Real-world experience with atrial fibrillation ablation: cause for concern

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This editorial refers to ‘The Atrial Fibrillation Ablation Pilot Study: a European survey on methodology and results in catheter ablation for atrial fibrillation conducted by the European Heart Rhythm Association†', by E. Arbelo et al., on page 1466

Atrial fibrillation (AF) ablation has undergone a huge increase in popularity in the past few years. The effectiveness of this treatment is supported by several small randomized controlled trials in a number of different AF patient groups. Most of the trials show significant reductions in recurrence of AF compared with medical therapy. Atrial fibrillation ablation is now endorsed as first-line therapy for some patients. Consequently AF ablation has now become a standard procedure at most medical centres in Western Europe and North America. It is supported by national and regional reimbursement bodies and is more and more widely used. It is appropriate to ask about the effects of this major change in practice on patient outcomes. Registries and cohort follow-up studies are the appropriate tools for addressing this question. Observational research studies are complementary to randomized trials, as they provide some insights into the effects of treatments as they are actually delivered in clinical practice, especially when these registries use robust methodologies. The best registries are population based, which avoids patient and centre selection biases. The Atrial Fibrillation Ablation Pilot Study, conducted by the European Heart Rhythm Association, is therefore a welcome addition to the literature reporting on the real world results of AF ablation in Europe.

The Atrial Fibrillation Ablation Pilot Study, planned as a precursor to a larger, more prolonged European observational study, was performed at 72 catheter ablation centres in 10 European countries, which were selected broadly to represent current European clinical practice. Sponsored financially by the European Heart Rhythm Association, National Cardiology Societies of each country agreed to participate and were locally responsible. Site selection was limited to hospitals with medium to high expertise in AF ablation. In order to provide a representative and relatively unbiased sample of patients, sites were asked to enrol the first 20 consecutive patients between October 2010 and May 2011 undergoing AF ablation. The data on patient selection and in-hospital results and complications have already been reported, and the report in this issue of the journal focuses on the 1-year results. Although 1410 patients were enrolled, follow-up data were available on only 1282. Taking into account a 3-month blanking period, the procedure was ‘considered a success’ by the physicians in 77% of patients. However, using the more accepted definition of successful ablation, which is freedom from AF recurrence without use of antiarrhythmic drugs, then success was achieved in 41% of patients at 1 year, despite the fact that 18% of patients were subjected to a second ablation procedure. It is also noteworthy that, in the year following the procedure, 30% of the AF ablation patients were re-admitted to hospital. Amongst patients in whom the procedure was considered a success, 34% continued to report symptoms of palpitations, dyspnoea, and fatigue. Complications were not rare. When considering both peri-procedural and late complications, there were major events in 2.5% of patients and some form of complication in 10%. The authors note that if one includes post-operative atrial tachycardia or flutter as a complication of the procedure, then the adverse event rate rises to 27%. These real-world population-based outcomes are highly consistent with a recent population-based real-world analysis reported by Brabandt et al. from the Belgian Healthcare Knowledge Centre. These authors had access to administrative healthcare data in Belgium and were able to provide complete population-based 2-year outcomes on all of the 830 patients undergoing a first catheter ablation procedure for AF in Belgium, between November 2007 and December 2008. About 77% of patients had paroxysmal AF and 26% underwent repeat ablations. The success of the first ablation procedure (taking into account a 3-month blanking period) was measured as freedom from repeat catheter ablation, from need for cardioversion, and from need for use of an antiarrhythmic drug. The success rate of an ablation procedure was 40% at 1 year and 34% at 2 years. The results of these ‘real-world’ experiences are remarkably consistent, indicating that the actual 1-year success of AF ablation procedures at the centres actually delivering this therapy in Europe today is well under 50%, a success rate quite a lot lower than often stated. Furthermore, the present study reports a...
significant risk of complications and a high rate of hospital readmission, with more than one in five patients presenting with a new atrial tachyarrhythmia (flutter or atrial tachycardia).

**Should we believe these two surveys?**

Do they truly reflect the results of AF ablation in Europe today? First let us consider the methodologies used. Both studies have made serious attempts to provide unbiased real-world data, but both have limitations. The Atrial Fibrillation Ablation Pilot Study sponsored by the European Heart Rhythm Association was carried out in a broad spectrum of practising sites over a wide geographic distribution within Europe and requested data on a small number of consecutive patients from each site as a means to avoid bias. Unfortunately this survey suffered from 6% loss to follow-up which might have led them to over- or underestimate the success rate. The Belgian study used administrative data, which has the benefit of completely avoiding selection bias, but which imposes some limitations on the extent of data that can be collected. In general I think that these approaches are an improvement over retrospective or single-centre analyses that have mostly been previously reported.

