

Low incidence of permanent complications during catheter ablation for atrial fibrillation using open-irrigated catheters: a multicentre registry

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Aims

Despite catheter ablation (CA) has become an accepted treatment option for symptomatic, drug-resistant atrial fibrillation (AF), the safety of this procedure continues to be cause for concern. The aim of the present study was to assess the incidence of complications with permanent sequelae of CA for AF using open-irrigated catheters in a contemporary, unselected population of consecutive patients.

Methods and results

From 1 January 2011 to 31 December 2011, data from 2167 consecutive patients who underwent CA for AF using an open-irrigated catheter in 29 Italian centres were collected. All the complications occurring to the patient from admission to the 30th post-procedural day were recorded. No procedure-related death was observed. Complications occurred in 81 patients (3.7%): 46 patients (2.1%) suffered vascular access complications; 13 patients (0.6%) cardiac tamponade, successfully drained in all the cases; six patients (0.3%) arterial thromboembolism (four transient ischaemic attack and two ischaemic strokes); five (0.2%) patients conservatively treated pericardial effusion; three patients (0.1%) phrenic nerve paralysis; three patients (0.1%) pericarditis; three patients (0.1%) haemothorax, and two patients (0.1%) other isolated adverse events. At multivariate analysis, only female sex [odds ratio (OR) 2.5, confidence interval (CI): 1.5–3.7, $P < 0.01$] and the operator experience (OR 0.5, CI: 0.4–0.7, $P < 0.01$) related to the complications. Only five (0.2%) patients developed permanent sequelae from their complications.

Conclusion

Catheter ablation for AF with the use of open-irrigated catheters is currently affected by a very low rate of complications leading to permanent sequelae.

Keywords

Atrial fibrillation • Catheter ablation • Permanent complications

Introduction

Catheter ablation (CA) of atrial fibrillation (AF) is a well-established treatment option for recurrent, symptomatic, drug-resistant AF.^{1,2} Despite the satisfactory results justifying^{3–5} the recommendation for CA by international guidelines in selected patients, the safety of

this procedure remains cause for concern.^{1,2,6} Previous studies reported a rate of complications ranging from 3.5 to 6.3%.^{7–12} These reports, however, gathered events with extremely different outcomes: from groin haematomas requiring few days of rest to pulmonary vein (PV) stenosis with pulmonary distress and thromboembolic events leading to permanent disability. Only one study

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What's new?

- This is the first multicentre study specifically aimed at collecting data regarding the incidence of complications with permanent sequelae in an unselected population of patients undergoing catheter ablation for atrial fibrillation by means of open-irrigated catheters.
- No procedure-related death was reported. Out of a cumulative complication rate of 3.7%, only 0.2% of the patients developed permanent sequelae.
- Complications were more frequent when catheter ablation was performed in females and by less experienced operators.

specifically focused on complications and reported prevalence and causes of fatal outcome following CA of AF.¹³ Thus, the effect on prognosis of complications recorded during CA for AF is unknown. Open-irrigated catheters (OIC) are widely used for radiofrequency CA¹⁴ in particular of AF.^{15–17} In fact, OIC overcome some limitations of 4 and 8 mm radiofrequency catheter, such as coagulum formation and insufficient power delivery in areas of low blood flow. However, concern has been raised regarding the safety of OIC, especially when used with high power, due to an increased occurrence of cardiovascular and gastrointestinal complications.¹⁵

The aim of the present study was to assess the incidence of complications with permanent sequelae of CA for AF using OIC in a contemporary population of consecutive patients.

Methods

Study population

We prospectively collected clinical and procedural data concerning consecutive patients who underwent CA for AF in 29 Italian electrophysiology laboratories between 1 January and 31 December 2011.¹⁸ In 2167 of these patients, CA was performed by using an OIC and they represented our study population. This observational study was approved by the local institutional review committees, and written informed consent was obtained from each patient.

Anticoagulation

Most of the patients were on oral anticoagulants (dicumarol or acenocoumarol) with a therapeutic international normalized ratio >2.0 for at least 4 weeks preceding the procedure, or performed transoesophageal echocardiographic assessment to exclude the presence of left atrial thrombus. Oral anticoagulants were withdrawn 2 or 3 days before ablation, and substituted with low-molecular-weight heparin until 12 h before the procedure. Unfractionated heparin infusion was started immediately after transeptal catheterization, to maintain the mean activated clotting time (ACT) between 300 and 400 s. Low-molecular-weight heparin was restarted 4–6 h after sheaths removal, and continued until oral anticoagulant therapy started on the same day of the procedure reached the therapeutic target.

