# UNIVERSITÀ DEGLI STUDI DI TORINO

# Symptomatic and asymptomatic long-term recurrences following transcatheter atrial fibrillation ablation

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**Abstract**

**Background** Atrial fibrillation (AF) relapses, following transcatheter AF ablation, are frequently reported based on patients' symptoms, scheduled electrocardiograms (ECGs) or 24-h Holter recordings. The aim of the present study is to determine the incidence of asymptomatic and symptomatic AF recurrences, using continuous subcutaneous ECG monitoring, in the long-term follow-up of patients with paroxysmal or persistent AF undergoing transcatheter ablation.

**Methods and Results** One hundred and thirteen consecutive patients symptomatic for paroxysmal or persistent AF were enrolled. All patients underwent pulmonary vein isolation plus left linear lesions. The Insertable Cardiac Monitor (ICM), subcutaneously implanted during the ablation procedure, recorded the amount of AF per day (Daily Burden) and per last follow-up period (total AF Burden). Based on symptoms and on scheduled 12-lead ECG performed during follow-up 40 patients (35.4%) suffered AF recurrences. By means of ICM data, however, arrhythmia relapses were recorded within 75 patients (66.3%) of whom 35 (46.7%) were asymptomatic. Patients suffering symptomatic AF recurrences resulted, at univariate analysis, older (66.6±8.4 vs. 61.6±10.7 years) and suffering greater AF burden (88.8±26.9 vs. 8.0±8.0%).

**Conclusions** AF ablation outcome based on patients' symptoms and/or scheduled ECGs underestimated relapses, as up to half of the patients, during a long-term follow-up, suffer asymptomatic recurrences.

Key-words: paroxysmal and persistent atrial fibrillation, asymptomatic recurrences, transcatheter ablation

## Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia and is associated with substantial morbidity, primarily related to symptoms, and thromboembolic events (1). Radiofrequency catheter ablation (RCA) has been proposed as an alternative treatment for highly symptomatic drug-refractory paroxysmal and persistent AF.

Following AF ablation anticoagulant and antiarrhythmic therapy, not free from side effects, are to date mainly prescribed based on the patients' symptoms, routine electrocardiograms (ECGs) or 24-h Holter recordings. For this reason, asymptomatic, paroxysmal recurrences of AF may remain undetected (2-6) basing the decision to terminate or continue such therapies on unreliable data.

Insertable cardiac monitors (ICMs) requiring a minimally invasive procedure have instead proven highly sensitive in detecting AF and accurate in measuring the duration of AF in terms of daily burden. (7).

The aim of the present study is to determine the incidence of asymptomatic and symptomatic AF recurrences, by ICM, in the long-term follow-up of patients with paroxysmal or persistent AF undergoing transcatheter ablation.

## Methods

*Patient population*

Paroxysmal atrial fibrillation (PAF) was defined according to the latest ESC guidelines (8) as one or more episodes self-terminating, within 48 hours. Although paroxysmal AF may continue for up to 7 days. Persistent AF was defined as an AF episode either lasting longer than 7 days or requiring termination by cardioversion, either with drugs or by direct current cardioversion (DCC).

Inclusion criteria for the present study were: 1) symptomatic drug-refractory AF (at least two anti-arrhythmic drugs attempted); 2) paroxysmal AF with documented monthly episodes; or 3) persistent AF in patients who had already undergone three or more electrical cardioversions. Exclusion criteria were: previous AF ablation procedure or patients who refused device implantation.

Out of the 123 consecutive patients undergoing transcatheter ablation of AF between January 2007 to December 2011 at the Civic Hospital of Ciriè, Turin (Italy) and meeting the inclusion criteria, 113 (91.9%) were willing to implant an implantable cardiac monitor and provided written informed consent.

*Study protocol*

*Pre-operative care.* A detailed clinical examination, thyroid function tests, ECG, chest radiography, Holter monitoring, and transthoracic and transesophageal echocardiography were routinely performed. All patients were treated with oral anticoagulation using warfarin sodium to achieve an international normalized ratio of 2 to 3 for three weeks before catheter ablation.

