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RADIOFREQUENCY ATRIAL FIBRILLATION ABLATION USING 3D MAPPING SYSTEM NAVIGATION: FIRST SINGLE-CENTRE EXPERIENCE IN NORTH AFRICA

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ABSTRACT

Introduction: We report the first single-centre experience in Tunisia with the navigation system in an unselected subset of patients with atrial fibrillation (AF).
Material and Methods: Data were recorded prospectively of all consecutive patients who underwent atrial fibrillation ablation with radiofrequency and 3D mapping navigation system at the Aberrahman Mami Hospital, in Tunisia, in North Africa, from January 2010 to December 2013. Outcomes were defined every three months.
Results: A total of 35 patients were included: 77% had paroxysmal AF, 17% had persistent AF and 6% had longstanding persistent AF. The mean procedure, fluoroscopy and ablation times were 21 min +/-10 min (with extreme: 8-58 min) and 180 min respectively. The procedural endpoint of the study was successfully achieved in 98% patients. The follow up was 17.72 months. At a median of 17.72 months follow up, 34% had atrial fibrillation recidive. Six patients had two procedures. The mean of procedure was 1.2 per patient. 74% were AF-free off anti-arrhythmic drugs AADs, and 89% were AF-free on AADs.
Conclusion: The 3D mapping navigation system offers a safe and effective approach for the treatment of AF in Tunisia. This benefit is long-lasting and important in the management of Tunisian patients who present atrial fibrillation.

INTRODUCTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia that affects patient morbidity and mortality. Catheter ablation for AF has emerged as a promising new treatment strategy to maintain normal sinus rhythm (NSR). Unlike antiarrhythmic drugs, catheter ablation directly eliminates the inciting factors for AF and offers the possibility of a lasting cure. Various methods of ablating AF have been tried. Haissaguerre *et al.* (Haïssaguerre *et al*., 1998) and Chen *et al*. **(**Chen *et al.,* 1999**)** found that most focal AF is initiated by premature beats from the orifices of the pulmonary veins (PVs) or from the myocardial sleeves inside the PVs, and radiofrequency (RF) catheter ablation of triggered foci has been shown to cure AF. Moreover, numerous techniques have evolved, from segmental PV isolation to extensive encircling PV isolation, (Pappone *et al.,* 2000) to LA linear ablation, (Hocini, 2005) box isolation, (Kumagai *et al*., 2007) ablation of complex fragmented atrial electrograms (CFAEs) **(**Nademanee *et al.,* 2004**)** and ablation of ganglionated plexi, **(**Kumagai, 2011**)** However, the benefit of catheter ablation in north of African patients with AF has not been reported. The objective of this observational study was to evaluate the safety and efficacy of catheter ablation for maintaining NSR in Tunisian patients with AF, as well as to evaluate the long-term clinical outcomes after ablation and also to investigate the clinical and echocardiographic predictors of AF recurrence after atrial fibrillation ablation.

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MATERIALS AND METHODS

Our study is a prospective analysis of collected data, which consisted of patients with symptomatic AF. Exclusion criteria were patients who were mentally unstable; who had alcoholism, myocardial infarction within 1 month of the study, terminal disease, or left atrial (LA) thrombus; who could not commit to participate in scheduled outpatient follow-up. All patients signed informed consent.

Electrophysiological study

The electrophysiological study and ablation procedure were performed under conscious sedation. A decapolar catheter was positioned within the coronary sinus for atrial pacing and signal reference. A quadripolar catherter was positioned on His. One or two 8-F long sheaths (SL1, St Jude Medical, Minnetonka, USA) were delivered into the LA using a modified Brockenbrough technique. The transseptal sheaths were flushed continuously with heparinized saline (20 ml/h) in order to prevent thrombus formation and air embolism. Heparin was administered to maintain an activated clotting time (ACT) of 300–350 seconds. After transseptal puncture, a 3.5-mm cool saline-irrigated ablation catheter (an irrigated-tip 4-mm saint jude medical catheters) was applied for mapping and ablation.

