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Long-term outcomes after "Zero X-ray" arrhythmia ablation

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Abstract

Purpose Radiation exposure related to conventional tachyarrhythmia radiofrequency catheter ablation (RFCA) carries small but definite risk for both patients and operators. Today, non-fluoroscopic mapping systems enable to perform catheter ablation with minimal or zero fluoroscopy. The purpose of this study was to evaluate the long-term outcome of patients who had undergone "Zero X-ray" ablation, since no information is available on the very long-term benefits.

Methods A total of 272 arrhythmias in 266 patients have been treated with catheter ablation by means of a zero-ray approach guided only by a nonconventional mapping system (EnSite NavX™, Ensite™ Velocity™ mapping system; subsequently Ensite™ Precision™ Abbott, St. Paul, MN). Fluoroscopy was never used.

Results Over a period of 6 years, patients were followed up for an average of 2.9 ± 1.6 years. A 100% rate of acute success was observed in the study population, with a complication rate of 0.8%. Chronic success was achieved in 90.8% of the total number of procedures (272). Patients in whom the same arrhythmia recurred during follow-up underwent to a redo catheter ablation procedure in 60.0% of cases, while the remaining 40.0% underwent pharmacological treatment. A new post-ablation arrhythmia occurred in 7.7% of the sample.

Conclusions The non-fluoroscopic approach is a feasible and safe alternative to fluoroscopy for arrhythmias ablation. This method ensures low complications rates, high acute procedural success rates, and comparable long-term outcomes with clinical benefits for both patients and physicians. The complete elimination of fluoroscopy during catheter ablation is advantageous and does not reduce patient safety.

Keywords Arrhythmia · Catheter ablation · Radiation risk · Zero fluoroscopy

1 Introduction

Since its introduction in 1987, radiofrequency catheter ablation (RFCA) has become the method of choice for supraventricular tachycardia therapy in symptomatic patients [1]. As indications have expanded, an increasing number of procedures have been carried out. This therapeutic approach is now in class I for all types of arrhythmias with the exception of the junctional tachycardia (IIb) [2]. Although fluoroscopy has traditionally been the primary imaging modality used for electrophysiological studies and RFCA, this approach carries a small but definite radiation risk for patients and operators. [3–5]. While it is not fully known how much damage this radiation may cause, there is no magnitude of radiation exposure that is known to be completely safe. For this reason, the ALARA policy (radiation doses "as low as reasonably achievable") constitutes a pivotal step towards minimizing radiation use in invasive cardiology [6]. Several tools have been developed to facilitate arrhythmia mapping and ablation, including three-dimensional electroanatomic mapping systems (EAMS), intracardiac echocardiography, and magnetic navigation, with a view to improving procedural outcomes and reducing fluoroscopy time. These alternative imaging systems enable ablation to be performed without, or with minimal, fluoroscopy, and procedural time and success and complication rates similar to those achieved with standard techniques have been reported in both pediatric and adult patients [7–13]. In a previous experience, we demonstrated that "Near-Zero X-ray ablation" was safe, feasible, and effective in a great variety of arrhythmic substrates [14]. In a recent pooled analysis of previous studies, no significant differences in acute success

All six authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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were observed between fluoroscopy and zero or near-zero RFCA groups. Long-term success rates (follow-up ranged between 43 and 606 days) were available in two groups [15]. However, no information is available on the very long-term benefits of "Zero X-ray" RFCA. The purpose of this retrospective, observational, single-center study was to evaluate the long-term outcome of patients who had undergone "Zero X-ray" ablation.

