

# Combined catheter ablation and left atrial appendage closure as a hybrid procedure for the treatment of atrial fibrillation

Naiara Calvo, Nahikari Salterain, Hugo Arguedas, Alfonso Macias, Alberto Esteban, Manuel García de Yébenes, Juan J. Gavira, Joaquín Barba, and Ignacio García-Bolao\*

Arrhythmia Unit, Department of Cardiology and Cardiac Surgery, University of Navarra, Av Pio XII, 36, 31008 Pamplona, Spain

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## Aims

Left atrial appendage (LAA) is the source of thrombi in up to 90% of patients with non-valvular atrial fibrillation (AF). Catheter ablation (CA) is an effective treatment for symptomatic AF and, in selected cases, LAA occlusion devices have been introduced as an alternative to oral anticoagulants (OACs). The safety and feasibility of combining CA and percutaneous LAA closure (LAAC) are unknown.

## Methods and results

Patients with symptomatic drug-refractory AF, CHADS<sub>2</sub> score of  $\geq 1$ , and CHA<sub>2</sub>DS<sub>2</sub>-VASc score  $\geq 2$  were included. Catheter ablation consisted in pulmonary vein isolation with or without roof line with radiofrequency and LAA was occluded with the Watchman or Amplatzer Cardiac Plug (ACP) devices guided by angiography and transoesophageal echocardiography. A total of 35 patients were included (71% male; 70 years). Median score was 3 on both CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED, 9% had prior stroke under OAC, and 48% had bleeding complications. Successful CA and device implantation were achieved in 97% of cases. The Watchman device was used in 29 patients and ACP in 6 patients. Periprocedural complications included three cases of cardiac tamponade. At 3 months, all patients met the criteria for successful sealing of the LAA. After a mean follow-up of 13 months (3–75), 78% of patients were free of arrhythmia recurrences and OAC was withheld in 97% of patients.

## Conclusions

The combination of CA and percutaneous LAAC in a single procedure is technically feasible in patients with symptomatic drug-refractory AF, high risk of stroke, and contraindications to OACs, although it is associated with a significant risk of major complications.

## Keywords

Catheter ablation • Atrial fibrillation • Left atrial appendage closure • Oral anticoagulation

## Introduction

The overall risk of stroke in patients with non-valvular atrial fibrillation (AF) is as high as 5% per year.<sup>1</sup> The left atrial appendage (LAA) has been shown to be the source of thrombi in up to 90% of the patients with non-valvular AF.<sup>2–4</sup> According to the ESC guidelines, oral anticoagulant (OAC) therapy is indicated in all patients at high thrombo-embolic risk.<sup>5</sup> Although both warfarin/acenocumarol or the more recently introduced factor II/Xa inhibitors can significantly reduce the risk of stroke in at-risk patients with AF, these OAC medications are associated with severe haemorrhagic complications.<sup>6–9</sup>

These challenges have led to interest in mechanical exclusion of the LAA to prevent thromboembolism in AF. Devices for percutaneous ligation have shown efficacy and safety in achieving this goal when OAC is contraindicated or declined by the patient.<sup>10,11</sup> The ESC guidelines on AF recommend that LAA closure (LAAC) may be considered in patients with high stroke risk and contraindications for long-term OAC use (Class IIb).<sup>5</sup>

Atrial fibrillation catheter ablation (AFCA) is an effective rhythm control strategy for patients with symptomatic, drug-refractory AF<sup>12</sup> but its role in stroke prevention remains unproved. According to guidelines, post-procedural anticoagulation is considered mandatory for at least 2 months after AFCA, regardless of the baseline

\* Corresponding author. Tel: +34 948 2554000; fax: +34 948 296500. E-mail address: igarciab@unav.es

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### What's new?

- Percutaneous LAA occlusion has shown efficacy and relative safety in achieving the goal of preventing thromboembolism in AF patients who do not wish or cannot receive OAC. In a controlled randomized study, the Watchman device demonstrated non-inferiority and later superiority when compared with warfarin in reducing stroke.
- According to clinical guidelines, percutaneous occlusion of the LAA is indicated in patients with thrombo-embolic risk who cannot be managed with OAC in the long term (indication IIb).
- Combining CA and percutaneous LAA closure procedures in a single session are technically feasible, although it is associated with a significant risk (9%) of major complications.

thrombo-embolic risk, and discontinuation of systemic anticoagulation therapy post-ablation is not recommended in patients with high risk of stroke.