Ablation

All ablation strategies aiming at isolating or encircling the PVs were included in the Registry. Additional linear lesions in the right or left atrium were also allowed. For the purpose of this study, we report data only on CA procedures performed by means of OIC [Navistar[®],

ThermoCool[®], or ThermoCool SF[®] (Biosense Webster Inc.) or Cool-path[®] or Cooflex[®] (St Jude Medical Inc. Endocardial Solutions)]. Radiofrequency pulses were delivered with a temperature setting of 45°C and radiofrequency energy up to 50 W. In several centres, when ablation was performed in the posterior wall of the left atrium, the radiofrequency power was usually reduced to 25 W to avoid the risk of injuring the adjacent structures. In the majority of centres, ablation was guided by a three-dimensional non-fluoroscopic mapping system [CartoTM system (Biosense Webster Inc.) or EnSite NavXTM (St Jude Medical Inc. Endocardial Solutions)] creating an electroanatomical map of left atrium and PVs with or without the integration of left atrial computed tomography or magnetic resonance scans.

A circular mapping catheter was widely used to confirm PV's electrophysiological isolation and intracardiac echo imaging was used to guide the PV antrum isolation in the two laboratories.

Definitions

Complications were defined as all unexpected events which required intervention or prolonged hospital stay beyond the scheduled period. Early tachyarrhythmias (AF or atrial tachycardia/flutter) were not included even if requiring cardioversion.

Complications with permanent sequelae were defined as those leading to death or causing permanent harm not resolving within 30 days from CA.

Procedures were done by different operators. Personal background as first operator was considered to classify the operator's experience: <100 procedures; between 101 and 500 procedures; and >500 procedures.

Data collection

The investigators were provided with the same data sheet for the collection of specific information on each ablation procedure. Data were collected retrospectively by each investigator, and sent via a computerized database in Excel format (Windows 7, XP, or Mac) to the coordinating centre for analysis. Each author took responsibility for data integrity.

The Registry considered complications occurring from hospital admission of the patient to the 30th post-procedural day. Complications occurring after the hospital stay and clinical status of patients developing complications were collected through outpatient visit or telephone interview.

Statistical analysis

Normally distributed continuous variables were expressed as means (SD) and compared with Student's *t*-test. Normality was assessed using the Shapiro–Wilk test. Skewed variables were expressed as medians (quartiles) and compared with the rank-sum test. Categorical variables were presented as counts and percentages, and compared with χ^2 or Fisher's exact test, as appropriate. A logistic regression model was designed and stepwise backward selection was performed to identify significant and independent predictors of complications. Independent variables were chosen when a $P < 0.10$ emerged at univariate analysis. The starting model included: gender; age; and operator's experience. A significant increase in risk was obtained if the 95% confidence interval (CI) exceeded 1 and the *P* value of the Wald test was <0.05.

Analysis was performed by means of SPSS (version 11.0, SPSS Inc.).

Results

Clinical and procedural data

The final patient cohort included 2167 consecutive patients. Baseline clinical characteristics of the study population are shown in *Table 1*, while the procedural data are listed in *Table 2*.

Table 1 Baseline clinical characteristics of the 2167 enrolled patients

Male gender (%)	74.8
Age (years)	60 (52–67)
Duration of AF history (years)	3.0 (2–6)
Arrhythmic profile (%)	
Paroxysmal AF	52.0
Persistent AF	27.3
Permanent AF	20.7
CHADS ₂ score	1 (0–1)
Mean left atrial diameter (mm)	42.0 (40–46)
Mean left ventricular ejection fraction (%)	57.4 (6.7)

Continuous variables are presented as mean (SD) or median (25–75 percentiles). AF, atrial fibrillation; REDO, patients who had already undergone PV catheter ablation.

