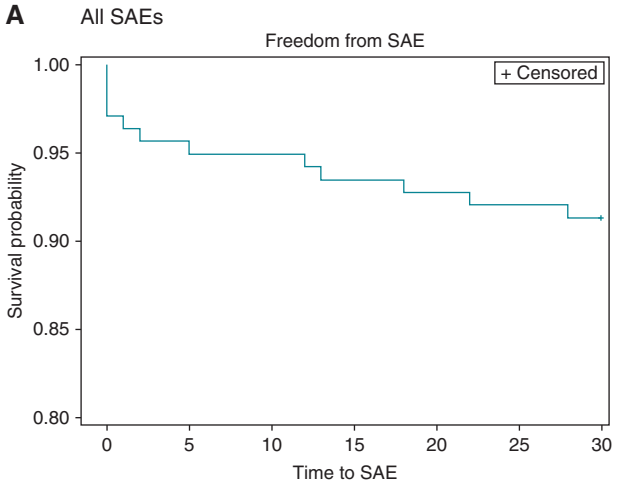
Discussion

This report represents the largest patient series to date and supports the feasibility of combining catheter ablation and Watchman LAA device closure procedures. The results replicate other single-centre series[11–14] but are now supported by two large international, multicentre registry experiences. The results support the EHRA/EAPCI expert consensus statement on catheter based LAA Occlusion[7] that proposed the combination procedure 'seems to be a valuable and practical approach: patients with a significant risk of thromboembolic events (CHA_2DS_2-VASc score of >2) undergoing an ablation procedure to treat symptomatic AF, who, in addition, have a strict or relative contraindication to (N)OACs.'

The results are remarkable for excellent documented periprocedural safety. In the hands of experienced AF ablation operators the pericardial effusion rate was 1.4%, pericardial tamponade rate requiring intervention 0.7%, with no periprocedural strokes or procedure-related deaths. The results are superior to previous Watchman trials[5,15] and remain consistent with the wider context of already published EWOLUTION registry results which demonstrated that contemporary implant techniques are achieving low periprocedural risk even in higher risk patient groups.[8] Indeed, the results of this substudy also compare favourably even to reported complication rates from catheter ablation alone in previous worldwide AF ablation surveys.[16] The results suggest that, for high volume operators, the addition of LAA occlusion to an ablation procedure for AF does not increase the chance of major complications.

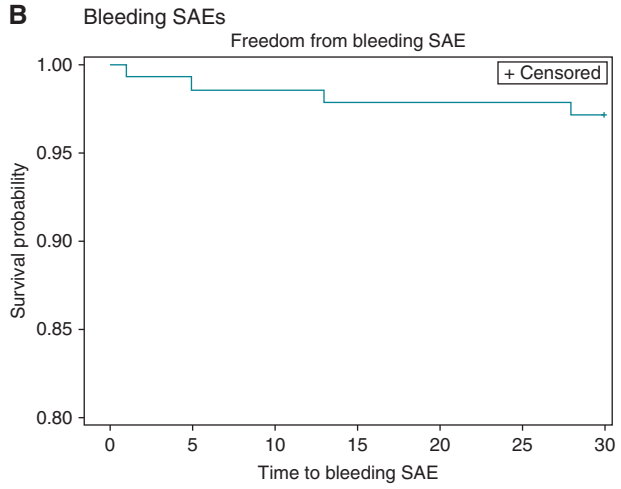
While the experience with LAAC implant technique continues to evolve, the results are also notable for 100% device implant success by the operators. This compares with 91% implant success in PROTECT AF,[5] 95% in PREVAIL trials,[15] and 98.5% in the overall EWOLUTION registry.[8] Very high rates of optimal device placement were also achieved with a small peri-device leak in only 2.9% of implants and minimal procedural device repositioning required.

However, the new occurrence of small peri-device leaks at first TOE follow-up requires further consideration. The rate of peri-device leaks increased significantly from 2.9% at implant to 39% at first follow-up (in the 105/139 patients studied). In two patients, this resulted in a leak >5 mm rendering a result of incomplete LAA occlusion at early follow-up, although the latter cases were determined to be due to device migration. The phenomenon of new peri-device leaks has been noted in other single-centre series of LAAC implant[17] as well as combined ablation with LAAC procedures.[11,12] Upon subsequent follow-up in the two series employing the combined procedure, the majority of leaks resolved or reduced in size.[11,12] PROTECT AF documented a 40.9% peri-device leak rate at 45 days follow-up[18] but also documented a reduction in leak rate to 32.1% over the first 12 months. The proposed explanations for the new occurrence of a post-implant peri-device leak have included a mismatch between circular device and non-circular LAA orifice, the effect of oedema at implant masking any mismatch in device size, and the potential for atrial remodelling to increase or decrease any leak over time.[11,17] The



