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# ESC-EUROObservational Research Programme: the Atrial Fibrillation Ablation Pilot Study, conducted by the European Heart Rhythm Association

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**Aims** The Atrial Fibrillation Ablation Pilot Study is a prospective, multinational registry conducted by the European Heart Rhythm Association of the European Society of Cardiology that has been designed to describe the clinical epidemiology of patients undergoing an atrial fibrillation (AFib) ablation procedure, and the diagnostic/therapeutic processes applied in these patients across Europe. We present the results of the short-term (in-hospital) analysis.

**Methods and results** A total of 72 centres in 10 European countries were asked to enrol 20 consecutive patients scheduled for a first AFib ablation procedure. Between October 2010 and May 2011, 1410 patients were included, of which 1391 underwent an AFib ablation (98.7%). The median age was 60 years [inter-quartile range (IQR) 52–66], and 28% were females. Two-thirds presented paroxysmal AFib and 38% lone AFib. Symptoms were present in 86%. The indications for ablation were mostly symptomatic AFib, but in over a third of patients there was also a desire for a drug-free lifestyle and the maintenance of sinus rhythm. Pulmonary vein isolation was attempted in 98.4% of patients, the roof line in 21.3% and the mitral isthmus line in 12.8%. Complex-fractionated atrial electrograms were targeted in 17.9% and the ganglionated plexi in 3.3%. Complications occurred in 7.7%, of which 1.7% was major (i.e. cardiac perforation, myocardial infraction, endocarditis, cardiac arrest, stroke, hemothorax, pneumothorax, and sepsis). The median duration of hospitalization was 3 days (IQR 2–4). At discharge, 91.4% of patients were in sinus rhythm, 88.3% of patients were given vitamin K antagonists, and 67% antiarrhythmic medication. There was one death after the ablation procedure.

**Conclusion** The AFib Ablation Pilot Study provides crucial information on AF ablation in clinical practice across Europe. These data are relevant for further improvement of the management strategies of patients suffering from atrial fibrillation.

**Keywords** Atrial fibrillation • Catheter ablation • Survey • Registry

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† Names of committee members and investigators are reported in the Appendix.

# Introduction

Atrial fibrillation (AFib) is the most common heart rhythm disorder and is associated with a reduced quality of life and an increased number of related hospitalizations and complications like stroke, heart failure decompensation, and increased mortality.[1–3]

Catheter ablation of AFib has quickly evolved from being a highly investigational technique—with unpredictable results—to a common procedure of clinical practice. Due to its effectiveness and positive effects on arrhythmia-related symptoms, quality of life, exercise capacity, and left ventricular function, and possibly also on morbidity and mortality secondary to heart failure, and thromboembolism,[4–8] the indications of this therapy have largely extended during the past decade. The 2010 Guidelines for the Management of Atrial Fibrillation of the European Society of Cardiology[9] states that catheter ablation is a valid option for the treatment of symptomatic patients refractory or intolerant to antiarrhythmic medication. Moreover, ablation has also been proposed as a first-line alternative to antiarrhythmic drug therapy in patients with recurrent symptomatic paroxysmal AFib with no or minimal heart disease and in selected symptomatic patients with heart failure and/or reduced ejection fraction.[9] All these recommendations and proposals are based on limited clinical data. A worldwide survey was conducted in 2005 and updated in 2010 on the methods, efficacy, and safety of catheter ablation of AFib.[10,11] However, it is possible that there is substantial variation across Europe with regard to both interpretation of the indications as well as ablation techniques and baseline and follow-up evaluation.

A survey to capture all the relevant clinical and procedural information of patients undergoing a catheter ablation of AFib could allow us to improve our knowledge on the use of this technique in the real world, in the context of updated epidemiology and outcomes of this disease in representative European countries.

# Methods

The European AFib Ablation Pilot registry, conducted by the European Heart Rhythm Association (EHRA) of the European Society of Cardiology (ESC), was designed to describe the clinical epidemiology of patients undergoing an AFib ablation procedure, and the diagnostic/therapeutic processes (including technical aspects, ways to measure the success of the procedure, and acute and chronic outcomes/complications of the procedure) applied in these patients across Europe. This study is intended as Pilot because it is also aimed to validate Protocol, CRF, and organizational structure of the study in the perspective of a larger European long-term study on the same matter.