2 Methods

The study group was composed of symptomatic patients sent to our laboratory [Santa Maria Nuova, Florence, Italy] from clinical cardiologists or emergency department for catheter ablation to treat paroxysmal supraventricular and ventricular tachycardia. Since March 2011, a total of 272 arrhythmias in 266 patients have been treated with catheter ablation by means of a zero-ray approach guided only by a nonconventional mapping system (EnSite NavX™, Ensite™ Velocity™ mapping system; subsequently Ensite™ Precision™ Abbott, St. Paul, MN) according to ALARA policy. Only one first operator (M.G.) with over 15-year experience performed all the ablation procedures, and fluoroscopy was never used. Zero fluoroscopy was defined as the achievement of ablation entirely without the use of any fluoroscopy. Patients who required any degree of fluoroscopy were excluded from this study. Since in our laboratory we rarely need the use of fluoroscopy as a first line of treatment for most ablation procedures, we excluded all pulmonary vein isolation for atrial fibrillation (AF) and left atypical atrial flutter ablation, unless a patent foramen oval (PFO) was present. In all other patients, Zero X-ray approach was successful, including those with left-sided accessory pathway ablation by retrograde aortic approach. Therefore, the only reason made necessary the X-ray utilization was trans-septal puncture, and all these cases were excluded from the present analysis. A class I indication for arrhythmia ablation had previously been established in all patients according to the current guidelines [2]. Only follow-up data ≥ 1 year after ablation were included in this study. Follow-up data were obtained from follow-up visits, during which 12-lead electrocardiography was performed, and in cases of palpitations 24-h Holter monitoring. In the event of missing follow-up data, patients were additionally contacted by telephone. The study was approved by the Institutional Committee on Human Research at our institution.

2.1 Procedure and substrates

Substrates mapping and ablation has been described previously [14]. The EnSite Velocity and Ensite Precision mapping systems were used to reconstruct the three-dimensional geometry of the vessels and chambers of interest in all cases. The mapping system was used to visualize the catheters from the beginning to the end of the procedure. The procedural time was defined as the interval from the first femoral puncture to extraction of the femoral venous sheaths at the end of the procedure. The first catheter inserted in the vein was a quadripolar/octopolar steerable catheter (Dynamic XT, Bard Electrophysiology Division, Lowell, MA, USA) through the femoral veins to be positioned in the coronary sinus (CS). From the femoral vein, the catheter was moved to the venous system collecting three-dimensional geometry points, and it was advanced until atrial signals were read by the bipoles. Once in the atrium, the catheter was advanced into the superior vena cava and then pulled back in the atrium along the septum, in order to localize the CS ostium. Once the catheter was inserted into the CS, system optimization and respiration compensation were performed. If the CS catheter was in a stable position, one of its electrodes was used as geometry reference from this point on, instead of the internal virtual reference calculated by the mapping system. Therefore, the other diagnostic catheters were inserted and advanced using the previously reconstructed geometry as a guiding path to navigate to the right atrium. While moving the catheters in the venous system and the right atrium, new anatomy points were collected to better define boundaries of areas of interest. His bundle region, CS ostium, tricuspid valve, right atrial appendage, and both inferior and superior vena cava ostium were marked during navigation as points of interest. A combined electroanatomic approach to identify target sites for ablation was used, regardless of the energy source. If necessary for the EP procedure, the right ventricle geometry was reconstructed. After positioning all diagnostic catheters, a standard EP study was performed, eventually followed by ablation when appropriate. In the case of left chamber arrhythmic substrates, no trans-septal puncture was performed and the ablation catheter was inserted through the right femoral artery (reconstructing anatomy from the beginning as for the venous system, see Fig. 1) or through a patent foramen ovale (PFO). If necessary during the procedure, new respiration compensation was performed. Cryoenergy was the preferred energy source in cases of parahisian pre-excitation, and radiofrequency was used in all other cases. Conscious sedation was used only in patients who required it, and in cases of prolonged procedures.

2.2 Statistical analysis

Statistical analyses were performed by means of STATA, version 13.1 (Stata Corp, College Station, TX). Data are presented as mean ± standard deviation for normal variables or median (interquartile range) for non-parametric variables. Categorical data are summarized as count and percentages.