*Mapping and ablation procedure.* CT scans of thorax were performed before the procedure. The left atrium (LA) and pulmonary veins (PVs) were explored through a transseptal approach. Real time three dimensional (3D) LA maps were reconstructed by using a no fluoroscopic navigation systems (Carto, Biosense Webster, or Nav-X, St. Jude Medical). Each PVs was encircled. The endpoint of

circumferential PV isolation was confirmed when Lasso mapping showed the disappearance of all PV potentials or the dissociation of PV potentials from left atrial activity. All patients were treated with PV isolation. Linear lesions were performed with left isthmus and roof line in patients with persistent AF. The cavotricuspid isthmus was ablated in case of concomitant demonstration of common atrial typical flutter.

*The device implant.* The ICM (Reveal XT, Medtronic, Minneapolis, Minnesota) was implanted during the same ablation procedure. ICM continuously classifies the heart rhythm of the patient by analyzing the beat-to-beat variability of cardiac cycles on a 2-minute ECG strip. The device records the amount of AF per day (Daily Burden, hours in AF in one day) and the AF Burden of the follow-up (FU) period, defined as the percentage of time in AF (AF%). The trend in daily AF burden, together with all AF-related parameters, are shown by the programmer on FU examination through the Cardiac Compass® Reports, a specific software that summarizes the data stored during the FU period. The ICM was implanted in the parasternal area of the chest. The technical requirement for guiding the final position was an R-wave amplitude >0.4 mV assessed by Vector Check.

ICM was programmed as proposed in the XPECT Trial (9) and all ICM data was independently reviewed by two physicians blinded to patient symptoms; conflict was resolved by common agreement referring to a third expert.

In brief, AF detection algorithm uses irregularity and incoherence of R-R intervals. The R-R intervals are analyzed within each 2-minute period of time, and the difference in duration between consecutive R-R intervals is calculated. Subsequently, the variability of these intervals is calculated, similar to constructing a Lorenz plot. When the R-R intervals within the 2-minute interval show a certain pattern of uncorrelated irregularity the heart rhythm in this interval is classified as AF. Based on this algorithm sensitivity, specificity, positive predictive value, and negative predictive value for identifying patients with any AF are 96%, 85%, 79%, and 97%, respectively with an overall accuracy of the ICM for detecting AF of above 98%.

*Post-operative care.* Following ablation, cardiac rhythm was monitored by telemetry for at least 4 h and 12-lead ECG was performed at 12, 24, 36h and 3-6-12 months or in case of symptoms, namely, palpitations, dizziness or dyspnea (if similar to that suffered pre-ablation). In case of symptoms the patients was recorded as "symptomatic" independently from eventual corroboration or not with a rhythm strip. All patients received the Carelink remote monitoring service (Medtronic, Minneapolis, Minnesota) for home monitoring. The transmission of ICM data was performed monthly in an established day or in case of symptoms.

The ICMs data and symptom diaries were collected at each visit. The telemetric data and the ECG stored were used to tailor the antiarrhytmic and oral anticoagulant therapy. In case of symptoms patient was suggested to perform a transmission of ICM or an ECG in order to confirm/exclude AF recurrence.

Oral anticoagulation was reinstituted the day after ablation and heparin infusion was continued until international normalized ratio levels exceeded 2. All patients were treated with warfarin for at least 3 to 6 months after ablation and then it was discontinued in patients without recurrence of atrial fibrillation and CHADs Vasc $\leq 1$ and with no other indications for anticoagulation. In case of recurrent AF, warfarin was reintroduced. In the absence of arrhythmia recurrence during this initial surveillance period, antiarrhytmic drugs were not prescribed. In the event of early AF recurrence, patients with or without of structural heart disease received Amiodarone, Sotalol or Flecainide.

*Statistical Analysis*

Univariate comparisons of categorical variables (presented as counts and percentages) were performed in crosstabulation tables by means of the Pearson chi-square test and of continuous variables (expressed as the mean value ± SD) by the two-tailed Student *t* test for unpaired data. Value of $p \leq 0.05$ was considered statistically significant. All analysis were performed using SPSS (version 20 SPSS Inc, Chicago, IL, USA).