Time	Number at risk	Number with events	Kaplan-Meier event rate	Peto standard error	Two-Sided 95% CI
0 Days	139	4	2.9%	1.4%	1.0%, 6.7%
1 Days	134	5	3.6%	1.6%	1.4%, 7.7%
7 Days	131	7	5.1%	1.9%	2.2%, 9.6%
30 Days	126	12	8.7%	2.4%	4.7%, 14.1%

Log-Rank *P*-value through 7-days: 0.5542
Log-Rank *P*-value through 30-days: 0.5765



Time	Number at risk	Number with events	Kaplan-Meier event rate	Peto standard error	Two-Sided 95% CI
0 Days	139	0	0.0%	0.0%	NA
1 Days	139	1	0.7%	0.7%	0.1%, 3.6%
7 Days	137	2	1.4%	1.0%	0.3%, 4.7%
30 Days	135	4	2.9%	1.4%	0.9%, 6.7%

Log-Rank *P*-value through 7-days: 0.9453
Log-Rank *P*-value through 30-days: 0.6884

Figure 1 Kaplan–Meier curves and rates at zero (0), 1, 7, and 30 days post-implant for (A) all serious adverse events and (B) all bleeding serious adverse events.

Table 3 Kaplan–Meier rates for serious adverse events at 30-days post-implant

Serious adverse event—30 days*	Number of events	Kaplan–Meier event rate
Pericardial effusions requiring intervention/cardiac tamponade	1	0.7%
Pericardial effusions not requiring intervention	2	1.4%
Coronary air embolism	1	0.7%
Bleeding (GI, haematuria, groin, knee haematoma)	4	2.9%
Urinary tract infection	1	0.7%
Pneumonia following traumatic knee haematoma	1	0.7%
Renal insufficiency following traumatic knee haematoma	1	0.7%
Right atrial flutter requiring ablation	1	0.7%
Recurrent atrial fibrillation requiring hospitalization	1	0.7%
Hypotension due to adverse drug reaction	1	0.7%
Device embolization	0	0%
Stroke	0	0%
Death	0	0%

GI, gastrointestinal.

degree of device oversizing at implant may also affect the long-term seal in the face of any remodelling forces. A previous series has demonstrated that persistent peri-device leaks at follow-up were more likely to be associated with lower achieved device compression (12 ± 3%) than implants achieving complete occlusion (15 ± 5%).[11] In the current study device compression was 14 ± 6% in patients with new or persistent leaks and 16 ± 6% in patients with complete occlusion at follow-up, however, the difference did not achieve statistical significance. Further analysis of the impact of recommended device oversizing on long-term complete occlusion rates is required.

Fortunately the clinical significance of small peri-device leaks has remained questionable as no association has been proven with subsequent stroke or thromboembolic events.[18]

Systemic anticoagulation is routinely recommended for a minimum of 2 months following catheter ablation for AF.[19] Increasingly, physicians are utilizing NOACs in place of warfarin as periprocedural anticoagulation for AF catheter ablation.[20] However, there has been limited experience to-date using the newer agents as a replacement for short-term warfarin for Watchman LAA closure. NOACs were used post-procedure in 55% of patients in this cohort, with no recorded cases of device-related thrombus. This international, multicentre experience now adds to the experience with the use of NOACs with the LAAC implant procedure[11] and suggests they are compatible with the prosthetic material. Further the 30-day bleeding SAE rate of 2.9% for the cohort (with events equally distributed between NOAC and warfarin use) is also consistent with contemporary results from catheter ablation alone.[20]

The results from the EWOLUTION registry demonstrated a statistically significant higher rate of SAE at 30 days for patients 'eligible for (and prescribed) oral anticoagulation treatment' than patients 'ineligible for oral anticoagulation treatment' (and hence prescribed either antiplatelet or no therapy) (6.5% vs. 10.2%, $P = 0.042$).[8] In the current substudy, the 30-day SAE rate was 8.7% for this particular group of predominantly anticoagulated patients. Further comparisons, however, are limited by significant differences in baseline characteristics of predominantly younger patients with lower risk scores than the general EWOLUTION cohort,[8] plus the added complexity of the combined procedure.

Study limitations and future directions

Multiple limitations arise from a real-world registry design including non-conformity of treatment (e.g. variation in ablation modality, post-discharge anticoagulation regimen) and non-conformity of follow-up (e.g. incomplete TOE follow-up). Further, because the registry dataset was primarily focused on device results data was not prospectively collected on arrhythmia outcomes for the cohort. Additionally since no Corelab or independent image adjudication was employed in either study, all TOE measurements (LAA diameter, device size, compression, and peri-device leak) are subject to operator interpretation and imaging system variability.