Combining AFCA and percutaneous LAAC could reduce the incidence of stroke in selected high-risk patients while simultaneously relieving AF symptoms in a single session. The aim of this study was to report the feasibility and outcomes of a combined procedure of AFCA and percutaneous LAAC.

## Methods

### Study population

Patients with symptomatic drug-refractory AF, a CHADS<sub>2</sub> score of  $\geq 1$ , a CHA<sub>2</sub>DS<sub>2</sub>-VASc score  $\geq 2$  and relative or absolute contraindications for OACs, or who refused OAC therapy despite adequate information were prospectively included. Thrombo-embolic and bleeding risk were defined according to the CHADS<sub>2</sub>/CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED scores, respectively.<sup>5</sup>

Written informed consent was obtained from all participants. The protocol was approved by the Ethics Committee of our institution.

### Pre-procedural assessment

The day before the procedure, patients underwent a transoesophageal echocardiography (TOE) and a cardiac CT scan. Pre-procedural TOE was utilized to document the absence of thrombi within the LAA, assess the features and type of the LAA, and determine the appropriate device size or type.

Patients were instructed to withhold acenocumarol therapy 3 days prior to the procedure and to start low molecular weight heparin (LMWH) 2 days before the ablation until the night before. Novel OACs (NOACs) were interrupted the day before the procedure.

### Atrial fibrillation catheter ablation procedure

The procedure was performed under general anaesthesia because of TOE guidance during transseptal puncture and LAAC.

A decapolar diagnostic catheter was positioned in the coronary sinus through the left femoral venous access. Through the right femoral vein, two transseptal accesses were obtained. Both pressure monitoring through the Brockenbrough needle and TOE were used to guide the double transseptal puncture. Inferior and posterior transseptal punctures were performed to allow further coaxial alignment with the appendage during LAAC.

Boluses of unfractionated heparin were given after the transseptal punctures according to a previously defined protocol,<sup>13</sup> to achieve activated clotting time  $>250$ – $300$  s.

A circular mapping catheter (Spiral, St Jude Medical) was used to map pulmonary vein (PV) potentials. Three-dimensional reconstruction of the left atrium and PVs was performed from the CT scan using Ensite NavX Verismo software (St Jude Medical, St Paul, MN, USA).

A steerable sheath (Agilis NXT, St Jude Medical) and a 4.0 open irrigated-tip catheter (Cool Path, St Jude Medical) were used to ablate the antrum of the PVs. In cases of paroxysmal AF, only PV isolation was performed. A roof line with demonstration of bidirectional block was performed in persistent cases. The CA endpoint was to eliminate local PV potentials and bidirectional conduction block between the left atrium and PVs.

### Left atrial appendage closure

Immediately after the AFCA, the LAAC procedure was performed by the same operator using fluoroscopy and TOE guidance. Prophylactic antibiotic with ceftriaxone was given at the end of the AFCA. Either Watchman (Boston Scientific) or Amplatzer Cardiac Plug (ACP) (St Jude Medical) devices were implanted, according to the LAA size and morphology and physician preferences. The more inferior and posterior transseptal sheath location was retained while the second sheath was withdrawn to the venous circulation. Once normal LA filling pressures (a mean LAA pressure measurement of  $\geq 10$  mmHg) were obtained, LAA ostial and depth dimensions were reassessed during AFCA by TOE. Implant of a Watchman or ACP LAA occluder device was then performed as previously described.<sup>14</sup> Briefly, the initial transseptal sheath was replaced by a 9–14 F access sheath and a pigtail catheter was positioned in the LAA. Angiography of the LAA was performed in right anterior oblique (RAO) caudal and cranial views, delineating shape and size.

A device size 10–20% greater than the largest diameter of the LAA body (as measured by TOE) was chosen. The sheath was then advanced over the pigtail catheter until the proximal marker corresponding with the device size matched the LAA ostium (in the case of Watchman device) or at least 15 mm inside the LAA (in the case of ACP). The pigtail was removed and the delivery catheter and device were advanced into the LAA. The devices were delivered by sheath retraction (combined with gentle pushing on the ACP device).

A sustained tug test for stability and several criteria [proper LAA position, no or minimal ( $<5$  mm) residual lateral flow past the device] was fulfilled before releasing the devices. After the release, the device position was reconfirmed by angiography and TOE.

A TOE was performed if the device was not properly identified by a chest X-ray and a transthoracic echocardiography, and patients were discharged the next day. Endocarditis prophylaxis was recommended for the first 6 months.

### Post-procedural anticoagulation

Anticoagulation was restarted with LMWH at a dose of 1 mg/kg/12 h while also restarting acenocumarol until the therapeutic international normalized ratio (INR) goal of 2.0–3.0 s was reached. Aspirin 100 mg was started the day after the procedure.