Mapping and ablation of AF: **Study protocol (the stepwise approach)**

The patients underwent non- fluoroscopic electroanatomic mapping with the NAVX system (Saint Jude Medical) as previously described. (Nademanee *et al.,* 2004). The three-dimensional geometry of LA was reconstructed using an electroanatomic mapping system (NAVX Saint Jude Medical) based on a venogram of the PVs and a computed tomography (CT) image of the LA.RF ablation with an irrigated-tip 4-mm was carried out with an energy output between 25 and 35 W, a temperature of 42ºC for 60 seconds, and a flow rate of saline irrigation set to 17 ml/min. However, at the posterior wall, RF was limited to a maximal power of 25 W for 60 seconds. A pre-determined stepwise study protocol was performed.

The initial circumferential PVA ablation using an electroanatomic mapping was realized firstly, as previously described in the literature (Liu, 2006; Ouyang, 2004 and Dong, 2009). The endpoint was attained at the complete electrical isolation of both ipsilateral PVs with continuous circumferential lesions, if AF was paroxysmal or persistent. The endpoint was the establishment of a complete bi-directional conduction block that can be demonstrated by pacing maneuvers. (Asirvatham, 2007; Asirvatham, 2007). In this case, when the AF recurred, a second procedure was programmed. First, an ablation catheter or a circular mapping catheter (Lasso, Saint Jude Medical,) was applied for the validation of PV isolation and closing residual gaps along the ablation line. If a conduction block of the ablation line was not confirmed, further ablation was performed in order to achieve a complete bi-directional conduction block. Secondly, we ablated area CFAE.

Targeting these CFAE areas, radiofrequency (RF) ablations were delivered until AF was converted to NSR or all CFAE areas were ablated. CFAE criteria were defined as previously described (Nademanee *et al.,* 2004; Haïssaguerre *et al.,* 2005) the endpoint may necessitate voltage reduction, AF organization, or the elimination of fractionated activity. CFAE detection and ablation were guided by visual inspection; however, all operators assessed sample CFAEs were reexamined in order to ensure uniformity in the selected area of ablation. Sometimes maps were created during AF and associated atrial anatomy with complex fractionated atrial electrogram (CFAE) areas. Targeting these CFAE areas, radiofrequency (RF) ablations were delivered until AF was converted to NSR or all CFAE areas were ablated. If the arrhythmias were not successfully reverted to NSR, external cardioversion was performed. However, in case of longstanding persistant AF, we begun with PVA ablation following by CFAE area ablation. No line ablation was created.

Anticoagulation management

Anticoagulation management for our patients, patients were treated with warfarin to maintain an international normalized ratio (INR) between 2 and 3 for at least 3weeks before the ablation. Warfarin was discontinued 4days before the ablation. Patients were given enoxaparin sodium 1mg/kg subcutaneously every 12 hours before the ablation. Both warfarin and enoxaparin were restarted immediately after the procedure, but enoxaparin was discontinued 3 days later. Heparin was also used during the procedure, with the aim of keeping the activated clotting time between 300 and 350 seconds. If the patient remained in NSR 6 months after ablation, warfarin was discontinued. Patients who developed recurrent AT/AF were restarted on warfarin. The outcome of the ablation was based on 24 hours monitoring ECG.

Follow up

Arrhythmia documentation was done by symptoms, periodical 12-lead ECG and an electrocardiogram Holter-monitoring at 1, 3, 6 and 12 months.

Statistical and data analysis

Data are reported as mean and standard deviation (SD) for continuous variables and as proportion (%) for categorical variables. Median and quartiles are presented for skewed data. The characteristics of patients were compared using the Student t test or Mann–Whitney test for continuous variables, and the Fisher exact test or $\chi 2$ test for categorical data where applicable. The percentage of patients free from AF recurrence was presented in a Kaplan-Meier survival curve. The estimates were evaluated with the log-rank test. A significant risk was determined if the 95% confidence interval (95% CI) exceeded 1, and the *P*-value was <0.05. All analyses were performed using the SPSS 19.0 software program (SPSS).

Definitions

One-year success is defined as patient survival free from any atrial arrhythmia, with or without antiarrhythmic drugs, as assessed from the end of the 3-month blanking period to 12 months following the ablation procedure. Arrhythmia recurrence is defined as an electrocardiographically documented episode of AF or atrial flutter lasting at least 30s, after a 3-month blanking period. Early recurrence is defined as a recurrence of any atrial arrhythmia, within 3 months from ablation. A blanking period of 3 months was employed after ablation. Recurrences within the first 3 months were not classified as failure of the procedure.