**What about the definition of atrial fibrillation ablation success?**

According to the HRS/EHRA/ECAS, Catheter and Surgical Ablation Task Force, ‘Freedom from AF/flutter/tachycardia off antiarrhythmic therapy is the primary endpoint of AF ablation’. Based on this definition, these two reports confirm a success rate well below 50% at 1 year for AF ablation. The authors of the present report and commentators on the Belgian report suggest that the AF ablation procedures could have been a success, even though antiarrhythmic drugs were not discontinued. In other words, it is possible that investigators may have chosen or forgotten to stop the drugs or patients did not want to. In general this is plausible but does seem unlikely. One of the major motivating factors for patients to choose to have an AF ablation is to avoid antiarrhythmic drugs and their well described, and potentially serious, side effects.

**Why the difference between the randomized trials and these real-world surveys?**

There are several plausible explanations for this divergence. Perhaps the centres performing in the randomized trials had greater expertise than those now delivering the procedure in Europe. This idea is not supported by the Atrial Fibrillation Ablation Pilot Study which observed no difference in outcomes according to the experience of the centres. Perhaps the randomized trials have overestimated the benefit of AF ablation? This is possible because the randomized trials were small, they were generally performed by enthusiastic, highly motivated investigators, and they were unblinded. Some randomized trial results are actually somewhat consistent with these survey results. The recent MANTRA-PAF trial reported that, on its primary outcome of AF burden, there was no advantage of AF ablation over antiarrhythmic therapy. The RAAFT-2 trial reported a significant benefit of ablation therapy over antiarrhythmic drugs at 21 months. However, the rate of arrhythmia recurrence in this trial, in the AF ablation arm, was 55%, a recurrence rate not too different from that reported in these two real-world surveys.

**What are the implications of these real-world surveys?**

First, we need more large and methodologically robust surveys. These should be prospective and population based with complete follow-up. There needs to be much greater standardization of follow-up procedures and methods for assessment of success. We also need to understand the recurrence rates of both symptomatic and asymptomatic AF episodes. One recent study suggests that asymptomatic episodes of AF are as common as symptomatic episodes after AF ablation, which has major implications for stroke prevention. We also need to understand how anticoagulation is being used, or not used, post-ablation. For now, physicians today need to be aware that the results of AF ablation in real-world practice do not appear to be as favourable as those that have been reported in randomized trials. Because the only strong rationale for an AF ablation is to control symptoms, before patients are referred for this procedure, there should be a very careful correlation between symptoms and arrhythmia occurrence. Many of the symptoms which patients associate with AF can be due to other causes. The observation in the European survey that one-third of patients still reported symptoms, even after supposedly successful ablation, suggests that symptom–rhythm correlation may not have been optimally performed prior to referral for ablation. Thus real-world surveys suggest that AF ablation should be reserved for patients who are very symptomatic despite treatment with antiarrhythmic drugs. The patient should be made aware of the fact that recurrence rates are high and complications can occasionally be very serious. Very experienced expert centres still need to push the barriers of the technique in special populations, but, for most centres, the procedure should mostly be confined to highly symptomatic patients with paroxysmal AF.

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**References**


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**CARDIOVASCULAR FLASHLIGHT**

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First in-human robotic rotor ablation for atrial fibrillation

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Pulmonary vein isolation (PVI) is the cornerstone of most atrial fibrillation (AF) ablation procedures. Recent studies demonstrate that in AF, rapidly activating spiral-circuits called ‘rotors’ can be localized with computational-mapping during an electrophysiological study. Radiofrequency ablation at the rotor may result in AF termination. Remote robotic-navigation (RN) is designed to improve catheter stability and decrease radiation exposure.

We report the first in-human rotor-mapping with a novel 64-electrode basket catheter (FIRMap®, Topera) (Panel A) and mapping system (RhythmView®, Topera) combined with a RN system (Sensei™, Hansen Medical), and assessed its feasibility for rotor-modulation and PVI.

A 73-year-old male with paroxysmal AF and no structural heart disease was referred for ablation. Two long sheaths were advanced into the left atrium (LA). Atrial fibrillation was induced with burst pacing from the septal PVs, and sustained for >5 min before a 60 mm FIRMap® basket catheter (Panel B) was used to map for rotors in both atria.

No rotors were identified in the right atrium. A rotor was identified at the LA mid-posterior wall near the right PV antrum before circumferential PVI (Panels C and D, Supplementary material online, Video). Radiofrequency current (30 W) was applied for 300 s using the RN Artisan® Extend catheter (Hansen Medical) and resulted in coronary sinus cycle-length prolongation (150 to 170 ms). Atrial fibrillation termination occurred 72 s after rotor ablation (Panel E). Repeat rotor-mapping confirmed no further rotors. Ipsilateral PVI was then performed, and AF was no longer inducible.

The combination of RN and rotor ablation using the novel FIRMap® catheter is feasible.

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