The post-procedure anticoagulation regimen was adopted based on HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation, PROTECT AF trial and LAA occluders' instructions. According to HRS/EHRA/ECAS Expert Consensus Statement, systemic anticoagulation with warfarin or with a direct thrombin or Factor Xa inhibitor is recommended for all patients for at least 2 months following AFCA. The anticoagulation protocol of the PROTECT AF trial [OAC for 6 weeks, dual antiplatelet therapy (DAT)

for 6 months, and aspirin for life] was adopted in the instructions for the use of the Watchman device. In the instructions for the use of the Amplatzer device, DAT only without an OAC is indicated.

Following these recommendations of the anticoagulation regimen after AFCA and after LAAC procedure, patients were on OAC and aspirin for a minimum of 3 months after the procedure.

## Follow-up

Follow-up consisted of outpatient clinic visits at 3, 6, and 12 months, and included a detailed history, 12-lead ECG, and 48 h Holter monitoring. Patients were instructed to contact the research team if any new symptoms or events requiring medical attention happened after the procedure.

At the first visit, a TOE was performed to evaluate LAA occlusion, thrombus formation, device position, and residual peri-device flow. If the echocardiographic criteria for successful sealing of the LAA were met (complete LAA occlusion or residual shunt <5 mm jet width in the absence of device surface thrombi), acenocumarol could be interrupted.

In patients who underwent Watchman implantation, aspirin was continued indefinitely, and clopidogrel was started (75 mg daily) for 3 months.

In patients receiving ACP, aspirin was continued for 3–4 months, or lifelong unless contraindicated.

If these echocardiographic criteria for successful sealing were not met, anticoagulation was maintained and TOE was repeated at 6 months.

Antiarrhythmic drug therapy was ceased after 3 months if no clinical or documented AF recurrences were identified.

## Acute and long-term outcome

Acute and long-term clinical outcomes included a successful implantation without major adverse events. Major complication was considered if any death, longer hospital stay, major disability, or rehospitalization occurred.

Major bleeding was defined as any vascular complications requiring percutaneous/surgical intervention or blood transfusion and pericardial effusions requiring percutaneous/surgical drainage or repair. Thromboembolic complications included ischaemic stroke or embolism, transient ischaemic attacks (TIA), and deep vein thrombosis.

Freedom from left atrial arrhythmias was described after a blanking period of 3 months.

## Statistical analysis

Continuous variables are presented as mean  $\pm$  standard deviation. Categorical variables are reported as percentages. All statistical analyses were performed using SPSS version 19 for Windows (SPSS Statistics, IBM Software Group).

## Results

A total of 35 patients [25 (71%) men, 70  $\pm$  7 years] were included. Baseline characteristics are shown in Table 1. The mean CHADS<sub>2</sub> score was 2.01 and CHA<sub>2</sub>DS<sub>2</sub>-VASc score was 3.1 (range 2–6). A history of prior stroke under OACs was present in 3 (9%) patients, and 17 (48%) had a history of a bleeding event. Median HAS-BLED score was 3 (range 2–6). Before the procedure, 24 patients (69%) were receiving acenocumarol for stroke prophylaxis. Atrial fibrillation was paroxysmal in 10 patients (29%) and persistent in the remaining 25 patients. Technical data on implants are shown in Table 2. Acute ablation endpoints and device implantation were achieved successfully in all patients but one (97% success). In the

**Table 1** Clinical and demographic characteristics

	n = 35 (%)
Age, year	70 $\pm$ 7
Male (%)	25 (71)
Hypertension (%)	26 (74)
Type of AF (%)	
Paroxysmal	10 (29)
Persistent	19 (54)
Long-standing persistent	6 (17)
Mean CHADS <sub>2</sub> score	2.01 $\pm$ 1
Mean CHA <sub>2</sub> DS <sub>2</sub> -VASc score	3.1 $\pm$ 1.1
Mean HAS-BLED score	3.1 $\pm$ 1
Antithrombotic therapy, pre-procedure	
OAC	24 (69)
Aspirin	0
Clopidogrel	0
NOAC	7 (20)
Heparin	3 (8)
Indication for implant	
History of major bleeding	17 (48)
Haematuria	4
Gastrointestinal bleeding	10
Intra-articular	1
Intramuscular	1
Severe epistaxis	1
History of ischaemic stroke on OAC	3 (9)
Labile INR	6 (17)
Personal preference	8 (23)
OAC intolerance	1 (3)

AF, atrial fibrillation; OAC, oral anticoagulation; NOAC, novel oral anticoagulants; INR, international normalized ratio.

remaining patient, after AFCA was performed, LAA ostial and depth dimensions were reassessed by TOE and angiography. Left atrial appendage closure was then aborted because LAA maximum ostial diameter and depth did not permit placing the initially planned Watchman device. Left atrial appendage closure procedure was performed the following day and an ACP device was successfully implanted.