RESULTS

Patients

From January 2010 through December 2013, we included 35 consecutive patients with drug-refractory symptomatic AF. The mean age was 51 +/- 10 years, and 66% of the patients were men. Definitions of paroxysmal, persistent, and longstanding persistent AF followed the American Heart Association/American College of Cardiology/European Society of Cardiology guidelines. (Fuster *et al.,* 2007) The majority of patients (77%) had paroxysmal atrial fibrillation, 17% had persistent atrial fibrillation and 6% had longstanding persistent atrial fibrillation.

Baseline clinical characteristics

Symptoms were present in all patients, mainly in the form of palpitations. However, there were other relevant symptoms associated to atrial fibrillation, such as lipothymia, dyspnoea, and angina. Fig.1.

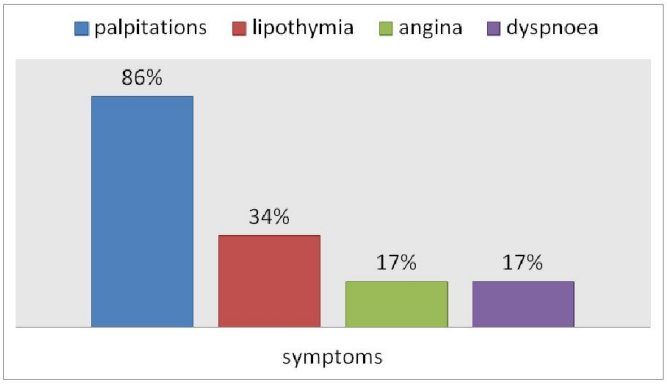

Figure 1. Symptoms of patients

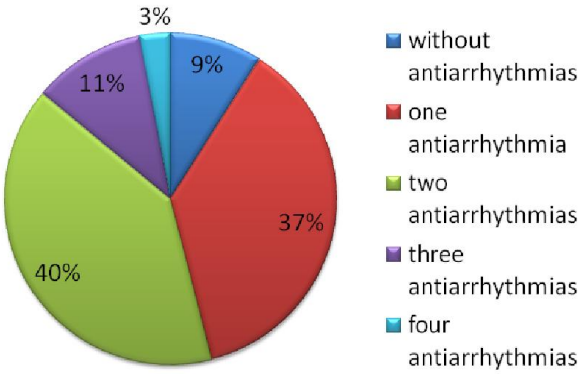

Figure 2. Antiarrhythmias before ablation procedure

The indications for catheter ablation were mostly symptomatic atrial fibrillation with antiarrhythmias. Over a half of patients, there were two or more antiarrhythmias. Fig. 2. A half of patient had a lone atrial fibrillation. Fig. 3.

Pre-operative evaluation

A baseline electrocardiogram at admission was performed in all patients. The heart rhythm was sinus in 86% of patients and atrial fibrillation in 14% before the procedure.

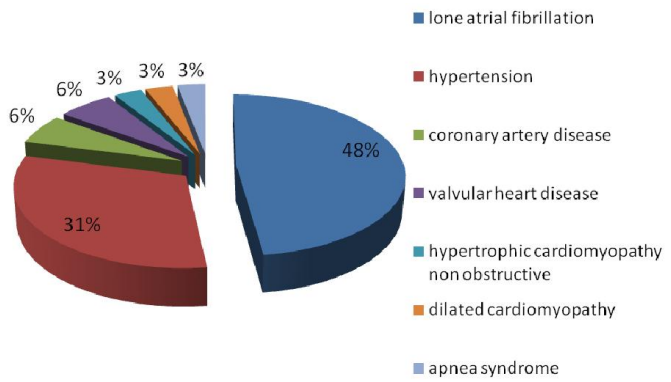

Figure 3. Underlying disorder (%)

An echocardiogram at admission was performed for all patients: 68% transthoracic, all patients had transesophageal 24-48 hours before ablation. The median left atrial area was 20 cm² and the median ejection fraction was 57%. Additionally, an imaging technique computed tomography scan to visualize the left atrial, pulmonary vein anatomy and atrial left volume was done in all patients. A Hatch score (16,17) was calculated. (Fig 4). The HATCH score (1*hypertension + 1*(age > 75) + 2*(stroke or transient ischemic attack) + 1*(chronic obstructive pulmonary disease) + 2* (heart failure)), was established to estimate the probability of AF progression in patients with paroxysmal AF (Tang *et al.,* 2012; Miao *et al.,* 2012; De Vos *et al.,* 2010).