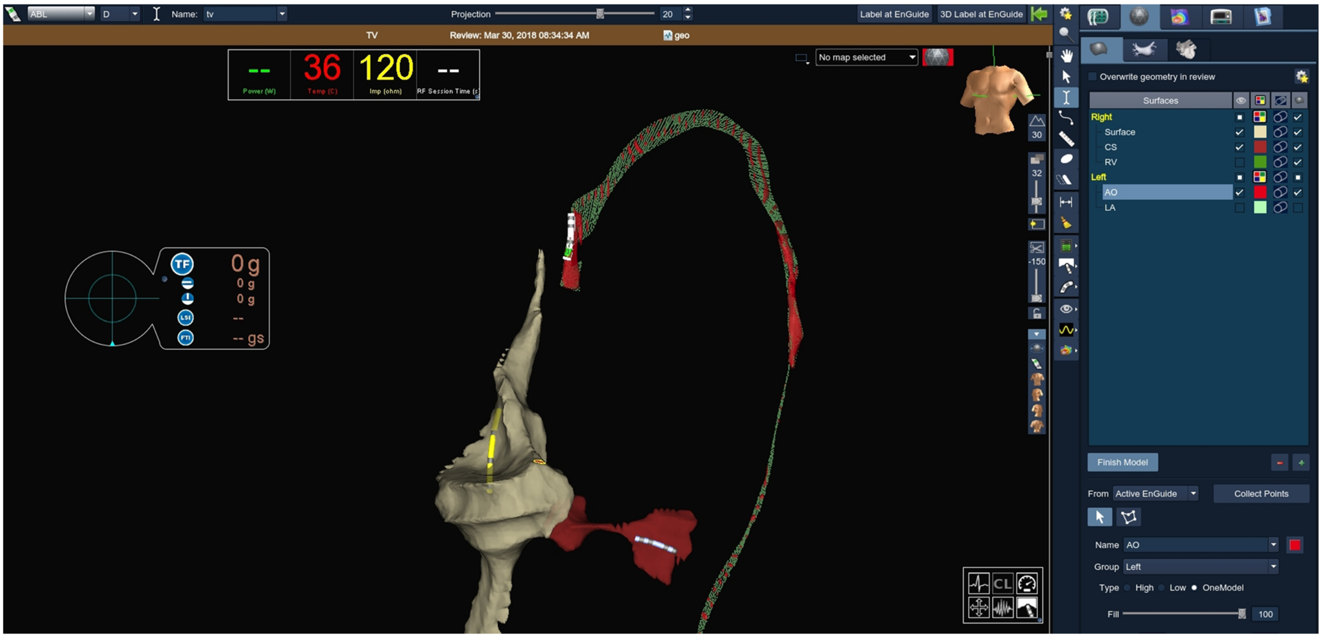

Fig. 1 Ablation catheter allows to monitor the contact force (0 g) in order to avoid aortic vessel-damage

3 Results

Over a period of 6 years, a total of 266 patients underwent ablation without the use of fluoroscopy and were followed up for an average of 2.9 ± 1.6 years [min = 1, max = 6]. The median age at the time of the procedure was 61.3 ± 16.3 years. Table 1 shows the patients' baseline characteristics. A 100% rate of acute success was observed in the study population, with a complication rate of 0.8%: one (0.4%) major complication (cardiac tamponade) and one (0.4%) minor complication (femoral thrombosis), both of which were resolved during hospitalization for the procedure (Table 2). Chronic success was achieved in 90.8% of the total number of procedures (272), as shown in Table 3. A new post-ablation arrhythmia occurred in 7.7% of the sample. The patients in whom the same arrhythmia recurred during follow-up underwent a redo RF ablation procedure in 60.0% of cases, while the remaining 40.0% underwent pharmacological treatment. Patients in whom the onset of a new arrhythmia was observed during follow-up underwent RF ablation in 28.6% of cases; in the remaining 71.4% of cases, we decided to treat the arrhythmia with pharmacological therapy. With regard to typical atrial flutter, we observed a recurrence of the same arrhythmia in 8.7% of cases and the occurrence of a new arrhythmia (AF) in 15.2%. In patients with AVRT treated with traditional RFCA (25) or with cryoablation (5), we observed a significant difference between the two procedures in terms of arrhythmia recurrence (RFCA = 2 vs cryoablation = 3, $p = 0.001$). Three AF cases were treated by means of the zero-fluoroscopy approach, owing to the presence of PFO. Table 4 shows mean procedural time for different arrhythmias.

4 Discussion

To our knowledge, the present retrospective study is the first to investigate the outcome of arrhythmia ablation performed totally without fluoroscopy over very long-term follow-up. This study confirmed that the non-fluoroscopic ablation of tachyarrhythmias is feasible, effective, and safe, and that its results remain good even over very long-term follow-up. Current EAMS have significantly reduced the need for fluoroscopic visualization by means of catheters [16, 17]. The potential benefits of these technologies include the following: more precise definition or localization of the mechanism of the arrhythmia, spatial display of catheters and arrhythmia activation, no exposure of patients and staff to radiation, and shorter procedure times, particularly in patients with complex arrhythmias or anatomies [18]. They have also created a precise and