A Watchman device was implanted (Figure 1) in 29 (82%) patients and an ACP (Figure 2) in 6 (18%) patients. In one patient, owing to the unsatisfactory compression diameter after expansion, the device was retrieved and a larger one was successfully deployed, which resulted in a median of 1.3 devices per patient.

The mean total combined procedure time was 160.5  $\pm$  33.75 min, while the mean subsequent LAAC procedure time was 42.05  $\pm$  11 min.

The periprocedural complications included three cases (8.57%) of severe pericardial effusion successfully treated by pericardiocentesis. In one of the cases, a light pericardial effusion was noticed at the end of the AFCA procedure, without haemodynamic compromise. Once the LAAC was successfully completed, the pericardial effusion had become significant, so a pericardiocentesis was performed. In the remaining two cases, the tamponade occurred at the end of the LAAC.

**Table 2** Periprocedural characteristics and follow-up

	<b>n = 35 (%)</b>
Successful implantation of LAA closure device, n (%)	34 (97)
LAA closure device, n (%)	
Watchman	29 (82)
Amplatzer	6 (18)
Number of implanted devices	1.03 (1–2)
Mean size of the device implanted (mm)	25 (16–30)
Median size of Watchman device (mm)	27
Median size of Amplatzer device (mm)	27
LAA measurements	
LAA width (mm)	21.19 ± 2.48
LAA length (mm)	26.16 ± 3.01
LAA morphology	
Cauliflower type	9 (25)
Chicken wing	20 (58)
Wind sock	6 (17)
Total procedure time (min)	160.5 ± 33.75
LAA closure time (min)	42.05 ± 11
Total fluoroscopy time (min)	31.75
LAO procedure fluoroscopy time (min)	6.62
Total radiation dose (mSv)	24.42 <sup>a</sup>
Periprocedural complications, n (%)	3 (8.6)
Pericardial effusion with tamponade	3 (8.6)
Air embolism	0
Major bleeding	0
Device embolization	0
Death	0
Ischaemic stroke/TIA	0
Peripheral vascular complication	0
Hospitalization, days	2.9 ± 3.7
Antithrombotic therapy at discharge, n (%)	
OAC	3 (8.6)
OAC + aspirin	26 (74)
Aspirin	0 (0)
LMWH	3 (8.6)
LMWH + aspirin	3 (8.6)
None	0
TOE follow-up at 3 months, n (%)	
Complete LAA sealing	34 (97)
Minimal residual flow (<5 mm)	1 (3)
Device-related thrombi	0
Device embolization	0
AF recurrence at follow-up, n (%)	7 (22)
Complications during follow-up, n (%)	2 (5.7)
Death	1 (2.86) <sup>b</sup>
TIA	1 (2.86)
Ischaemic stroke	0
Haemorrhagic stroke	1 (2.86) <sup>b</sup>
Device embolization	0
Major bleeding	0

LAA, left atrial appendage; CA, catheter ablation; TIA, transient ischaemic attack; TOE, transoesophageal echocardiography; OAC, oral anticoagulation; LMWH, low molecular weight heparin.

<sup>a</sup>The total radiation dose did not include the radiation dose of contrast-enhanced cardiac CT performed pre-procedure. Mean values of effective dose of cardiac CT scan were 9.75 ± 1.48 mSv.

<sup>b</sup>One patient died due to haemorrhagic stroke.

No thrombo-embolic complications were found. Mean hospital stay was 2.9 ± 3.7 days.

## Follow-up

At 3-month follow-up, 35 patients (100%) met the criteria for successful sealing of the LAA. Oral anticoagulant was interrupted in 27 patients (77%): clopidogrel was initiated in all of these patients with a Watchman device, and all patients with an ACP device except one continued aspirin indefinitely (Figure 3).