**Results**

One hundred and thirteen consecutive patients (64.3±10.3 years, 78 males) were enrolled. Baseline characteristics are depicted in Table 1. Patients were followed for 1222, 6±4364.9 days after the ablation procedure. None of them were lost at follow-up.

The duration of transcatheter ablation procedure and ICM implantation was on average 183±64.1 min, fluoroscopic time was 26.3±8.8 min and the radiofrequency application per patient was 56.4±16.2 min. We had 4 inguinal hematomas and 1 atrio-ventricular fistula, none requiring treatments. There was 1 pericardial effusion which did not require pericardiocentesis. No complications regarding ICM implantation.

Based on symptoms and on 12-lead ECG performed at follow-up 40 patients (35.4%) had symptomatic AF recurrences. At univariate analysis these patients were older (66.6±8.4 vs. 62.3±10.9 years; p 0.027), more hypertensive (85.0 vs. 57.5; p=0.039) and presented greater ICM AF burden (88.8±26.9 vs. 4.5±3.5%; p < 0.01; (Table 2).

By means of ICM - intra-observer variability between the two physicians reading ICM records was 6% - 75 patients (66.3%) documented an atrial arrhythmia recurrence, asymptomatic in 35 cases (46.7%; Figure 1).

Baseline characteristics, medical therapy at discharge, procedural and follow-up data of patients stratified by symptomatic or asymptomatic atrial fibrillation recurrences are reported in Table 3. At univariate analysis more advanced age (66.6±8.4 vs. 61.6±10.7 years; p 0.029) and a greater AF burden (88.8±26.9 vs. 8.0±8.0%; p<0.001; Figure 2) related to symptoms during AF recurrences.

Ventricular rate during AF relapses, in addition, was higher in symptomatic (100 ± 3.2 bpm) vs. asymptomatic (vs. 80±4.6 bpm, p< 0.001) patients.

Based on ICM findings 6 (5.3%) patients continued oral anticoagulants due to asymptomatic AF despite a CHADS-Vasc score <1 and 35 (30.9%) discontinued oral anticoagulants due to absence of AF despite a CHADS-Vasc score ≥1.

## Discussion

Long-term continuous monitoring detects more atrial arrhythmia recurrences following AF transcathter ablation compared to patient referred symptoms or intermittent ECG monitoring (7). In our study two out of three patients suffered an AF relapse over a median follow-up of about two years.

Weerasooriya *et al.* have previously followed 100 patients with paroxysmal or persistent AF undergoing transcatheter ablation finding that arrhythmia free survival rates were 87%, 81% and 63% at 1,2 and 5 years, respectively (10). On the other hand, Ouyang *et al.* found that after a median follow-up of 4.8 years, stable sinus rhythm was achieved in 79.5% of the patients with symptomatic paroxysmal AF undergoing circumferential pulmonary vein isolation (11). A previous experience of our group, instead, documented that 53% of the patients with paroxysmal AF was in sinus rhythm at 3-year follow-up (vs. 57% at 12-months follow-up), while 41% of the patients with persistent AF was in sinus rhythm at 3-year follow-up (vs. 45% at 12-months follow-up) (12).

Although the wide variation of relapses reported in the already mentioned long-term experiences, most probably due to the high heterogeneity of patients and arrhythmia durations (paroxysmal vs. persistent) involved, the percentage of relapses detected by continuous rhythm monitoring is indeed higher. In fact, the silent form of AF may otherwise be noticed only incidentally through pre-planned physical examinations, office electrocardiography, preoperative assessments, or population surveys. In some cases, asymptomatic AF is revealed only after complications such as stroke or congestive heart failure have occurred (13). In the present population, over a median follow-up about of 2 years, about half of the patients suffering a relapse were asymptomatic. In search of asymptomatic relapses Pontoppidan *et al*. followed 149 patients after pulmonary vein ablation by 7-day Holter monitoring and found that 44% of the patients had asymptomatic arrhythmia recurrences at 12 months (14). Moreover Hindricks G *et al*. found that even in patients presenting with highly

symptomatic AF, asymptomatic episodes may occur and significantly increase after catheter ablation (5 vs.37%) (15). In lack, to date, of proven pre or post ablation predictors of asymptomatic recurrences of AF the present dataset, although based on univariate analysis only, proposes age and AF as parameters potentially related to asymptomatic AF recurrences. The latter, confirming the recent report from Verma *et al*. showing that the post ablation state was the strongest independent predictor of asymptomatic AF recurrences and that asymptomatic patients suffered shorter episodes (16).