Table 1 Demographic characteristics

Demographic characteristics [patients 266]	
Age [mean ± Std]	61.3 ± 16.3
Male [*n*, %]	162, 61.0
Coronary artery disease [*n*, %]	32, 12.0
Hypertension [*n*, %]	133, 50.0
Diabetes [*n*, %]	32, 12.0
Dyslipidemia [*n*, %]	56, 21.0
Smoke [*n*, %]	72, 27.0
Renal failure [*n*, %]	15, 5.5
COPD [*n*, %]	11, 4.0
Obesity [*n*, %]	24, 9.0

Table 2 Success and complication rates

Type of arrhythmias [*n*, %]	Acute success [*n*, %]	Chronic success [*n*, %]	Major complications [*n*, %]	Minor complications [*n*, %]
PVCs [1, 0.4]	[1, 100.0]	[0, 0.0]	[0, 0.0]	[0, 0.0]
AF [3, 1.1]	[3, 100.0]	[3, 100.0]	[0, 0.0]	[0, 0.0]
Typical AFl [92, 33.8]	[92, 100.0]	[84, 91.3]	[0, 0.0]	[0, 0.0]
Atypical AFl [2, 0.7]	[2, 100.0]	[0, 0.0]	[0, 0.0]	[0, 0.0]
AV node ablation [30, 11.0]	[30, 100.0]	[28, 93.3]	[0, 0.0]	[0, 0.0]
AVNRT [83, 30.5]	[83, 100.0]	[78, 94.0]	[1, 0.4]*	[1, 0.4]**
Atrial tachycardia [25, 9.2]	[25, 100.0]	[23, 92.0]	[0, 0.0]	[0, 0.0]
Ventricular tachycardia [6, 2.2]	[6, 100.0]	[6, 100.0]	[0, 0.0]	[0, 0.0]
AVRT/accessory pathway [30, 11.0]	[30, 100.0]	[25, 83.3]	[0, 0.0]	[0, 0.0]

PVCs, premature ventricular contractions; *AF*, atrial fibrillation; *AFl*, atrial flutter; *AV*, atrioventricular; *AVNRT*, atrioventricular nodal reentry tachycardia; *AVRT*, atrioventricular reentry tachycardia

*Tamponade

**Femoral thrombosis

reliable "virtual environment" capable of guiding complex mapping and ablation procedures, sometimes without the use of fluoroscopy, but with a greater ability to reveal the anatomical relationships between different structures, thereby reducing the risk of complications, such as complete atrioventricular (AV) block leading to pacemaker implant. Existing literature represents our study control group. Indeed, no AV block occurred in our study; by contrast, the literature reports percentages of complete AV block followed by pacemaker implantation ranging from 0.2% during cavotricuspid isthmus (CTI) ablation to 0.3% in accessory pathway ablation and 0.7% in AV nodal reentrant tachycardia ablation (2). In our study, the new onset of AF after CTI ablation was 15.2% over a 6-year follow-up, in patients with no pre-ablation history of AF, confirming that atrial flutter and AF may occur in the same clinical setting and in the same patient. This prevalence is slightly lower than those found in the literature, in which, one meta-analysis reported a percentage of 23.1% in the same type of patients [19]. Risk factors for the onset of AF after atrial flutter ablation include the following: previous AF, depressed left ventricular function, structural heart disease or ischemic heart disease, inducible AF, and increased left atrial size. We observed more recurrences of AVRT than those reported in the literature (16.7 vs 8%). Furthermore, in four out of five procedures performed with cryoenergy, AVRT recurred. While cryoenergy offers greater selectivity and safety of ablation close to the normal conduction system, this advantage is counterbalanced by a higher risk of recurrence, even very late [20, 21]. In our series, a recurrence occurred up to the third year of follow-up after cryoenergy ablation. Our complication rate was, on the other hand, comparable to that reported in previous study already published. In the NO-PARTY trial, the complication rate was slightly higher (1.1%), even though our population was treated entirely without the use of fluoroscopy [22]. The adoption of radiation-reducing strategies can minimize the radiation dose to the patient and operator. The current standard is to apply the "as low as reasonably achievable" (ALARA) principle, on the assumption that there