Table 2 Procedural data of the 2167 enrolled patients

Pre-ablation imaging (%)	
MRI	13.0
CT	22.0
TEE	49.0
Mapping system (%)	
None	7.0
CARTO	56.9
NavX	36.0
Other	0.1
Number of vascular accesses	3.0 (3–5)
Number of transseptal punctures	1 (1–1)
Number of ablated PVs	4 (4–4)
CTI ablation (%)	19.2
Mitral to inferior left PV isthmus ablation (%)	40.3
Left atrial roof ablation (%)	43.1
Duration of fluoroscopy exposure (minutes) ^a	22 (13–43)
Duration of RF delivery (minutes) ^b	31 (24–39)
Ongoing warfarin (%)	6.0
Learning curve level (%)	
≤ 100 patients	6.0
101–500 patients	22.0
≥ 501 patients	70.0

Continuous variables are presented as mean (SD) or median (25–75 percentiles).

^aAnalysis based on 1920 subjects.

^bAnalysis based on 1775 subjects.

MRI, magnetic resonance imaging; CT, computed tomography; CTI, cavotricuspid isthmus; LA, left atrium; PV, pulmonary vein; RF, radiofrequency; TEE, transoesophageal echocardiography.

Complications

No procedure-related death was observed. Complications occurred in 81 patients (3.7%): 46 patients (2.1%) suffered vascular access complications; 13 patients (0.6%) developed cardiac tamponade, successfully drained in all the cases; six patients (0.3%) had arterial

thromboembolism (four transient ischaemic attack and two ischaemic strokes); five patients (0.2%) presented pericardial effusion not requiring specific intervention; three patients (0.1%) had phrenic nerve paralysis during right PV isolation; three patients (0.1%) had pericarditis; three patients (0.1%) had haemothorax requiring drainage in two cases. Other isolated but serious adverse events were documented in two patients (0.1%): haemorrhagic stroke in one; transient ST elevation in one.

In Table 3, clinical and procedural characteristic of patients with and without complications are shown. At univariate analysis, patients with complications were older and more frequently females, and the ablation was less frequently performed by the experienced operators. At multivariate analysis, female gender [odds ratio (OR) 2.5, CI: 1.5–3.7, $P < 0.01$] predicted complications, while higher operator experience (OR 0.5, CI: 0.4–0.7, $P < 0.01$) inversely related to complications.

Complications with permanent sequelae

In five patients (0.2%) a complication with a permanent sequelae was observed: three permanent neurological sequelae (two ischaemic and one haemorrhagic stroke), and two permanent symptomatic phrenic nerve palsy. Clinical and procedural characteristics of patients with permanent complications are presented in Table 4.

Discussion

Main findings

This is the first multicentre study specifically aimed at collecting data regarding the incidence of complications with permanent sequelae in an unselected population of patients undergoing CA for AF by means of OIC. No procedure-related death was reported. Out of a cumulative complication rate of 3.7%, only 0.2% of patients developed permanent sequelae. Complications were more common when CA was performed in females and by less experienced operators.

Complications in catheter ablation for atrial fibrillation

The demonstration of superiority of CA over antiarrhythmic therapy in the management of several settings of AF patients^{3–5} has greatly increased the procedure of AF CA in the last decade.^{19,20} Despite technological improvements, CA of AF is still affected by a high amount of complications mainly related to the extension of lesions in the left atrium, the need of a deep anticoagulation, and the increasing number of centres starting to approach AF ablation.^{12,17,21} Thrombo-embolic complications seem to be affected by ablation technologies and by energy.^{22,23} In particular, OICs have been reported to reduce the risk of thrombus formation at the electrode–tissue interface, and the risk of steam pop.²⁴ On the other hand, OICs deliver a large amount of saline solution during prolonged ablation procedures, and make deeper and larger lesions that might increase the risk of pericardial effusion or perforation.

Our study is the first to be designed to evaluate the complications during radiofrequency CA for AF by means of OICs, with an overall complication rate of 3.7%, slightly lower than that reported by recent multicentre studies using different technologies.^{12,18,21} Also, the rate of thrombo-embolic complications (0.3%) and pericardial effusion or

Table 3 Univariate analysis for comparisons between patients with and without complications