Clinical implications. Assessment of clinical results of transcatheter AF ablation by long-term follow-up is crucial given the high percentage of recurrences reported already after the first year. Great caution must be taken before judging AF "suppressed" or "cured"; in fact there is a high prevalence of asymptomatic recurrences. Continuous AF monitoring provides an optimal picture of both symptomatic and asymptomatic daily AF burden and a better assessment of therapy.

Study limitations. This is a single-center study with a limited simple size. For this reason, although correlations were not significant at univariate analysis at discharge, a multivariate approach investigating whether drug treatment at follow-up (e.g. antiarrhythmic or ß-blockers) may blunt patient perception of arrhythmia remains unresolved. Second, symptoms considered within "symptomatic" patients might not necessarily be related to AF (17). The plausible over estimation of symptoms would, however, not artificially emphasize study results but, in case, limit the gap within "conventional" and ICM-based follow-up. Third, our population was primarily composed of patients with persistent AF treated in more than 90% of the cases by additional linear lines on top of PV isolation. Given the poor sensitivity and specificity of the ICM algorithms used to detect AF on regular atrial tachyarrhythmias, their incidence may result underestimated.

## Conclusion

Transcatheter AF ablation outcome should not be based on symptoms or pre-planned ECG follow-up, as half of the patients with recurrences are asymptomatic during a long-term follow-up. The management of oral anticoagulation therapy and anthiarrhytmic drugs should therefore be based on more reliable data increasing knowledge on this arrhythmia and offering the possibility of tailored therapy.

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**Figure 1.** Atrial fibrillation recurrences over the long-term follow-up based on symptoms and follow-up 12-lead ECGs and ICM data.

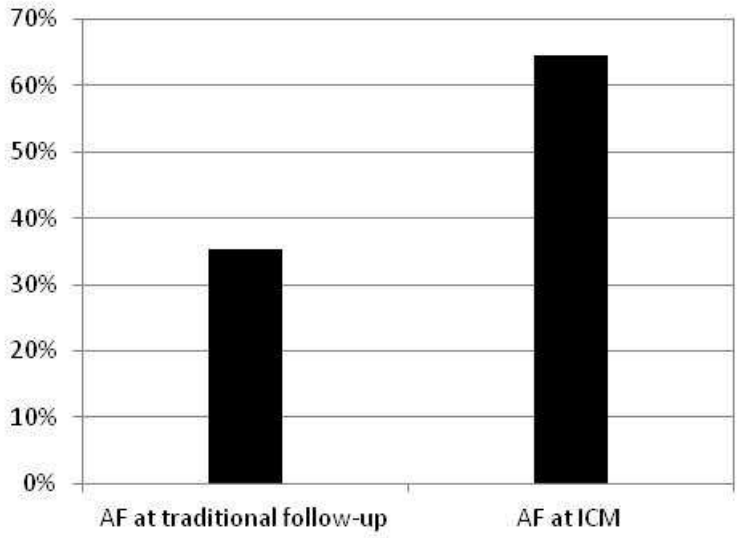


**Figure 2.** AF burden (%) over the long-term follow-up based on Insertable Cardiac Monitor data in patients reporting asymptomatic and symptomatic atrial fibrillation recurrences.