## Study design

The AFib Ablation Pilot study is a prospective, multicentre, observational survey of consecutive patients undergoing a first AFib ablation procedure in 74 cardiology centres in 10 European countries, selected to represent the different regions of the European continent.

- four Western European countries: Belgium, France, Germany, and the Netherlands;
- two Eastern European countries: Czech Republic and Poland;
- three Southern European countries: Greece, Italy and Spain;
- one Northern European country: Denmark.

The National Cardiology Societies of each country agreed to participate in the programme, assisting in the selection of centres and updating the European Society of Cardiology and the investigators with the ethical and legal requirements with regard to the survey. The National Coordinator was responsible for contacting the investigators at national level and for the implementation of the protocol in their country, ensuring performance of the enrolling centres and quality of national data. The number of centres in each country varied according to its size and the number of centres available.

Site selection targeted hospitals with a medium-to-high expertise (performing $\geq$50 AFib ablation procedures/year), focusing on describing the epidemiology of patients undergoing an AFib ablation, and the diagnostic/therapeutic processes applied across Europe. Participating centres were asked to enrol, between October 2010 and May 2011, 20 consecutive patients undergoing a first AFib ablation procedure and follow them up for 1 year. The investigator centres accepted on a voluntary basis through National Coordinators and using the information provided by the Network of Centres developed by the EHRA.

The EURObservational Research Department of the ESC was appointed to operationally coordinate the project, provide support to the Committees, National Coordinators, and participating centres and guard the methodological concepts of the survey. The database was set up at the European Heart House of the ESC (France), according to the requirements defined by the appointed Executive Committee with the support of the EURObservational Research Department.

## Population

All consecutive patients scheduled for a first AFib ablation procedure in the participating centres during the enrolment period were included up to a number of 20 patients. There were no exclusion criteria. The survey was approved by the national and/or local institutional review board, according to the regulations of each participating country. Data were collected after detailed information was given to the patient and a signed informed consent was obtained.

## Data collection

All centres were asked to complete a one-time site questionnaire describing the type and size of the centre, reference area population, facilities, and number of invasive procedures performed.

Data were collected using a web-based system. An electronic case report form was developed by the Executive Committee to capture the following information for each enrolled patient:

- *Enrollment data*: demographics, risk factors and co-morbidities, precipitating factors, type of AFib, signs and symptoms, pharmacological and non-pharmacological treatments, invasive/non-invasive diagnostic procedures, and echocardiographic characteristics (imaging techniques prior to the procedure);
- *Procedural data*: number of personnel, laboratory setting, type of catheters, type of energy, type of imaging techniques, type of anaesthesia, anticoagulation protocol, type of procedure, Rx exposure, outcomes used to define success, and complications;
- *Post-procedural data*: periodical ECG, 24-hour Holter monitoring, trans-telephonic ECG monitoring, implanted systems of monitoring, and other.

## Statistical analysis

Continuous variables are reported as mean $\pm$ standard deviation or as median and inter-quartile range (IQR). Categorical variables are reported as percentages and compared by the $\chi^2$ test. Continuous variables are compared by the *t*-test or the Mann–Whitney U test.

A *P* value of $<0.05$ was considered statistically significant. All tests were two sided. Analyses were performed with SAS system software (SAS Institute, Inc., Carolina, NC, USA).

# Results

## Participating centres and total cohort

A total of 1410 patients were included by 72 Cardiology Centres across Europe. *Figure 1* shows the number of centres and patients stratified by country.

The median number of inhabitants for the hospital reference area was 500 000 (IQR 200 000–1 500 000). The median annual number of AFib ablation procedures was 179 (IQR 80–346).

In 19 patients the ablation procedure was not performed (1.3%). In seven patients an intracardiac thrombus was discovered just before the beginning of the procedure and it was cancelled. In four patients non-procedure-related complications prevented the procedure to be started. In the remaining eight patients the procedure was initiated but complications during the preparation phase prevented the ablation procedure to be performed: cardiac tamponade during transeptal puncture in seven patients and a cerebrovascular event in one patient.