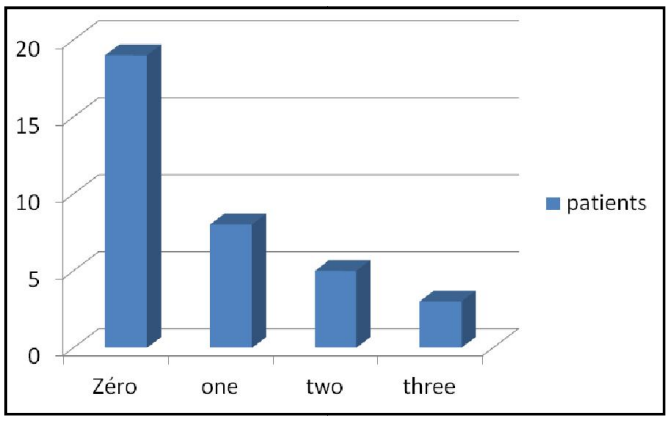

Figure 4. Hatch score

Procedure

Ablation technique

The procedure was performed under general anaesthesia. With regard to anticoagulation therapy, our centre used unfractionated heparin. The median duration of the procedure was 180 min, with a median fluoroscopy time of 21 min (IQR 8-58). The ablation was performed with an open irrigation-tip catheter. A 3D mapping system was used for all patients. Pulmonary vein isolation was attempted for all patients and complete conduction block was achieved. No left atrial linear lesions. Complex-fractionated atrial electrograms were targeted in 9% of patients. Finally, ganglionated plexi were ablated in 3%. In 11% of patients in atrial fibrillation during the procedure the arrhythmia converted to sinus rhythm during ablation. At the end of the procedure, the inducibility was not evaluated. (Fig. 5.) For two patients (5.7%), an adverse event

in relation with the ablation procedure was reported. Pericarditis caused by Cardiac perforation occurred in 2.8% of patients undergoing catheter ablation of atrial fibrillation. A cardioembolic event was reported in one patient (2,8%): transient ischaemic attacks. No atrio-oesophageal fistula occurred. There were no deaths in relation with the procedure.

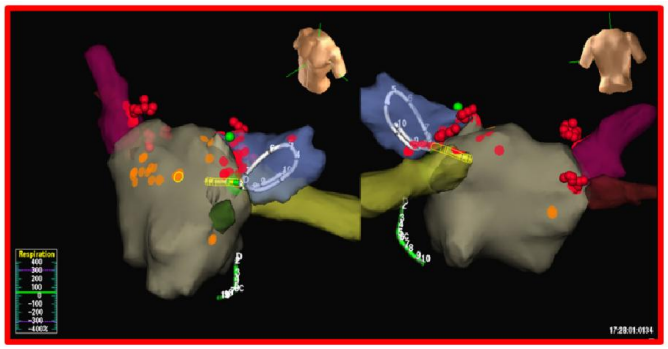

Figure 5. Pulmonary vein isolation (Right point) and Complex-fractionated atrial electro grams were targeted (orange point)

Complications related to the ablation procedure

Discharge status

The median duration of hospitalization was 3 days (IQR 2–4). At discharge, 97.1% of patients were in sinus rhythm, 2.8% in atrial fibrillation. Anticoagulation was used in all patients. 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 betablockers or blockers of the angiotensin–aldosterone system was used in variable proportions. No patient died during the hospitalization following the ablation procedure.

Follow up

Based on symptoms, on scheduled 12-lead ECG and 24 hours monitoring ECG performed during a follow-up of 17,72 months, success without antiarrhythmic drugs was achieved in 74,3% of patients and success under antiarrhythmic treatment was 88.6%. Twelve patients (34.3%) suffered from AF recurrences. Six patients (17%) underwent repeat ablation, a mean of 1.2 procedures per patient. No patient died. Many predictive factors were analyzed (tab1). The predictors of recurrence after ablation were the presence of hypertension, type of FA, long duration of AAR in AF, enlarged left atrial with left atria area superior to 20 cm², atrial left Volume ≥ 135ml. (Table. 1.) The HATCH Score was significantly limited. (Fig. 6.)

