

Atrial Fibrillation Ablation: Efficacy and Safety in Acute and Long-Term Follow up of Nmarq™ and Thermocool® Catheters

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Keywords Atrial fibrillation; Pulmonary
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catheter; Standard focal ablation
technology; Long-term clinical follow-up

Abstract

Background: The circular nMARQ™ ablation catheter is a useful tool for pulmonary vein isolation (PVI). We assessed acute and long-term efficacy of nMARQ™ ablation catheter for PVI in paroxysmal and persistent AF.

Methods and Results: We report a case series of 200 patients (mean age 56±9 years; 73% male) referred to our center to perform PVI. One hundred patients (group 1) underwent PVI with the nMARQ™ and 100 patients (group 2) with the single tip Thermocool® ablation catheters. All patients performed 24 months of FU. AF recurrences were documented in 13 patients of group 1 (13%) and 32 patients of group 2 (32%) (p=0.003). Regarding the patients with paroxysmal AF, 8 patients in group 1 (11%) and 20 patients in group 2 (26%) had AF recurrences at clinical FU (p=0.02). In patients with persistent AF, 8 patients in group 1 (33%) and 12 patients in group 2 (59%) had AF recurrences at clinical FU (p=0.06). A trivial pericardial effusion not requiring any pharmacological or interventional correction appeared in 10 patients of group 1 (10%) and 6 patients of group 2 (6%); two patients reported groin haematoma.

Conclusion: The use of nMARQ™ ablation catheter for PVI is feasible and safe. Compared to standard single tip approach, we found a significant higher success rate in the nMARQ™ group at long term FU.

Introduction

Atrial Fibrillation (AF) is the most common sustained cardiac arrhythmia, occurring in 1–2% of the general population [1]. Current guidelines recommend catheter ablation of AF in symptomatic patients after failure or intolerance of antiarrhythmic drugs [2,3]. The pathogenesis of AF is complex, but several studies reported that Pulmonary Vein (PV) foci play a critical role in both initiation and perpetuation of this arrhythmia. PV isolation, therefore, is the cornerstone of catheter ablation in AF treatment [2,3].

PV isolation can be performed either with single tip ablation catheters or "single-shot" devices involving either balloon technology or multipolar ablation catheters [4-12]. Recently, some studies have reported the usefulness of a novel irrigated decapolar Radio Frequency (RF) energy circular ablation catheter (nMARQ™, Biosense Webster, Diamond Bar, USA), integrated into the CARTO3 system (Biosense Webster, Diamond Bar, USA) [4,11]. These studies, however, reported only a short-term efficacy of this ablation catheter in a small number of patients.

The primary aim of this study was to analyze the acute and long term efficacy of nMARQ™ ablation catheter compared to single tip one.

Methods

Study population

We report a case series of 200 patients (mean age 56±9 years; 73% male) referred to our center from November 2012 to December 2014 to perform PV isolation for symptomatic AF, according to the latest European Society of Cardiology guidelines [2]. Patient were included only if follow up

was completed. Patients had either paroxysmal or persistent AF but no history of previous ablation procedures. One hundred patients (group 1) underwent PV isolation with the irrigated decapolar radiofrequency energy circular ablation catheter nMARQ™ and 100 patients (group 2) underwent AF catheter ablation with the single tip Thermocool® ablation catheters (Biosense Webster, Diamond Bar, USA).

Clinical data collected in each patient included previous hospitalizations, cardiovascular risk factors (diabetes mellitus, hypertension, family history of coronary artery disease, hypercholesterolemia, hypertriglyceridemia, smoking, body mass index), pharmacological therapy, clinical history, left atrial size and all procedural data. This study was approved by the Ethics Committee.

nMARQ™ catheter ablation

The nMARQ is a steerable 8.4 French ablation and mapping 10-pole irrigated radiofrequency catheter with a novel irrigation design [4,11]. Each 3 mm-electrode is irrigated via 10 irrigation holes using a constant flush of 4 ml/min during mapping and 60 ml/min flushing rate during ablation. The 10 electrodes are arranged in a nearly circular array and the diameter may shift from 23 mm to 35 mm. The catheter is connected to a novel multi-channel radiofrequency system ablation generator (Biosense Webster, Diamond Bar, USA) capable of synchronously delivering energy to all 10 electrodes. Each electrode is controlled by a single generator with a continuous check of temperature and impedance. RF power is automatically and/or manually titrated by this information. Radiofrequency ablations are pre-set at a maximum of 60 s duration in temperature-controlled mode and energy delivery can be individually arranged over each combination of the 10 electrodes in unipolar mode (maximum 25 W and 45°C) or bipolar mode over two adjacent electrodes (maximum 15 W and 45°C). The nMARQ™ catheter is visualized with the CARTO3 system (Biosense Webster, Diamond Bar, USA). The nMARQ catheter has the Tissue Connect technology that reports information about the electrode contact on the left atrial tissue.