## Baseline clinical characteristics

*Table 1* summarizes the clinical baseline characteristics of the patients who underwent an AFib ablation procedure. According to the definitions of the 2010 ESC guidelines,[9] 11.4% of patients presented long-lasting AFib (i.e. $\geq$1 year when the rhythm control strategy was adopted).

The median age was 60 years (IQR 52–66), 31% were over 65 years of age and 28% females. Half the population were hypertensive and 25% were considered obese ($>30$ kg/m$^2$). A prior history of stroke was seen in 7% of patients and the $CHADS_2$ score was $\geq$1 in 57.8% ($CHA_2DS_2$-VASc $\geq$1 in 78.9%).

### Characteristics of atrial fibrillation

*Table 2* summarizes the clinical history of the clinical arrhythmia. Two-thirds of patients undergoing AFib ablation presented paroxysmal AFib with a median of two episodes (IQR 1–7) in the month prior to the procedure. In 532 patients (38%), no evident cause for AFib was found (i.e. lone AFib). Among the rest, the most frequent aetiologies were hypertension and valvular heart disease. Identifiable precipitating factors (such as physical exercise, alcohol intake, heart failure, etc.) were rare (16.7%): one risk factor in 12.9% of patients, two precipitating factors in 3.1%, and $\geq$3 in 0.7%.

At the time of inclusion in the registry, symptoms were present in 86% of patients, mainly in the form of palpitations. However, there were other relevant symptoms associated to AFib, such as fatigue, dyspnoea, and weakness.

Over half the population (56.5%) experienced at least one cardioversion (40% electrical and 29% pharmacological) with a median of one electrical cardioversion (IQR 1–2) and one pharmacological cardioversion (IQR 1–2) in the past year.

The indications for catheter ablation were mostly symptomatic AFib, but in over a third of patients, there was also a desire for a drug-free lifestyle and the maintenance of sinus rhythm (*Table 2*). In asymptomatic patients, the indications for the AFib's ablation were quality of life (54.6%), desire for a drug-free style (45.4%), and/or the maintenance of sinus rhythm (44%). Eighty per cent of patients presented more than one motivation.

### Pre-operative evaluation

A baseline electrocardiogram at admission was performed in 1369 patients (98.4%). The heart rhythm was sinus in 65% of patients and Afib in 31% before the procedure, with a median ventricular rate of 68 b.p.m. (IQR 60–85).

An echocardiogram at admission was performed in 84.7% of patients: 57.8% transthoracic, 67.2% transesophageal, and 40.3%