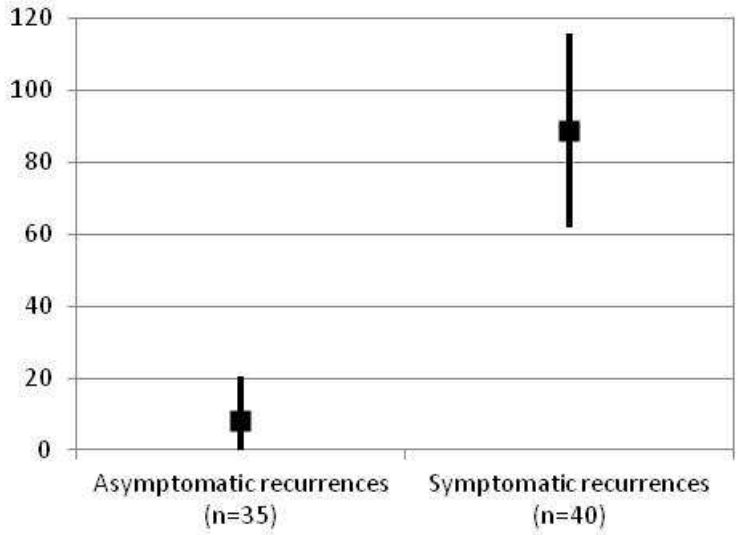

**TABLE 1**

Baseline characteristics of the Patient Population

| **Variables** | **All N=113** |
|---|---|
| Age, years ( SD) | 64.3±10.3 |
| Male, n (%) | 78 (69) |
| **Type of atrial fibrillation, n (%)** | |
| Paroxysmal | 10 (8.8) |
| Persistent | 103 (91.2) |
| **Risk factors for thromboembolism, n (%)** | |
| Cardiac failure | 2 (1.8) |
| Hypertension | 76 (67.2) |
| Diabetes mellitus | 15 (13.3) |
| Prior stroke/TIA | 6 (5.3) |
| Vascular disease* | 7 (6.5) |
| LVEF, % (SD) | 57.9±5.3 |
| **Medical therapy at discharge, n (%)** | |
| Beta blockades | 71 (62.8) |
| Digitalis | 6 (5.3) |
| Calcium channel blockers | 3 (2.7) |
| Antiarrhythmic drugs | 42 (37.2) |
| Anticoagulants | 113 (100) |
| Antiplatelet agents | 9 (8) |
| **Type of ablation, n(%)** | |
| PVI<br>PVI plus linear lesions | 10 (8.8)<br>103 (91.2) |
| CTI | 18 (15.9) |
| **Follow up (±SD)** | |
| Duration of follow up, days | 1222.6±4364.9 |
| Mean AF burden, % of time | 35.1±30.6 |
| Max AF duration, hours | 18.7±17.6 |

*Defined as prior peripheral artery disease or presence of aortic plaque. SD= standard deviation; LVEF= left ventricular ejection fraction; PVI=pulmonary vein isolation ; CTI= cavotricuspidal isolation; AF= atrial fibrillation. TIA= transient ischemic attack.

**TABLE 2**

Baseline characteristics of the Patient Population based on symptoms and follow-up by 12-lead ECGs.