Thermocool ablation catheters

The Thermocool catheters used for ablation procedure were Navistar Thermocool® (66%), Thermocool Smart-touch® (18%) and Thermocool SF® (16%) (Biosense Webster, Diamond Bar, USA). These catheters are open irrigated radio-frequency energy ablation catheter, available in either bidirectional or unidirectional steering, with a 3.5 mm tip electrode and three 1 mm sensing ring electrodes. In particular, the Smart-touch catheter has the contact force sensing capability to assess the catheter contact and force vector on the myocardial tissue while, the Thermocool SF catheter provides enhanced cooling efficiency because the tip incorporates 56 small diameter (0.0035") irrigation holes distributed all around the electrode surface. During RF delivery, the physicians can utilize parameters such as contact force values, electrograms, impedance drop, fluoroscopy, tip temperature to perform optimal lesions on the myocardial tissue. The Thermocool ablation catheters are visualized in the CARTO3® system (Biosense Webster, Diamond Bar, USA).

Ablation procedure

PV isolation was performed as previously described [2,3]. All procedures were performed by an experienced operator

(MG). All patients underwent pre-procedural trans-esophageal echocardiography (TEE), within 24 hours before procedure, to exclude left atrial thrombosis. All procedures were carried out in conscious sedation with intravenous infusion of diazepam (max 10 mg), paracetamol 1 g and fentanyl (0.05-0.2 mg). All patients received barium sulfate swallow (10-15 cc) to visualize the esophageal dimension and location. Furthermore, an esophageal temperature probe (Esotherm Plus, FIAB, Italy) with 3 thermocouples (T1, T2 and T3) was advanced in the esophagus at the level of target PV to monitor intraesophageal temperature throughout the ablation procedure. Transseptal access to the left atrium was achieved using standard technology [13].

In group 1, we utilized the Agilis™ steerable transeptal sheath (8.5F inner diameter, St. Jude Medical, St. Paul, USA) and in group 2, we utilized the Preface™ transeptal sheath (8.5F inner diameter, Biosense Webster, Diamond Bar, USA). Preceding left atrial access, a bolus of heparin (5000U) was intravenously administered. Following transseptal puncture, heparin boli were intravenously administered up to ACT levels >300 s. The trans septal sheath was continuously irrigated with heparinized saline (2 ml/min) by a Cool Flow Pump (Biosense Webster, Diamond Bar, USA). All patients underwent the procedure under uninterrupted warfarin therapy having aINR PT between 2 and 3.

The nMARQ™ ablation catheter was introduced into the left atrium through the deflectable sheath. In group 2, a ring-shaped multipolar diagnostic catheter (LASSO®, Biosense Webster, Diamond Bar, USA) was introduced through the transseptal sheath into the left atrium. The ablation catheter was advanced into the left atrium through the same trans-septal access after withdrawal of the long sheath holding a guidewire in left atrium.

In both groups, the left atrial anatomy was assessed using the CARTO3 Fast Anatomical Mapping. A pre-ablation computed tomography with segmentation of the left atrium and image integration with CARTO anatomy was used in 17 patients of group 1 (17%) and 2 patients of group 2 (1%).

The ablation catheters were positioned at the PV ostia and antrum in order to get PV electrical isolation. Intracardiac electrograms, ablation catheter impedance and temperature, and esophageal temperature were continuously monitored during ablation. In particular, in group 1, in order to reduce the risk of esophageal injury, we used bipolar energy (max 15W) or unipolar energy (max 18W) when electrodes were close to esophagus on the posterior atrial wall [9]. Furthermore, in all patients with persistent AF, we also performed ablation of atrial complex fractionated atrial electrograms (CFAEs) to restore sinus rhythm. In patients without sinus rhythm restoration during ablation, we performed external electrical cardioversion [14].

After ablation, effective PV isolation was confirmed by mapping with the nMARQ ablation catheter and the LASSO catheter. In all patients; early PV reconnection was tested 30 minutes after PV isolation also during isoproterenol infusion.

During our first experience with this catheter, the first 30 patients of group 1 performed brain magnetic resonance the day before and after procedure and endoscopic evaluation of esophagus the day after procedure.

Clinical follow up

In our center we usually perform a clinical follow-up after 3, 6, 12, 18, 24 months in all patients ablated for symptomatic AF. All patients performed an ambulatory clinical visit. Patients were asked in detail about clinical events occurring during the period of follow-up. Furthermore, patients evaluated in this study were followed up with trans-telephonic monitoring (TTM); in particular, the patients used TTM one time each month and when they had symptoms. TTM reported records with duration of 30 seconds. Furthermore, the patients had 24-hours ECG-Holter monitoring during ambulatory visits. The first 3 months after ablation were considered as blanking period and the AF episodes occurred were not considered as recurrences.

Statistical analysis

All variables showing a distribution not significantly different from normal according to Kolmogorov-Smirnov were compared by parametric tests, whereas variables showing a distribution significantly different from normal were compared by non-parametric tests.

Accordingly, between-group comparisons of continuous variables were compared by unpaired t-test or Mann-Whitney U test, as indicated, whereas within-group comparisons were done by Wilcoxon signed-rank test. Between-group and within-group proportions were compared using Fisher exact test and McNemar test, respectively.