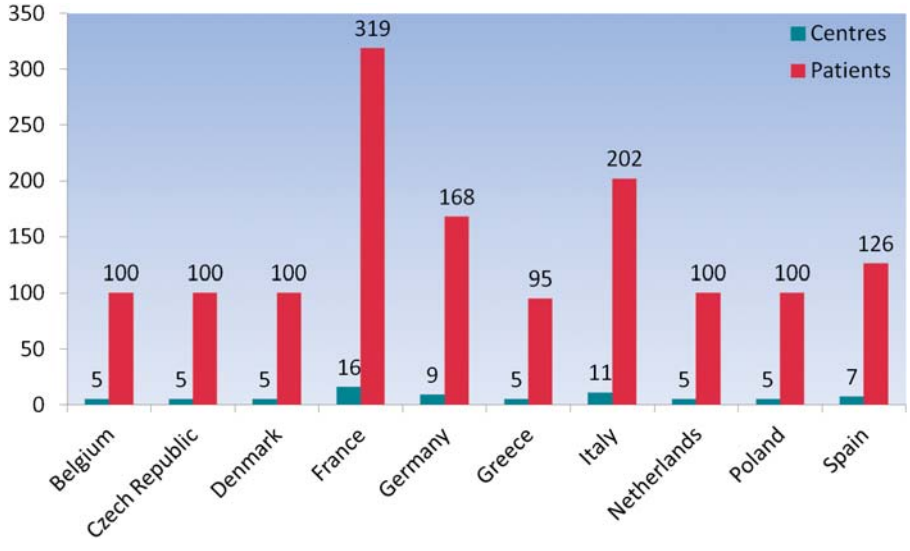


**Figure 1** Distribution of centres and patients included in the AFib Ablation Pilot by country.

**Table 1 Baseline clinical characteristics**

| | Total ($n$ = 1391) |
|---|---|
| Age (years) | |
| Median (IQR) | 60 (52–66) |
| >65 years (%) | 31.2 |
| Females (%) | 27.9 |
| Body mass index (kg/m$^2$) | |
| Median (IQR) | 27 (25–30) |
| >30 kg/m$^2$ (%) | 25.2 |
| SBP (mmHg) | |
| Median (IQR) | 130 (120–140) |
| >140 mmHg (%) | 19.8 |
| Creatinine (mg/dL), median (IQR) | 0.9 (0.8–1.1) |
| Cardiovascular risk factors (%) | |
| Diabetes mellitus | 8.3 |
| Hypertension | 50.0 |
| Active smokers | 11.4 |
| Hypercholesterolemia | 31.6 |
| Co-morbidities (%) | |
| Hyperthyroidism | 3.2 |
| Chronic kidney disease | 1.8 |
| Chronic obstructive pulmonary disease | 3.2 |
| Sleep apnoea | 4.3 |
| Peripheral vascular disease | 2.0 |
| Implanted devices | |
| PM | 2.9 |
| ICD | 1.3 |
| CRT | 0.3 |
| Previous thromboembolism (%) | |
| Stroke/TIA | 6.8 |
| Peripheral embolism | 1.1 |
| Pulmonary embolism | 0.8 |
| $CHADS_2$ Score | |
| 0 | 587 (42.2%) |
| 1 | 552 (39.7%) |
| 2 | 181 (13.0%) |
| 3 | 50 (3.6%) |
| 4 | 17 (1.2%) |
| 5 | 4 (0.3%) |
| $CHA_2DS_2$-VASc | |
| 0 | 294 (21.1%) |
| 1 | 398 (28.6%) |
| 2 | 348 (25.0%) |
| 3 | 215 (15.5%) |
| 4 | 80 (5.8%) |
| 5 | 39 (2.8%) |
| 6 | 11 (0.8%) |
| 7 | 6 (0.4%) |

IQR, interquartile range; PM, pacemaker; ICD, implantable cardioverter defibrillator; CRT, cardiac resynchronization therapy; TIA, transient ischaemic attack.

**Table 2 Characteristics of atrial fibrillation ($n$ = 1391)**

| | Total ($n$ = 1391) |
|---|---|
| Type of AFib (%) | |
| Paroxysmal | 66.8 |
| Persistent | 27.6 |
| Permanent | 4.5 |
| Not defined | 1.2 |
| Underlying disorder (%) | |
| Lone atrial fibrillation | 38.2 |
| Hypertension | 27.9 |
| Valvular heart disease | 12.3 |
| Coronary artery disease | 3.6 |
| Dilated cardiomyopathy | 3.2 |
| Hypertrophic cardiomyopathy | 2.9 |
| Chronic heart failure | 2.6 |
| Other cardiac disease | 2.7 |
| Hyperthyroidism | 2.4 |
| Chronic obstructive pulmonary disease | 0.7 |
| Not defined | 3.5 |
| Associated symptoms | 85.8 |
| Type of symptoms (%) | |
| Palpitations | 72.3 |
| Fatigue | 41.8 |
| Dyspnoea | 37.6 |
| Weakness | 24.4 |
| Dizziness/presyncope | 13.7 |
| Chest pain | 10.4 |
| Syncope | 3.8 |
| No symptoms | 13.1 |
| Unknown | 1.1 |
| Precipitating factors (%) | |
| Physical exercise | 5.5 |
| Alcohol abuse | 3.3 |
| Heart failure | 2.6 |
| Thyreotoxicosis | 1.8 |
| Sexual activity | 1.8 |
| Surgical intervention | 1.7 |
| Pulmonary infection | 0.5 |
| Prior cardioversions (%) | 56.5 |
| Electrical | 40.0 |
| Pharmacological | 29.3 |
| Indications for ablation (%) | |
| Symptoms | 89.7 |
| Quality of life | 73.4 |
| Desire for drug-free lifestyle | 34.9 |
| Desire for sinus rhythm | 39.6 |

both. Two-thirds of patients in sinus rhythm (64.8%) and 72.3% of patients in AFib underwent a pre-procedural transesophageal echocardiogram. Forty per cent of patients undergoing a pre-

procedural echocardiogram presented a $CHADS_2$ score of 0. Patients in sinus rhythm with a $CHADS_2$ score of 0 had this test done in 18.7% of cases.