DISCUSSION

This report describes the main characteristics of Tunisian patients, admitted to hospital to undergo an atrial fibrillation (AF) catheter ablation. This is the first study in north of Africa. The population undergoing an ablation procedure for AF represents only a minority of the overall population suffering from this arrhythmia, with a high prevalence of paroxysmal AF without evident underlying cardiac disease. However, it was worth noting must be noted that the population undergoing an AF ablation is much younger with respect to the general population with AF and mean age was the same found in ESC-EUR Observational Research Programme (Arbelo *et al.,* 2012). Palpitations remain the most frequent symptom associated with AF 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 (Arbelo *et al.,* 2012).

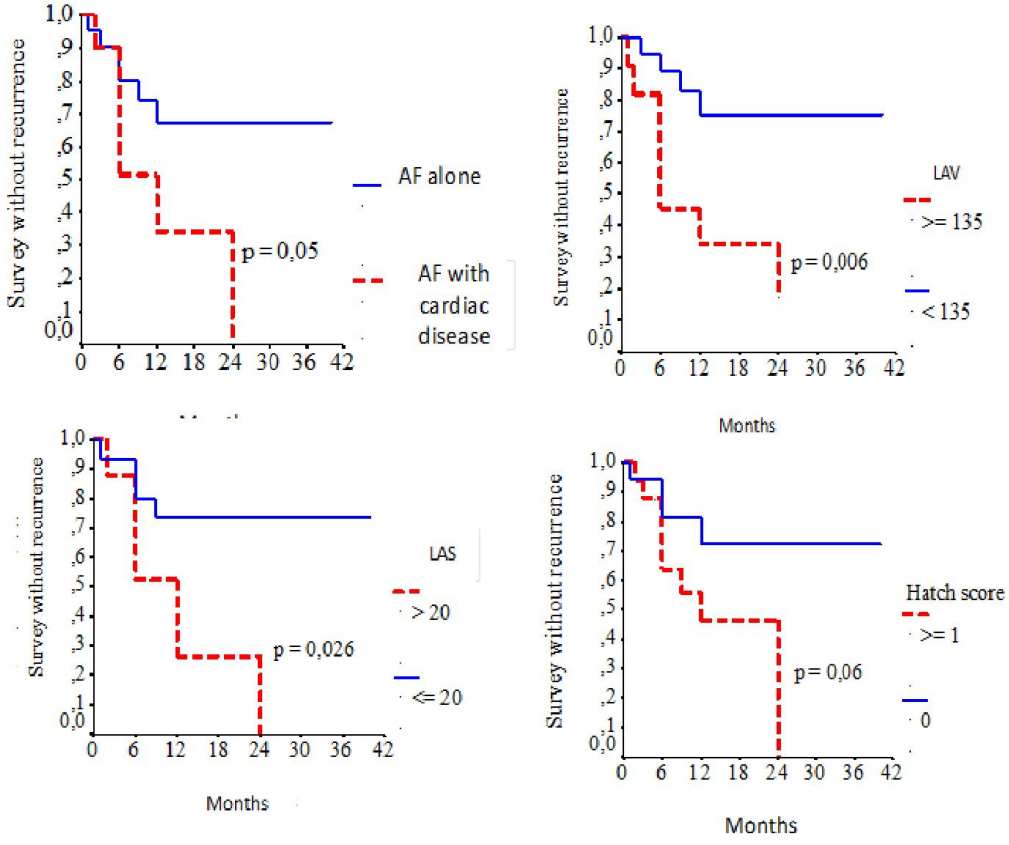

Figure 6. The predictors of recurrence after ablation were LAV (left atrial volume), LAS (left atrial surface). The presence of cardiac disease and Hatch score were significantly limited

In our study, palpitation was the most frequent symptoms. Indications for the ablation were in accordance with the current guidelines. (European Heart Rhythm Association, 2010) 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 CHADS2 score ≥2, and therefore, the interruption of anticoagulation should be weighed against the risk of a cardioembolic event. Despite the high prescription of OAC, 1-year mortality and morbidity remain high in AF patients, in particular due to heart failure and re-hospitalizations, (Lip *et al.,* 2014). In our series, no patient was died.