Oral anticoagulant was maintained in eight patients (23%), mainly (5/8) due to AF recurrences within the blanking period (Figure 3). Four patients underwent an electrical cardioversion and OAC were interrupted at 6-month follow-up. In a patient with paroxysmal symptomatic recurrences, a redo ablation was performed. The LAA device (Watchman device) was not affected and did not interfere with the redo procedure. Oral anticoagulant was maintained until the redo ablation was performed (4 months after the initial AFCA) and during the first 3 months thereafter. In another patient, a typical flutter appeared during follow-up. Cavotricuspid isthmus ablation was performed and OAC was maintained 1 month after this procedure. In one patient, the OAC was maintained according to the cardiologist's preference on the basis of recurrent stroke episodes under therapeutic OAC levels prior to the combined AFCA/LAAC procedure.

The remaining patient had a peri-device (Watchman) leak of 4 mm width. In this patient, OAC was maintained and a TOE was performed at 3 months, which showed complete sealing of LAA; OAC was then interrupted.

There were no device embolization events during follow-up. Two patients developed haematuria within the first 3 months post-procedure while still on OACs and antiplatelet therapy; both resolved spontaneously.

There was one case of TIA at 2 years post-procedure. The TOE did not reveal LA thrombus and there was complete closure of the LAA. This patient was placed on clopidogrel for secondary prevention.

One patient had a sudden death 17 days after the procedure. He was on OAC and aspirin. Although the INR monitoring 2 days before his death showed an extremely high value,<sup>9</sup> no immediate measures were taken to correct these suprathreshold levels. The autopsy revealed an intracerebral haematoma.

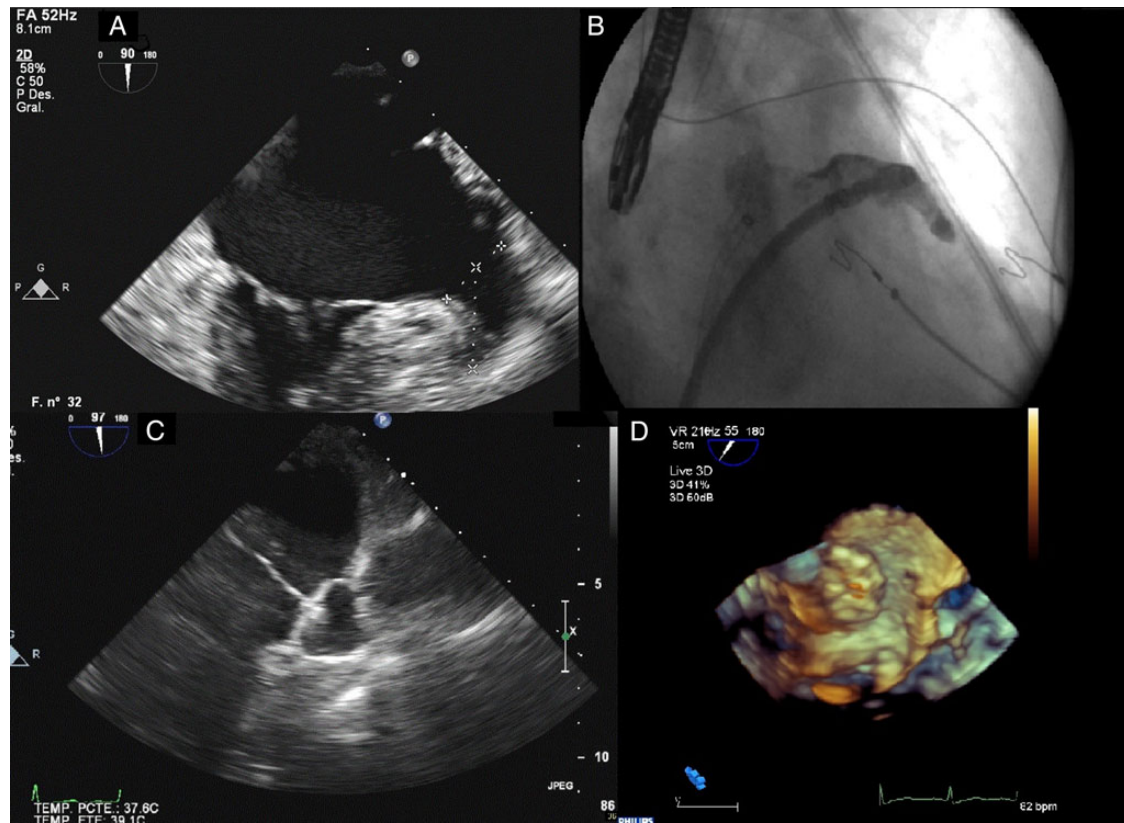
At a mean follow-up of 13 months (3–75), 78% of patients were free of arrhythmia recurrences and 97% discontinued OAC (Figure 3). The observed ischaemic stroke rate was 2.6% per year.