The median left atrial diameter was 42 (IQR 39–47) mm and the median ejection fraction was 60% (IQR 55–65). Additionally, an imaging technique to visualize the left atrial and pulmonary vein anatomy was done in 60.5% of patients: a computed tomography scan 49.9% and a magnetic resonance imaging scan in 10.6%. Other pre-operative interventions included: Holter monitoring, exercise test, coronary angiography, and electrophysiological study (*Table 3*).

## Procedure

### Ablation technique

The procedure was performed under general anaesthesia in 21.2% of patients, with the aid of transesophageal echocardiogram in 10.5% and intracardiac echocardiography in 17.9%. With regard to anticoagulation therapy, most centres used unfractionated heparin; vitamin K antagonists were continued during the procedure in only 19.2% of patients and 12.5% were performed under low-molecular-weight heparin. The rate of use of anticoagulation and antiarrhythmic drugs before admission, during the procedure, and at discharge is shown in *Figure 2*.

**Table 3 Preprocedural evaluation**

| | Total ($n$ = 1391) |
|---|---|
| Electrocardiogram (%) | 98.4 |
| Transthoracic echocardiogram (%) | 57.8 |
| Transesophageal echocardiography (%) | 67.2 |
| Holter (%) | 23.7 |
| Exercise test (%) | 3.2 |
| Coronary angiography (%) | 3.0 |
| EP study (%) | 13.9 |
| CT scan | 49.9 |
| MRI scan | 10.6 |

The median duration of the procedure was 180 min (IQR 130–220) with a median fluoroscopy time of 26 min (IQR 15–45). The ablation was performed with an open irrigation-tip catheter in 77.8% and with cryo in 13.4%. Other energy sources like laser or duty-cycled radiofrequency were only used in a minority of cases (*Table 4*). A 3D mapping system was used in 77.4%, remote navigation and ablation system in 7.4%, and rotational angiography 3D reconstruction in 4%.

Pulmonary vein isolation was attempted in 98.4% of patients. Of these, complete conduction block was achieved in 88%. Left atrial linear lesions were performed in 21.3%: roof line in 19.3%, mitral isthmus in 12.8%, and other lines in 8%. Complete conduction block across the roof line was achieved in 54.1% and across the mitral isthmus in 65.2%. The superior vena cava was ablated in only 2.6% and the cavo-tricuspid isthmus in 17.4% (achieving block in 90.9%). Complex-fractionated atrial electrograms were targeted in 17.9% of patients, which slowed activation or terminated AFib in 50.6% of cases. Finally, ganglionated plexi were ablated in 3.3% (*Table 5*). The use of complex fractionated electrogram or ganglionic plexi ablation was rarely done as an isolated procedure (1.3% in both cases).

In 31.1% of patients in AFib during the procedure the arrhythmia converted to sinus rhythm during ablation. At the end of the procedure, inducibility was evaluated in 41.4% of patients: 27.7% were non-inducible, whereas 13.7% had either atrial fibrillation or left atrial flutter still inducible. In the remaining 58.6%, inducibility was not evaluated.