	No complications N = 2084	Complications N = 81	P
Age (years)	60 (53–66)	64 (60–68)	0.03
Male gender (%)	72.7	53.1	<0.001
CHADS ₂ score	1 (0–1)	1 (0–1)	0.49
Arrhythmic profile (%)			
Paroxysmal	51.7	61.7	0.50
Persistent	27.6	21.0	
Permanent	20.7	17.3	
Duration of AF history (years)	4 (2–6)	3 (2–5)	0.12
Mean left atrial diameter (mm)	41 (40–45)	42 (40–45)	0.25
Left ventricular ejection fraction <55% (%)	18.0	14.8	0.27
Pre-ablation imaging (%)			
TEE	49.0	44.4	0.36
MRI	13.0	8.6	
CT	23.3	28.4	
ICE (%)	12.7	16.0	0.67
Mapping system (%)			
None	7.1	6.2	0.92
CARTO	56.9	55.5	
NavX	35.9	38.3	
Other	0.1	0	
Number of vascular accesses	3 (3–5)	3 (3–4)	0.34
Number of transseptal punctures	1 (1–1)	1 (1–1)	0.38
Number of isolated PV	4 (4–4)	4 (4–4)	0.73
CTI ablation (%)	19.1	21.0	0.68
Mitral to inferior isthmus ablation (%)	40.6	33.3	0.19
Left atrial roof ablation (%)	43.4	34.6	0.11
Duration of fluoroscopy exposure (minutes)	21 (13–41)	33 (14–49)	0.23
Duration of RF delivery (minutes)	30 (24–40)	33 (24–38)	0.11
Ongoing warfarin (%)	5.7	6.1	1.0
Learning curve level (%)			
<100 patients	5.7	11.1	<0.001
101–500 patients	21.5	35.8	
>501 patients	72.8	53.1	

MRI, magnetic resonance imaging; CT, computed tomography; CTI, cavotricuspid isthmus; LA, left atrium; PV, pulmonary vein; RF, radiofrequency; TEE, transoesophageal echocardiography.

cardiac tamponade (0.8%) seems to confirm the safety of OICs, as recently reported.^{14,16,17}

We found an increase of complication rate when procedures were performed by less experienced operators. This finding is consistent with the observation that the operators' experience and the hospital volume related to better outcomes.^{12,21}

Complications with permanent sequelae

The more feared complications of CA are obviously those leading to death or to permanent sequelae.¹³ In the present study, only a 0.2% of permanent sequelae was reported. Two of these were permanent symptomatic phrenic nerve palsy occurred during ablation of the right PVs. Impedance monitoring, and strict monitoring of phrenic nerve function by means of regular pacing of the nerve, from the superior vena cava and the left atrium, before ablation, are crucial to

avoid this complication, and should become mandatory during ablation especially of the right PVs.

Two out of five permanent complications were related to embolic events. This observation underlines once again the need of an aggressive procedural and peri-procedural anticoagulation regimen. In particular, maintaining an ACT value ≥ 350 ms during ablation, and performing the procedure on warfarin have been effective in reducing such complications.²⁵ However, some embolic events may have been caused by thermally induced blood clots and this phenomenon is totally unresponsive to anticoagulation.

Previous registries^{12,13,21} have reported a rate of death ranging from 0.1 to 0.46%. Although the low rate of death could require larger study populations to assess its true incidence, the lack of procedure-related death observed in our study further supports the safety of OICs.

Table 4 Clinical and procedural characteristics of the five patients with permanent complications

	Complication	Gender	Age	CHADS ₂	Type of AF	Hypertension	CHF	Diabetes	Previous stroke/TIA
#1	PNP	Female	60	2	Paroxysmal	Yes	No	Yes	No
#2	PNP	Female	62	1	Paroxysmal	Yes	No	No	No
#3	Haemorrhagic stroke	Male	69	1	Persistent	No	No	No	No
#4	Ischaemic stroke	Female	72	1	Persistent	Yes	No	No	No
#5	Ischaemic stroke	Female	75	6	Persistent	Yes	No	Yes	Yes

PNP, phrenic nerve palsy; AF, atrial fibrillation; CHF, congestive heart failure; TIA, transient ischaemic attack.

Limitations

Unfortunately, we did not have a control group of patients undergoing CA with different technologies, such as cryoablation or multielectrode catheters associated with duty-cycled radiofrequency energy. For this reason, any conclusion on the superiority of one tool over the others can be derived from the present study. However, the safety profile of the OICs seems to be evident when comparing the present to the previously published data.

By study design, data collection focused on complications occurring within 1 month after ablation: some rare but feared complications like PV stenosis and late pericardial tamponade could be under-represented.