There is very limited data on 'real-world' on AF ablation. In 2005, a worldwide survey on the methods, efficacy, and safety of catheter ablation of AF was published. (Cappato *et al.,* 2005) Arbelo and al (Arbelo *et al.,* 2012) 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, (Cappato *et al.,* 2010). Arbelo and al (Arbelo *et al.,* 2012) showed 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%. (Arbelo *et al.,* 2012) Ablation of complex fractionated electrogram ablation or autonomic ganglionated plexi ablation was used only in a minority of cases.

In our study, the electrical isolation of pulmonary vein was achieved in all cases. The risk of early complications is increased by female sex, hypertrophic cardiomyopathy, valvular heart disease, deep sedation, and complex fractionated atrial electrocardiogram ablation. It is decreased by preprocedural transesophageal echo- cardiography, periprocedural novel oral anticoagulant, and irrigated-tip catheter use, (Inoue *et al.,* 2014). The incidence of complications in our study was 5.7%, which is in the range of other real-world multicentre surveys 7,7% (Arbelo *et al.,* 2012; Cappato *et al.,* 2010). There isn't a case of pulmonary stenosis. The incidence pulmonary vein stenosis was being looked for during follow-up. Arbelo and Al (Arbelo *et al.,* 2012), reported, 91,4% were in sinus rhythm at discharge and 67% had antiarrhytmic medication. Success without antiarrhythmic drugs was achieved in 40.7% of patients at 1-year follow-up (Arbelo *et al.,* 2014). Manganiello and al was reported during a follow-up of 12+/-11 months, delayed cure occurred in 35.6% of the patients with AF ablation (Manganiello *et al.,* 2014). In our study at discharge, 97.1% of patients were in sinus rhythm, 2.8% in atrial fibrillation.

Success without antiarrhythmic drugs was achieved in 74, 3% of patients and success under antiarrhythmic treatment was 88,6%. Twelve patients (34.3%) suffered from AF recurrences. Six patients (17%) underwent repeat ablation, a mean of 1.2 procedures per patient. No patient died. Several clinical parameters, biomarkers, and imaging parameters have been reported to predict AF recurrence after RFCA. (Kim *et al*., 2014) The reported predictors of recurrence after ablation are the presence of hypertension, long duration of AF, prolonged procedural time, enlarged LA diameter (LAD), or increased LA volume (LAV) and decreased LA function, (Abecasis *et al.,* 2009; Von Bary *et al*., 2012). Echocardiography has a well-recognized and essential role in the current guidelines for the assessment of cardiac structure and function in patients with AF (Fuster *et al.,* 2007; Li *et al.,* 2008). Several echocardiographic parameters for predicting the maintenance of SR after cardioversion, including LA size, mitral A wave velocity, and left atrium and LA appendage (LAA) mechanical function (Park *et al.,* 2008; Okçün *et al.,* 2005; Park *et al.,* 2010) have been reported. However, these echocardiographic predictors of AF recurrence have only been evaluated during a relatively short-term follow-up period. Moreover, the study population was not homogenous across the studies. (Kim *et al.,* 2014) In our study, we reported that hypertension, left atria area>20cm², left atrial volume≥135 ml and Long duration of AAR predicted AF recurrence.

Study limitations

Our study was not designed to determine whether our ablation technique was superior to others but merely to demonstrate that if NSR is maintained in Tunisian population with acceptable complications. At any rate, the overall results of our study are similar to those of other studies, which performed PVI and adjunct CFAE area ablation but had a relatively smaller sample size and a shorter follow-up period, with respect to the effectiveness of the catheter ablation in maintaining NSR

Conclusion

This Study was the first in Tunisia. Our findings show Tunisian patients with AF benefit from AF ablation, which is safe and effective in maintaining sinus rhythm like the literature and is associated with lower complication. This benefit is long-lasting and important in the management of Tunisian patients who present atrial fibrillation.

Declaration of interest

The author declares that there is no conflict of interest that could be perceived as prejudicing the impartiality of the review.

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