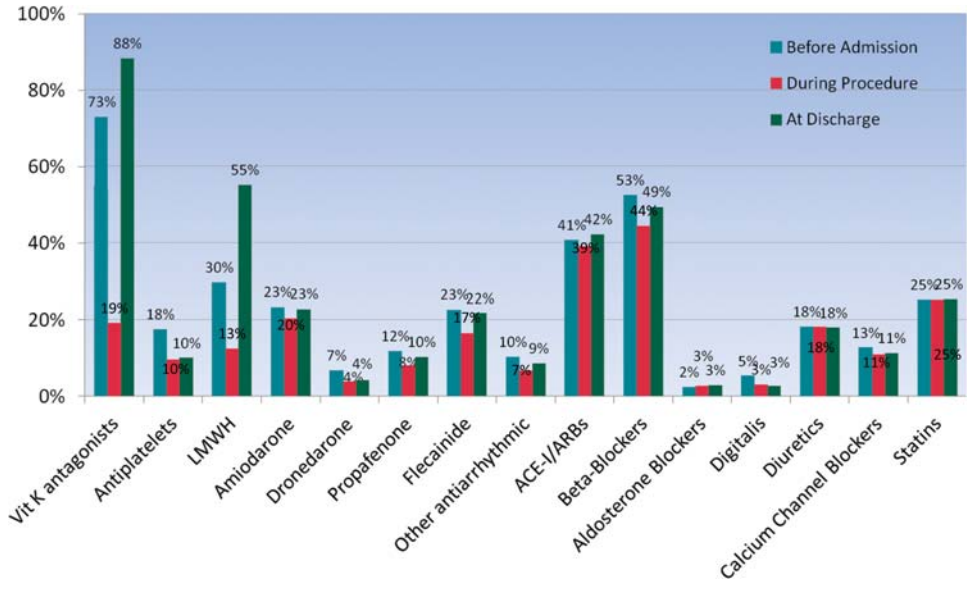


**Figure 2** Rate of use of pharmacological treatment before, during the procedure, and at discharge.

**Table 4** Procedural data ($n$ = 1391)

| | Total ($n$ = 1391) |
|---|---|
| General anaesthesia during procedure (%) | 21.2 |
| Energy source (%) | |
| Non-irrigated radiofrequency | 4.0 |
| Radiofrequency with closed irrigation | 2.2 |
| Radiofrequency with open irrigation | 77.8 |
| Cryo | 13.4 |
| Duty-cycled radiofrequency energy | 4.4 |
| Laser balloon (endoscopic ablation system) | 0.8 |
| Procedure duration (min), median (IQR) | 180 (130–220) |
| Fluoroscopy total time (min), median (IQR) | 26 (15–45) |
| Transesophageal echocardiogram (%) | 10.5 |
| Intracardiac echocardiogram (%) | 17.9 |

### Complications related to the ablation procedure

In 107 patients (7.7%), an adverse event in relation with the ablation procedure was reported (*Table 6*). The most frequent complication was cardiovascular (3.3%), mostly secondary to pericarditis. Cardiac perforation occurred in 0.8% of patients undergoing catheter ablation of AFib. Taking into account the additional seven patients in whom perforation prevented the ablation procedure, an overall incidence of 1.3% was recorded. A cardioembolic event was reported in nine patients (0.6%): four strokes, four transient ischaemic attacks, and one peripheral embolism. No atrio-oesophageal fistula occurred, but in one patient oesophageal ulceration was diagnosed. There were no deaths in relation to the procedure.

## Discharge status

The median duration of hospitalization was 3 days (IQR 2–4). At discharge, 91.4% of patients were in sinus rhythm, 5.8% in atrial fibrillation, and 1.6% in atrial flutter.

**Table 5** Ablation strategy

| | Paroxysmal AF ($n$ = 929) | Persistent/permanent AF ($n$ = 446) | Total ($n$ = 1391) |
|---|---|---|---|
| Attempt of | | | |
| LSPV isolation (%) | 97.3 | 98.2 | 97.4 |
| LIPV isolation (%) | 97.3 | 97.5 | 97.2 |
| RSPV isolation (%) | 97.1 | 97.8 | 97.1 |
| RIPV isolation (%) | 94.3 | 97.1 | 94.9 |
| Achievement of entrance and exit block (%) | | | |
| LSPV | 89.5 | 85.6 | 88.3[a] |
| LIPV | 88.9 | 86.2 | 88.2[a] |
| RSPV | 88.7 | 86.2 | 88.0[a] |
| RIPV | 87.7 | 85.9 | 87.2[a] |
| Left atrial linear lesion (%) | | | |
| Roof line | 10.0 | 38.6 | 19.3 |
| Mitral isthmus line | 5.8 | 27.3 | 12.8 |
| Other left atrial linear lesion | 3.4 | 17.7 | 8.0 |
| Verification of complete conduction block across linear left atrial lesions (%) | | | |
| Roof line | 52.7 | 54.6 | 54.1[a] |
| Mitral isthmus line | 70.4 | 63.1 | 65.2[a] |
| Other left atrial line | 15.6 | 16.5 | 16.1[a] |
| Right atrial linear lesion (%) | | | |
| Superior vena cava | 1.9 | 4.0 | 2.6 |
| Cavotricuspid linear lesion | 15.0 | 22.2 | 17.4 |
| Achievement of bidirectional CTI block | 89.9 | 92.9 | 90.9[a] |
| Ablation at fractionated electrogram sites (%) | | | |
| In the left atrium | 7.9 | 37.2 | 17.4 |
| In the right atrium | 2.1 | 11.0 | 5.0 |
| Ablation of fractionated sites slowed activation or terminated AF | 41.3 | 54.7 | 50.6[a] |
| Ablation of autonomic ganglionated plexi | 2.1 | 5.6 | 3.3 |

LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein; RSPV, right superior pulmonary vein; RIPV, right inferior pulmonary vein; CTI, cavo-tricuspid isthmus.
[a]With regard to patients in whom ablation was attempted.

**Table 6 Adverse events of catheter ablation of atrial fibrillation**

| | Total ($n$ = 1391) |
|---|---|
| Cardiovascular (%) | 46 (3.3%) |
| Pericarditis (%) | 17 |
| Cardiac perforation (%) | 11 |
| Myocardial infarction | 1 |
| Endocarditis | 1 |
| Atypical atrial flutter (no AFib) | 4 |
| Bradycardia requiring pacemaker | 3 |
| Cardiac arrest | 1 |
| Other | 12 |
| Peripheral/vascular (%) | 18 (1.3%) |
| AV fistula | 6 |
| Pseudoaneurysm | 6 |
| Hematoma or bleeding requiring evacuation or transfusion | 5 |
| Peripheral thromboembolic event | 1 |
| Neurological (%) | 9 (0.65%) |
| Stroke | 4 |
| TIA | 4 |
| Phrenic nerve damage | 2 |
| Pulmonary (%) | 8 (0.56%) |
| Hemothorax | 3 |
| Pleural effusion | 2 |
| Pneumothorax | 1 |
| Gastrointestinal (%) | 1 (0.07%) |
| Oesophageal ulceration | 1 |
| General (%) | 6 (0.43%) |
| Allergic reaction | 4 |
| Sepsis | 2 |
| Other (%) | 30 (2.2%) |

AFib, atrial fibrillation.

The use of pharmacological treatment at discharge is shown in *Figure 2*. Some kind of anticoagulation was used in almost every patient (98.6%). Two-thirds of patients were discharged under antiarrhythmic medication, predominantly amiodarone or flecainide, with a tendency to continue whatever drug the patient was under at admission. Other pharmacological treatment like beta-blockers or blockers of the angiotensin–aldosterone system was used in variable proportions.

One patient died during the hospitalization following the ablation procedure. It was a 71-year-old woman with the diagnosis of hypertrophic cardiomyopathy and an implanted pacemaker, undergoing catheter ablation for symptomatic paroxysmal AFib. No adverse event occurred during the procedure but she subsequently presented infective endocarditis and cardiac arrest.

# Discussion

This report describes the main characteristics of a relatively large cohort of patients, admitted to hospital to undergo an AFib catheter ablation. This is the first, systematic, prospective international study specifically aimed at collecting information on the population currently undergoing a procedure of AFib ablation and the relevant technical approaches adopted in Europe.

The population undergoing an ablation procedure for AFib represents only a minority of the overall population suffering from this arrhythmia, with a high prevalence of paroxysmal AFib without evident underlying cardiac disease. This is in line with the available clinical evidence showing better results of the ablation in paroxysmal AFib as compared with persistent/permanent AFib.[9,12–15] Thus, the scenery presented in Europe was expected. However, it must be noted that the population undergoing an AFib ablation is much younger with respect to the general population with AFib.

Palpitations remain the most frequent symptom associated with AFib in patients for whom an ablation is indicated; however, a not negligible number of patients also present with more unspecific but limiting symptoms such as dyspnoea, fatigue, or exercise intolerance. In all, 89.4% of indications for the ablation were in accordance to the current guidelines.[9] Most patients wanted to be free of symptoms, but up to a third wanted a drug-free life style. We will have to wait until the 12-month follow-up results to evaluate if these expectations will be met. Actually, in accordance with what has been observed by others,[16–21] antiarrhythmic drugs were commonly prescribed at discharge in order to prevent early arrhythmic recurrences. Moreover, it must be considered that up to 50% of patients presented a $CHADS_2$ score $\geq 2$, and therefore, the interruption of anticoagulation should be weighed against the risk of a cardioembolic event.