| **Variables** | **No recurrences N=73** | **Recurrences N=40** | **P value** |
|---|---|---|---|
| Age, years (±SD) | 62.3±10.9 | 66.6±8.4 | **0.027** |
| Male, n (%) | 55 (75.3) | 23 (57.5) | 0.335 |
| **Type of atrial fibrillation, n (%)** | | | |
| Paroxysmal | 9 (12.3) | 1 (2.5) | 0.078 |
| Persistent | 64 (87.7) | 39 (97.5) | 0.078 |
| **Risk factors for thromboembolism, n (%)** | | | |
| Cardiac failure | 1 (1.4) | 1 (2.5) | 0.730 |
| Hypertension | 42 (57.5) | 34 (85.0) | **0.039** |
| Diabetes mellitus | 10 (13.7) | 5 (12.5) | 0.797 |
| Prior stroke/TIA | 3 (4.1) | 3 (7.5) | 0.541 |
| Vascular disease* | 2 (2.7) | 5 (12.5) | 0.061 |
| LVEF, % (SD) | 57.8±5.2 | 58.5±5.1 | 0.495 |
| **Medical therapy at discharge, n (%)** | | | |
| Beta blockades | 47 (64.4) | 24 (60) | 0.156 |
| Digitalis | 2 (2.7) | 4 (10) | 0.095 |
| Calcium channel blockers | 1 (1.4) | 2 (5) | 0.243 |
| Antiarrhythmic drugs | 27 (37.0) | 15 (37.5) | 0.067 |
| Anticoagulants | 73 (100) | 40 (100) | - |
| Antiplatelet agents | 6 (8.2) | 3 (7.5) | **0.018** |
| **Type of ablation, n (%)** | | | |
| PVI | 9 (12.3) | 1 (2.5) | 0.157 |
| PVI plus linear lesion | 64 (87.7) | 39 (97.5) | 0.157 |
| CTI | 16 (21.9) | 2 (5.0) | 0.143 |
| **Follow up (±SD)** | | | |
| Duration of follow up, days | 713.8±264.5 | 788.2±288.2 | **0.027** |
| Mean AF burden, % of time | 4.5±3.5 | 88.8±26.9 | **<0.001** |
| Max AF duration, hours | 16.5±16.5 | 26.2±21.7 | 0.265 |

*Defined as prior peripheral artery disease or presence of aortic plaque. AF=atrial fibrillation; SD= Standard deviation; LVEF= Left ventricular ejection fraction; PVI= Pulmonary vein isolation; CTI= cavotricuspidal isolation; TIA= transient ischemic attack

**Table 3**

Characteristics of Patient Population based on ICM data.

| **Variables** | **Asymptomatic patients N=35** | **Symptomatic patients N=40** | **P value** |
|---|---|---|---|
| Age, years (SD) | 61.6±10.7 | 66.6±8.4 | **0.029** |
| Male, n (%) | 27 (77.1) | 23 (57.5) | 0.262 |
| **Type of atrial fibrillation, n (%)** | | | |
| Paroxysmal | 4 (11.4) | 1 (2.5) | 0.088 |
| Persistent | 31 (88.6) | 39 (97.5) | 0.088 |
| **Risk factors for thromboembolism, n (%)** | | | |
| Cardiac failure | 0 (0) | 1 (2.5) | 0.347 |
| Hypertension | 24 (68.6) | 34 (85) | 0.133 |
| Diabetes mellitus | 3 (8.6) | 5 (12.5) | 0.612 |
| Prior stroke/TIA | 1 (2.8) | 3 (7.5) | 0.374 |
| Vascular disease* | 1 (2.8) | 5 (12.5) | 0.125 |
| LVEF, % (SD) | 58.4±4.2 | 58.5±5.1 | 0.918 |
| **Medical therapy at discharge, n (%)** | | | |
| Beta blockades | 19 (54.3) | 24 (60) | 0.249 |
| Digitalis | 1 (2.8) | 4 (10) | 0.185 |
| Calcium channel blockers | 1 (2.8) | 2 (5) | 0.223 |
| Antiarrhythmic drugs | 12 (34.3) | 15 (37.5) | 0.084 |
| Anticoagulants | 35 (100) | 40 (100) | - |
| Antiplatelet agents | 3 (8.6) | 3 (7.5) | **0.029** |
| **Type of ablation, n (%)** | | | |
| PVI | 4 (11.4) | 1 (2.5) | 0.279 |
| PVI plus linear lesion | 31 (88.6) | 39 (97.5) | 0.279 |
| CTI | 10 (28.6) | 3 (7.5) | **0.036** |
| **Follow up (±SD)** | | | |
| Duration of follow up, days | 669.6±288.9 | 788.2±282.2 | 0.137 |
| Mean AF burden, % of time | 8.0±8.0 | 88.8±26.9 | **<0.001** |
| Max AF duration, hours | 18.9±18 | 26.2±21.7 | 0.402 |

*Defined as prior peripheral artery disease or presence of aortic plaque. AF=atrial fibrillation; SD= Standard deviation; LVEF= Left ventricular ejection fraction; PVI= Pulmonary vein isolation; CTI= cavotricuspidal isolation; TIA= transient ischemic attack