## Discussion

Our study reveals that the combination of AFCA and percutaneous LAA occlusion in a single procedure is a feasible strategy in patients with symptomatic drug-refractory AF, contraindications or resistance to taking OAC, and high risk of stroke.

The Watchman device is the only LAA occlusion device that has been evaluated in randomized trials.<sup>15,16</sup> The PROTECT AF study<sup>15</sup> was designed to assess the non-inferiority of the device against warfarin therapy. Adverse events in the Watchman group occurred primarily on the day of the procedure, while the event rate was lower than that of the control group after the periprocedural period.





**Figure 1** Transoesophageal echocardiography and fluoroscopic (RAO projection) images during the combined ablation procedure and implant of Watchman device. (A) Echocardiographic measurements during the procedure (LAA ostium diameter and LAA depth) for selection of an appropriately sized Watchman device. (B) Angiography of the LAA, RAO projection. (C) Deployment of Watchman device. Optimal position and compression was confirmed with no residual leaks, a tug test was performed demonstrating simultaneous movement of the device and LAA and device was released. (D) Three-dimensional TOE view of Watchman device.

The effect of increased operator experience was demonstrated in the CAP<sup>16</sup> registry with shorter implant time, higher implant success rate, lower complications, and higher warfarin discontinuation rate.

The PREVAIL study<sup>15</sup> confirmed that procedural complications occurring after Watchman LAA occlusion were infrequent and significantly improved compared with the PROTECT AF trial. Watchman LAA occlusion was non-inferior to warfarin for the prevention of stroke and systemic embolism beginning 1 week after randomization. However, non-inferiority was not achieved for overall efficacy (ischaemic stroke, systemic embolism, and cardiovascular or unexplained death) at 18 months of follow-up, probably because the event rates were unexpectedly low in the warfarin group.

More recently, the ASAP registry<sup>17</sup> included 150 patients with non-valvular AF and a CHADS<sub>2</sub> score > 1 who were ineligible for OAC therapy. Following the Watchman implant, patients were administered 6 months of clopidogrel or ticlopidine and lifelong aspirin. The ischaemic stroke rate was less than that expected based on the CHADS<sub>2</sub> scores of the cohort, suggesting that LAAC with the Watchman device can be safely performed without a warfarin transition.

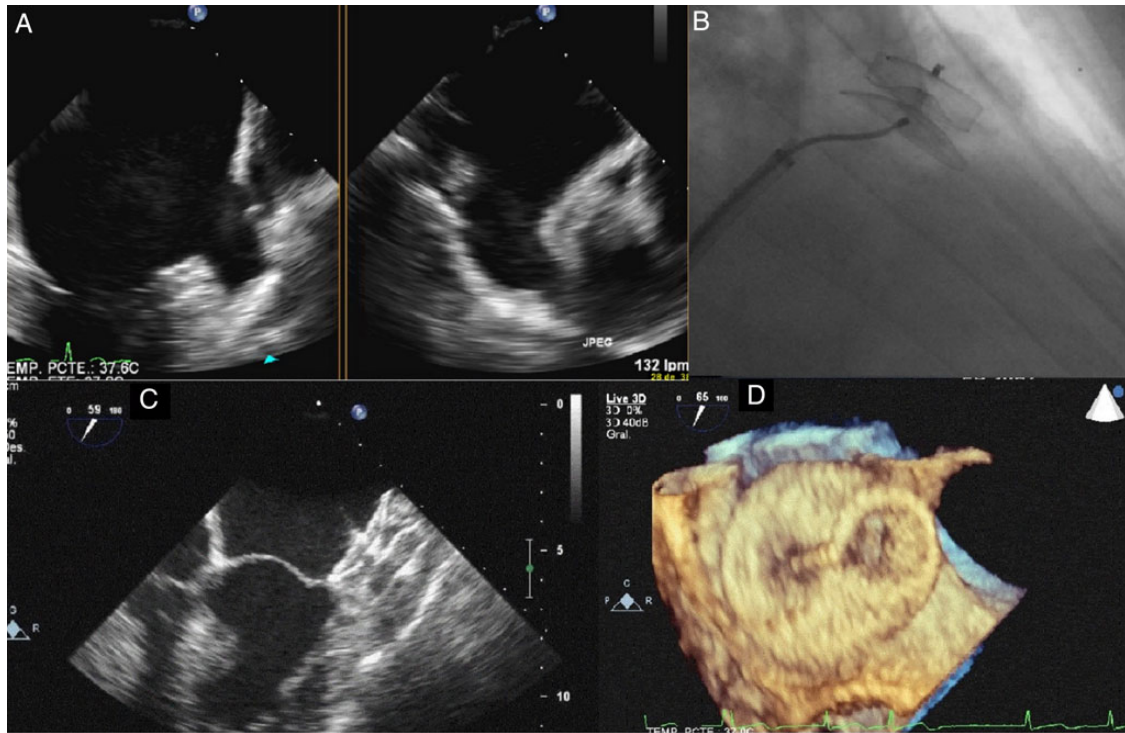
Data on the safety and feasibility of LAAC with the ACP device comes from retrospective registries,<sup>14</sup> with a technical success of 97–100%, a major complications rate between 2 and 7% and an