There is a great variety in type and proportion of tests performed before the ablation procedure. Policies of patient hospital care differ between countries and centres. Further analyses will provide more insight into the regional/geographical differences in AFib management in Europe.

This survey provides useful information on how the ablation procedure is performed across Europe. Radiofrequency delivered by an irrigated-tip catheter is the most widespread energy source. Other energies like cryo, duty-cycled radiofrequency, or laser are used to a minor extent, but the picture may change in the future. The most commonly employed ablation strategy in Europe is the electrical isolation of the pulmonary veins. On the contrary, left atrial linear was only performed in a minority of patients, with a proportion of conduction block of 55–65%. In this regard, the role of additional lines AFib ablation remains controversial;[22] isolation of the posterior wall does not seem to achieve better outcomes[23] and it has been demonstrated that incomplete block across the ablation lines can be responsible for occurrence of macroreentrant arrhythmias during follow-up.[24–26] Hence, if additional linear lesions are applied, line completeness should be the endpoint. Ablation of complex fractionated electrogram ablation or autonomic ganglionated plexi ablation was used only in a minority of cases.

The overall incidence of complications was 7.7%, which is in the range of other real-world multicentre surveys[10,11] but slightly higher than single-centre experiences,[27–34] probably because this survey includes centres with different procedure volumes. This is not a negligible number and it must be taken into account when indicating an ablation procedure for AFib in a low-risk population such as described by this survey. Additionally, the incidence of

post-ablation atypical atrial flutter and pulmonary vein stenosis is still to be evaluated during follow-up.

There is very limited data on 'real-world' on AFib ablation. In 2005, a worldwide survey on the methods, efficacy, and safety of catheter ablation of AF was published.[11] This study collected the experience of 181 centres that voluntarily responded to a questionnaire between 1995 and 2002. More recently, an update of this survey was reported, describing the reported safety and efficacy outcomes of 182 centres between 2003 and 2006.[10] Both studies provide a description of the ablation technique, complications, and results. However, these two surveys are mainly focused on the procedure, providing limited information on the clinical characteristics of the patient undergoing an ablation. The current registry offers a very detailed profile of the AFib ablation population, analysing demographic factors, cardiovascular risk factors as well as the clinical history of the patient. On the other hand, the processes associated with the AFib ablation procedure (i.e. pre-procedural evaluation) has not been previously evaluated in a 'real-world' setting. Finally, this is the first survey to describe the incidence and reasons for not performing an AFib ablation once it has been indicated. A single follow-up visit at 1 year will provide patient information and mid-term clinical outcomes.

### Limitations

This survey was based on voluntary participation and recruitment of patients. The centres were selected proportionately to the size of the population of the participating countries in order to favour representativeness of the cohort. However, not all contacted the centres finally contributed to the registry in its Pilot phase. All the same, the high rate of response (73% of the contacted centres) minimizes the risk of an inclusion bias, and offers a good picture of the real situation of AFib ablation across Europe. On the other hand, no local audit was performed to ensure centre's compliance with the protocol. Yet, the need for consecutiveness of enrolment was emphasized and reinforced by the requirement of only 20 patients by centre during the recruitment months. Additionally, the EURObservational Research Programme Department of the ESC monitored the study data closely and all study data underwent extensive automatic edit and plausibility checks to detect inaccuracies and inconsistencies.

## Conclusions

The Atrial Fibrillation Ablation Pilot Study provides relevant information on the current clinical practice of AFib ablation across Europe. These data are relevant for further improvement of the management strategies of patients suffering from atrial fibrillation. This Pilot experience also provided invaluable information for the refinement of the data-set for its implementation in a long-term Atrial Fibrillation Ablation pan-European Registry. Evaluation of the results at the 12-month follow-up will give us more insight into real-life outcomes of the ablation of atrial fibrillation. Finally, further analyses by geographical areas may identify local or more generalized needs in relation to this procedure.

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## Appendix

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