Table 3 Rates of arrhythmia recurrence and new-onset arrhythmias

Type of arrhythmias [*n*, %]	Recurrent arrhythmias [*n*, %]	Onset of new arrhythmias post-ablation [*n*, %]
PVCs [1, 0.4]	[1, 100.0]	[0, 0.0]
AF [3, 1.1]	[0, 0.0]	[0, 0.0]
Typical AFl [92, 33.8]	[8, 8.7]	[14, 15.2]
Atypical AFl [2, 0.7]	[2, 100.0]	[0, 0.0]
AV node ablation [30, 11.0]	[2, 6.7]	[0, 0.0]
AVNRT [83, 30.5]	[5, 6.0]	[3, 3.6]
Atrial tachycardia [25, 9.2]	[2, 8.0]	[2, 8.0]
Ventricular tachycardia [6, 2.2]	[0, 0.0]	[0, 0.0]
AVRT/accessory pathway [30, 11.0]	[5, 16.7]	[2, 6.6]

PVCs, premature ventricular contractions; *AF*, atrial fibrillation; *AFl*, atrial flutter; *AV*, atrioventricular; *AVNRT*, atrioventricular nodal reentry tachycardia; *AVRT*, atrioventricular reentry tachycardia

Table 4 Mean procedural time for different arrhythmias

Type of arrhythmias [*n*]	Mean procedural time [min]
PVCs [1]	[75 ± 0]
AF [3]	[133 ± 11]
Typical AFl [92]	[47 ± 28]
Atypical AFl [2]	[145 ± 15]
AV node ablation [30]	[43 ± 26]
AVNRT [83]	[62 ± 17]
Atrial tachycardia [25]	[90 ± 18]
Ventricular tachycardia [6]	[128 ± 21]
AVRT/accessory pathway [30]	[83 ± 16]

PVCs, premature ventricular contractions; *AF*, atrial fibrillation; *AFl*, atrial flutter; *AV*, atrioventricular; *AVNRT*, atrioventricular nodal reentry tachycardia; *AVRT*, atrioventricular reentry tachycardia

is no threshold below which ionizing radiation is free from harmful biological effects. The lifetime age and sex-average risk of a fatal malignancy resulting from catheter ablation requiring 60 min of fluoroscopy has been reported to range from 0.03 to 0.23% [23–27]. Alternative imaging systems, such as electroanatomic mapping and intracardiac echocardiography, and electrophysiological tools, such as the contact force catheter, have enabled ablation to be performed without, or with minimal, fluoroscopy, while achieving success and complication rates similar to those yielded by standard techniques [28]. A reduced-fluoroscopy approach is particularly important in pediatric patients and during pregnancy. Owing to their younger age, pediatric patients have a higher lifetime risk of developing radiation-induced cancers than adult patients. However, adult patients, and especially adults who are occupationally exposed to radiation, also display an increased malignancy rate over the long term [29]. In all procedures, "fluoro-less" ablation is feasible regardless of the arrhythmic substrates to be treated. Like Gaita et al., we believe that not only patients but also cardiologists and internists need to be fully aware of the risks of radiation exposure and must be convinced that adopting a zero-fluoroscopy approach, instead of the conventional "fluoro" approach, can significantly reduce the risks of cancer and mortality [30].

5 Limitations

This registry represents a retrospective, single-center, observational experience; as such, it may have been affected by collection and entry bias and possible residual confounding. It would be desirable to conduct a study involving a large number of operators and centers such as a randomized trial comparing the non-fluoroscopic approach with the standard approach over long-term follow-up. Another limitation is that we performed left-sided ablation only in the presence of a PFO, as cases in which it was absent required fluoroscopy for the trans-septal approach; these latter cases were excluded from the present analysis. However, we have demonstrated that trans-septal puncture is feasible under echoscopic guidance, which means that Zero X-ray ablation may be performed in almost all cases [31]. Finally, as we analyzed real "Zero X-ray" procedures, we had a different distribution of treated arrhythmias: a large number of supraventricular arrhythmias, but few cases of vetricular tachycardia. In future studies, it could be useful to assess the outcomes of homogeneously distributed arrhythmias.

6 Conclusions

The non-fluoroscopic approach is a feasible and safe alternative to fluoroscopy for arrhythmias ablation. This method, like the fluoroscopic approach, ensures low complication rates, high acute procedural success rates, and comparable long-term outcomes. However, in accordance with the ALARA policy, it yields clinical benefits for both patients and physicians. The complete elimination of fluoroscopy during catheter ablation is therefore advantageous and does not reduce patient safety.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

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