ischaemic stroke rate lower than would be expected from the CHADS<sub>2</sub> scores of the patient cohort.

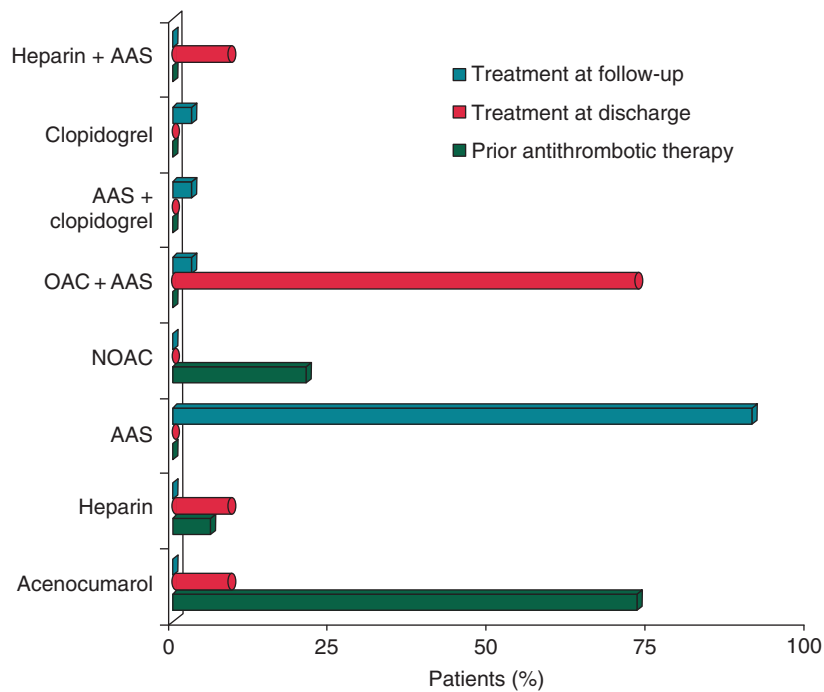
To date, only a few studies have evaluated the safety and feasibility of a combined strategy of AFCA and percutaneous LAAC with the Watchman device. A combined approach could reduce the risk associated with a new vascular access, a new transseptal puncture for LAAC, and anticoagulation during the procedure. Furthermore, in patients with a significant risk of thrombo-embolic events and a strict or relative contraindication to (N)OACs undergoing an ablation procedure to treat symptomatic AF, the combined procedure might reduce the risk of thrombo-embolic or haemorrhagic complications after AFCA procedure.

The disadvantages of the combined procedure are the regular use of general anaesthesia because of continuous TOE monitoring, and longer procedure and fluoroscopy times. Additionally, patients are required to be on OAC for at least the first 2–3 months after the procedure. However, the use of antiplatelet therapy, NOACs, or LMWH for a shorter period of time might be an alternative, although further studies are needed to determine the role of these drugs in ablation and LAAC.

Swaans *et al.*<sup>18</sup> evaluated 30 patients who had AFCA using multi-electrode catheters and LAAC (Watchman). Successful Watchman



**Figure 2** Transoesophageal echocardiography and fluoroscopic (RAO projection) images during the combined ablation procedure and implant of ACP device. (A) Baseline two-dimensional echocardiographic evaluation of LAA ostium diameter and LAA depth for selection of an appropriately sized ACP device. (B) Fluoroscopic view (RAO) during delivery of the ACP device. (C) Two-dimensional and (D) three-dimensional TOE views after ACP device were released.



**Figure 3** Antithrombotic therapy prior to the procedure, at discharge and at follow-up. Data are presented as percentages. AAS, aspirin; OAC, oral anticoagulation with acenocumarol; NOAC, novel oral anticoagulants.

device implantation was achieved with a median of 1.5 devices. At 60 days, all patients had successful LAA sealing. At 12-month follow-up, no thrombo-embolic events occurred with a 30% of AF recurrence. Walker *et al.*<sup>19</sup> included patients who underwent PV isolation procedures by radiofrequency ablation, followed by implant of a Watchman device. There were no acute complications. At 6-week follow-up, all patients had satisfactory LAA occlusion. Twenty patients remained free of arrhythmia at follow-up.