The authors acknowledge that the lack of arrhythmia outcomes is a major drawback of the current report. A previous small randomized trial suggested that combining Watchman LAA closure with catheter ablation for AF had no effect on long-term AF recurrences.[13] However larger randomized trials are needed to address the relative risk-benefit of performing the procedures separately vs. a combined approach and to specifically address any differences that might arise from choice of ablation modality e.g. cryoballoon vs. radiofrequency energy.

The authors also acknowledge that reimbursement considerations in different regions around the world will tend to either drive or hinder the adoption of the combined approach.

Conclusion

The outcomes from this international, multicentre registry support the feasibility and safety of performing combined procedures of catheter ablation and Watchman LAA device implant for patients with non-valvular AF and high stroke risk. Further data are needed on the long-term outcomes for the hybrid technique on all-cause stroke and mortality.

Conflict of interest: K.P. received consultancy fees and honoraria for clinical proctorship and advisory board participation from Boston Scientific, Medtronic and St Jude Medical; A.R. received speaker honoraria from Medtronic, Boston Scientific, Biosense Webster; K.M.S. and N.G. are employees of B.S.C.; O.R. received proctorship fees and speaker's honoraria from Boston Scientific; L.V.A.B. received personal fees from Boston Scientific, Medtronic outside the submitted work.

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References

1. Steinberg JS, Palekar R, Sichrovsky T, Arshad A, Preminger M, Musat D *et al.* Very long-term outcome after initially successful catheter ablation of atrial fibrillation. *Heart Rhythm* 2014;**11**:771–6.
2. Jacobs V, May HT, Bair TL, Crandall BG, Cutler M, Day JD *et al.* The impact of risk score (CHADS2 versus CHA2DS2-VASc) on long-term outcomes after atrial fibrillation ablation. *Heart Rhythm* 2015;**12**:681–6.
3. Kornej J, Hindricks G, Kosiuk J, Arya A, Sommer P, Husser D *et al.* Comparison of CHADS2, R2CHADS2, and CHA2DS2-VASc scores for the prediction of rhythm outcomes after catheter ablation of atrial fibrillation: the Leipzig Heart Center AF Ablation Registry. *Circ Arrhythm Electrophysiol* 2014;**7**:281–7.
4. Kirchhof P, Benussi S, Kotecha D, Ahlsson A, Atar D, Casadei B *et al.* 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. *Europace* 2016;**18**:1609–78.
5. Holmes DR, Reddy VY, Turi ZG, Doshi SK, Sievert H, Buchbinder M, PROTECT AF Investigators *et al.* Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. *Lancet* 2009;**374**:534–42.
6. Holmes DR, Jr, Doshi SK, Kar S, Price MJ, Sanchez JM, Sievert H *et al.* Left atrial appendage closure as an alternative to warfarin for stroke prevention in atrial fibrillation: a patient-level meta-analysis. *J Am Coll Cardiol* 2015;**65**:2614–23.
7. Meier B, Blaauw Y, Khattab A. EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion. *Europace* 2015;**10**:1109–25.
8. Boersma LV, Schmidt B, Betts TR, Sievert H, Tamburino C, Teiger E *et al.* Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry. *Eur Heart J* 2016;**37**:2465.
9. Mehran R, Rao SV, Bhatt DL, Gibson CM, Caixeta A, Eikelboom J *et al.* Standardized bleeding definition for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. *Circulation* 2011;**123**:2736–47.
10. Sairaku A, Yoshida Y, Nakano Y, Maeda M, Hirayama H, Hashimoto H *et al.* Who is the operator, that is the question: a multicenter study of catheter ablation of atrial fibrillation. *Europace* 2016;**18**:1352–6.
11. Phillips KP, Walker DT, Humphries JA. Combined catheter ablation for atrial fibrillation and Watchman® left atrial appendage occlusion procedures: Five-year experience. *J Arrhythm* 2016;**32**:119–26.
12. Alipour A, Swaans MJ, van Dijk VF, Balt JC, Post MC, Bosschaert MAR *et al.* Ablation for atrial fibrillation combined with left atrial appendage closure. *JACC: Clin Electrophysiol* 2015;**1**:486–95.
13. Romanov A, Pokushalov E, Artemenko S, Yakubov A, Stenin I, Kretov E *et al.* Does left atrial appendage closure improve the success of pulmonary vein isolation? Results of a randomized clinical trial. *J Interv Card Electrophysiol* 2015;**44**:9–16.
14. Calvo N, Salterain N, Arguedas H, Macias A, Esteban A, García de Yébenes M *et al.* Combined catheter ablation and left atrial appendage closure as a hybrid procedure for the treatment of atrial fibrillation. *Europace* 2015;**17**:1533–40.
15. Holmes DR, Kar S, Price MJ, Whisenant B, Sievert H, Doshi S *et al.* Prospective randomized evaluation of the watchman left atrial appendage closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL Trial. *J Am Coll Cardiol* 2014;**64**:1–12.
16. Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman J *et al.* Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. *Circ Arrhythm Electrophysiol* 2010;**3**:32–8.