Clinical implications

Complications with permanent sequelae in CA for AF with the use of OICs are very rare and in 40% of the cases related to embolic events. Based on this evidence, it becomes acceptable to pay attention to a higher potential risk of haemorrhagic events to reduce dreadful cerebral embolic complications, particularly in females. The overall rate of complications of CA for AF by means of OICs is below 4%, but the hazard is increased when CA is performed by less experienced operators raising once again the issue of recommending a volume threshold to enhance the safety of the procedure.

Conflict of interest: C.T. is a Medtronic Inc. Board member and received payment for lectures from Medtronic Inc. and St Jude. All other authors have no conflicts to declare.

Supplementary material

Supplementary material is available at *Europace* online.

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Left superior pulmonary vein ectopic rhythm mimicking normal sinus rhythm

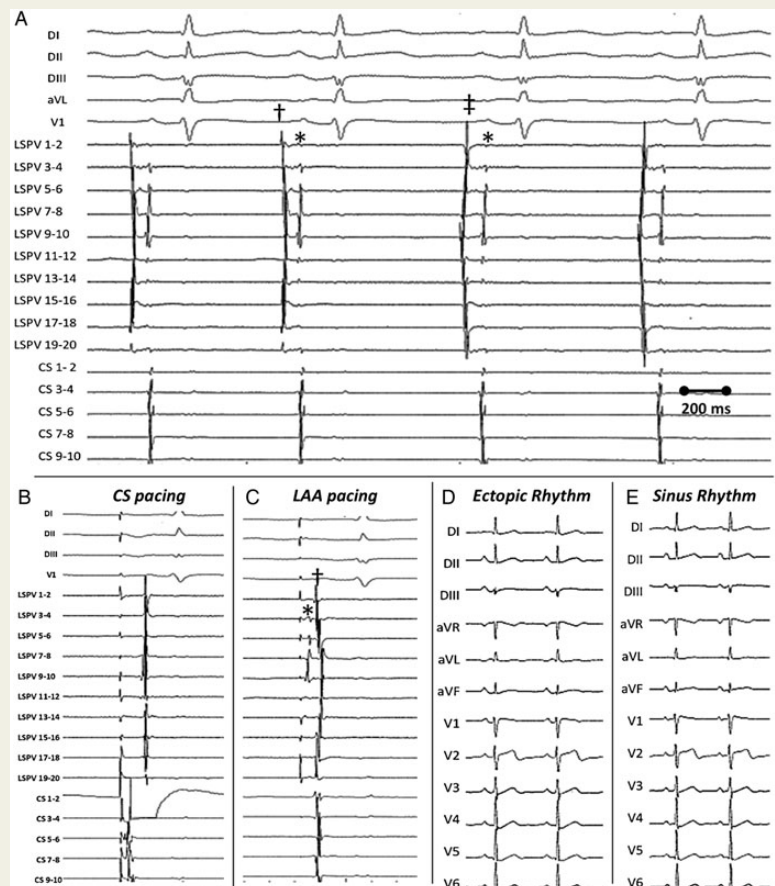
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A 45-year-old man underwent pulmonary vein (PV) isolation for paroxysmal atrial fibrillation. Two alternating regular rhythms were recorded at the left superior PV (LSPV—Panel A). The dominant rhythm had a cycle length (CL) of 672 ms, with an initial near-field electrogram (EGM) and circumferential distribution (†) that preceded the P-wave by 40 ms (earliest activation on bipoles 1–2 and 19–20), followed by a far-field EGM (*). During the second rhythm (CL of 839 ms), the near-field component demonstrated the earliest activation on bipoles 9–10 and preceded P-wave by 73 ms (‡). Differential pacing confirmed the LSPV origin. While coronary sinus pacing demonstrated synchronous activation, left atrial appendage (LAA) pacing showed reversal activation (Panel B). Once isolation was achieved a change was observed in P-wave (Panel C). A stable dissociated PV rhythm was observed up to 60 min post-LSPV isolation.

Subtle differences in the P-wave can be appreciated, during the ectopic rhythm the P-wave axis was more rightward, with a morphology that was consistent with a posterior left atrial (LA) origin. Electrogram interpretation and differential pacing were required to differentiate a focal PV source from a posterior LA or LAA origin.



The full-length version of this report can be viewed

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