Although all of these studies are limited single-centre experiences and therefore the findings do not allow a general recommendation, the EHRA/EAPCI consensus on catheter-based LAA occlusion<sup>14</sup> suggests that patients with a significant risk of thrombo-embolic events ( $\text{CHA}_2\text{DS}_2\text{-VASc}$  score  $>2$ ) undergoing an AFCA procedure, who also have a strict or relative contraindication to OACs, might be acceptable candidates.

Our study describes for the first time the feasibility and outcomes of a combined AFCA/LAAC procedure with either Watchman or ACP devices. In our experience, a successful implantation was achieved on the first attempt in 97% of patients. The rate of major complications, mostly pericardial tamponade, was higher than in the two previous studies discussed but in line with that reported in randomized and non-randomized registries. The cardiac tamponade may happen due to an incorrect transeptal puncture or manipulation of catheters, guidewires, or devices in the LA or the LAA, leading to injuries of the left atrial or LAA wall. In addition, the anticoagulation regimen required during AFCA and LAAC procedures could increase the risk of bleeding complications. Furthermore, we describe the experience of a combined AFCA/LAAC procedure with two different devices, which could represent a longer learning curve. At 90 days, all patients met the criteria for successful sealing. Although 22% of patients had a documented AF recurrence, none of them were still using OAC at a mean follow-up of 13 months. The mean  $\text{CHADS}_2$  score was 2.01, which equates to a predicted ischaemic stroke rate of  $\sim 4.5\%$  per year (3.5–5.9) using data from a cohort of AF patients taking aspirin.<sup>20</sup> Thus, our observed ischaemic stroke rate of 2.6% per year represents 42.3% fewer events than expected.

According to current guidelines, decisions regarding the use of systemic anticoagulation  $>2$  months post-ablation should be based on the patient's risk factors for stroke and discontinuation of anticoagulation post-ablation is not recommended in patients who are at high risk of stroke. These recommendations are based on the following observations: (i) AF recurrences are common post-ablation, (ii) asymptomatic AF is common post-ablation, (iii) AF ablation destroys a portion of the atria, with an unknown impact on long-term stroke risk, and (iv) no randomized trials have assessed the safety of stopping anticoagulation in this population. These arguments highlight the advantage of our strategy of combining ablation and LAAC in selected patients—those with AF and high stroke or bleeding risk and those with an anticipated reduced efficacy of AFCA. This is a technically challenging procedure with a significant risk of complications and should only be carried out by clinicians with specific training and appropriate experience in both AF ablation and LAAC procedure. In addition to the implanter, an anaesthesiologist and an experienced echocardiographer with specific training in supporting LAA occlusion should be part of the procedural team.

## Limitations

This is a prospective observational study performed in a single centre with consecutive patients and a relatively short follow-up. The small sample of our study, which analyses the outcomes of a combined procedure with the use of two different types of LAAO devices, as well as the lack of control group, limits the power of the outcomes and do not allow to draw definitive conclusions about efficacy and safety. However, it describes our experience and the feasibility of this novel strategy and could stimulate further multicentre trials to clarify best practice and the safety profile of the combination of AFCA and percutaneous LAAC in a single procedure.

We followed the recommendations of AF guidelines and all patients were anticoagulated with acenocumarol until at least 3 months after the procedure, regardless of the type of LAAC device implanted.

Another limitation was the follow-up method of 48-h Holter recordings. Asymptomatic arrhythmias or non-documented symptomatic episodes might have been missed.

Finally, there are no scientific data directly comparing long-term LAA occlusion with NOACs, or analysing the safety of NOACs compared with OACs after LAAC. None of our patients were treated with NOACs post-procedure, so our conclusions should be limited to patients undergoing AFCA and percutaneous LAAC in a single procedure and receiving anticoagulation with acenocumarol for at least 3 months post-procedure.

## Conclusions

The combination of AFCA and percutaneous LAAC in a single procedure is a feasible strategy in patients with symptomatic drug-refractory AF, high risk of stroke, and strict or relative contraindication to OACs. Patient selection and management should be carried out by a multidisciplinary team including a cardiologist and other clinicians experienced in the management of patients with AF at risk of stroke. There is a significant risk of periprocedural complications, so the procedure should only be carried out by operators with specific training and appropriate experience in both AF ablation and LAAC procedure.

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