17. Bai R, Horton RP, DI Biase L, Mohanty P, Pump A, Cardinal D *et al.* Intraprocedural and long-term incomplete occlusion of the left atrial appendage following placement of the WATCHMAN device: a single center experience. *J Cardiovasc Electrophysiol* 2012;**23**:455–61.
18. Viles-Gonzalez JF, Reddy VY, Petru J, Mraz T, Grossova Z, Kralovec S *et al.* Incomplete occlusion of the left atrial appendage with the percutaneous left atrial appendage transcatheter occlusion device is not associated with increased risk of stroke. *J Interv Card Electrophysiol* 2012;**33**:69–75.
19. Calkins H, Kuck KH, Cappato R, Brugada J, Camm AJ, Chen SA *et al.* 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design. *Europace* 2012;**14**:528–606.
20. Vallakati A, Sharma A, Madmani M, Reddy M, Kanmanthareddy A, Gunda S *et al.* Efficacy and safety of novel oral anticoagulants for atrial fibrillation ablation: an updated meta-analysis. *Cardiol Ther* 2016;**5**:85–100.

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Thoracoscopic left atrial appendage clipping as novel treatment option for peri-device leakage

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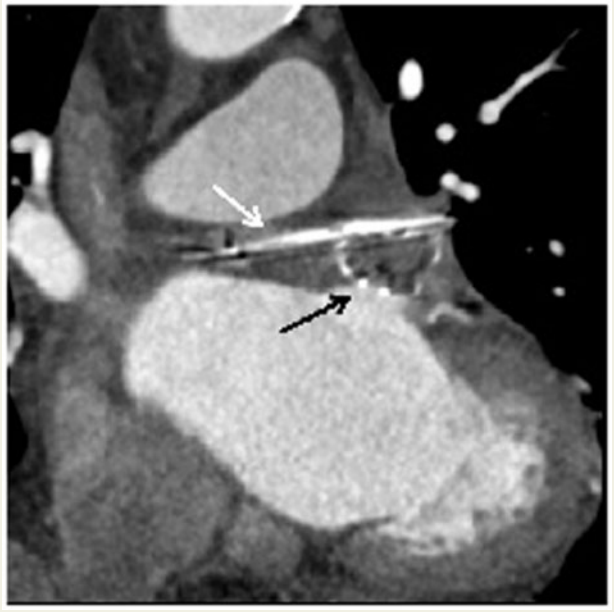
A 69-year-old woman known with symptomatic antiarrhythmic drug refractory paroxysmal atrial fibrillation (AF), stroke (CHA_2DS_2-VASc score 5), and therapy-resistant epilepsy resulting in collapses with risk for head trauma (HAS-BLED score 3), underwent catheter ablation and transcatheter left atrial appendage (LAA) occlusion (WATCHMAN™ 24 mm, Boston Scientific, Natick, MA, USA). Computed tomography (CT) scan revealed significant peri-device leakage (4–5 mm). Due to the absolute contra-indication for oral anticoagulation therapy, the patient was referred for thoracoscopic LAA-clipping (Atriclip PRO 145, AtriCure Inc., Dayton, OH, USA). Additionally, a totally thoracoscopic MAZE procedure (TT-MAZE) was performed. Perioperative Transesophageal echocardiography (TEE) showed complete closure of the LAA, which was confirmed on CT-scan performed 2 months after surgery.



A 77-year-old male with a history of permanent AF (CHA_2DS_2-VASc score 4), prostate carcinoma, and gastro-intestinal bleedings (HAS-BLED score 3), underwent a WATCHMAN LAA occlusion (24 mm). Computed tomography scan revealed significant peri-device leakage (9 mm). The patient was referred for thoracoscopic LAA-clipping (Atriclip PRO 150). Additionally, a TT-MAZE was performed. Post-operative CT scan showed complete closure of the LAA as shown in Figure (the WATCHMAN (black arrow) and Atriclip (white arrow) are both *in situ* with no contrast in the LAA).

Thoracoscopic LAA-clipping seems to be a feasible treatment option for peri-device leakage after incomplete transcatheter LAA-closure.

The full-length version of this report can be viewed at: http://www.escardio.org/Guidelines-&-Education/E-learning/Clinical-cases/Electrophysiology/EP-Case-Reports.