Furthermore, event-free survival curves were constructed using the Kaplan-Meier method and curves were compared using log-rank tests. As an event, we considered separately AF and atypical flutter recurrences.

Data are reported as mean±standard deviation or proportions. A two-tailed p value <0.05 was considered as statistically significant. Data were analyzed using the SPSS 20.0 statistical software (SPSS Italia, Inc., Florence, Italy).

Results

General findings and procedural data

The main clinical characteristics of patients are reported in table 1. The patients were matched for age, sex, paroxysmal/persistent AF,

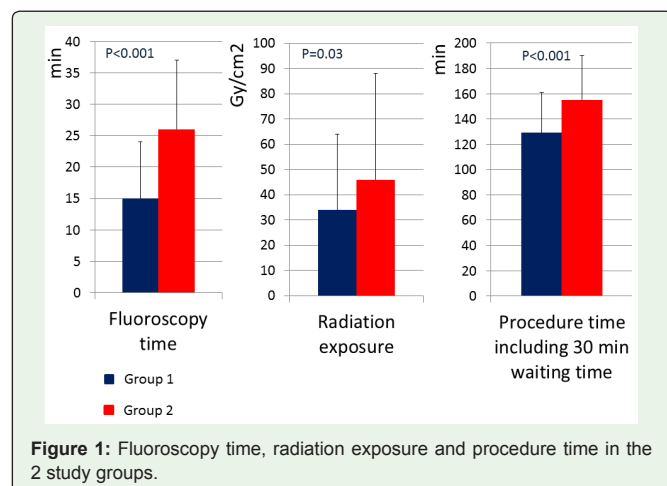


Figure 1: Fluoroscopy time, radiation exposure and procedure time in the 2 study groups.

HAS-BLED and CHA2DS2-VASc scores. In group 1, 75 patients (75%) had paroxysmal AF and 25 (25%) had persistent AF; in group 2, 78 patients (78%) had paroxysmal AF and 22 (22%) had persistent AF. No significant differences were found between the 2 groups with regards to the CHA2DS2-VASc and HAS-BLED scores.

No patient had evidence of left atrial thrombosis on the TEE and PV isolation was achieved in all patients. A common ostium of left PVs was found in 7 patients (7%) in group 1 and 9 patient (9%) in group 2. In patients with persistent atrial fibrillation, external electrical cardioversion was performed in 6 patients (24%) of group 1 and in 9 patients (40%) of group 2.

Compared to group 2, group 1 had a significantly lower procedural fluoroscopy time (15±9 vs. 26±11 min; p<0.001), radiation exposure (34±30vs. 46±42Gy/cm2; p=0.03) and procedure time (129±32vs. 155±35min; p<0.001 (Figure 1).

Procedural complications

A trivial pericardial effusion without tamponade appeared in 10 patients of group 1 (10%) and 6 patients of group 2 (6%); in all these patients the pericardial effusion was never recorded soon after the procedure but the day after. In all these patients the pericardial effusion resolved spontaneously without any drug administration. Two patients reported a groin haematoma not requiring any intervention. No other procedure-related complications occurred in any patient.

Clinical follow-up

All the patients performed 24 months of follow-up. AF recurrences were documented in 13 patients of group 1 (13%) and 32 patients of group 2 (32%) (p=0.003). Regarding the patients with paroxysmal AF, 8patients in group 1 (11%) and 20 patients in group 2 (26%) had AF recurrences at clinical FU (p=0.02).Inpatients with persistent AF, 8 patients in group 1 (33%) and 12 patients in group 2 (59%) had AF recurrences at clinical FU (p=0.06) (Figure 2).

Regarding atypical flutter, we documented 7recurrences (7%) in group 1 and 2 (2%) in group 2 (p=0.14). In group 1, atypical atrial flutter occurrence was documented in 2 patients with paroxysmal AF and 4 patients with persistent AF while, in group 2, it was documented in 3 patients with persistent AF.

Kaplan Meier curves regarding the event (both AF and atypical flutter recurrences) free survival of two study groups are reported in figure 3.

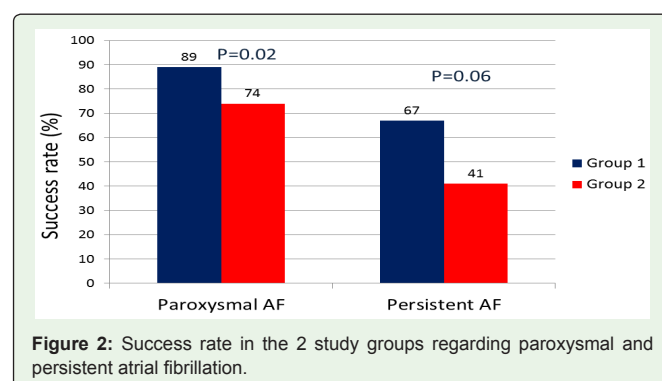


Figure 2: Success rate in the 2 study groups regarding paroxysmal and persistent atrial fibrillation.

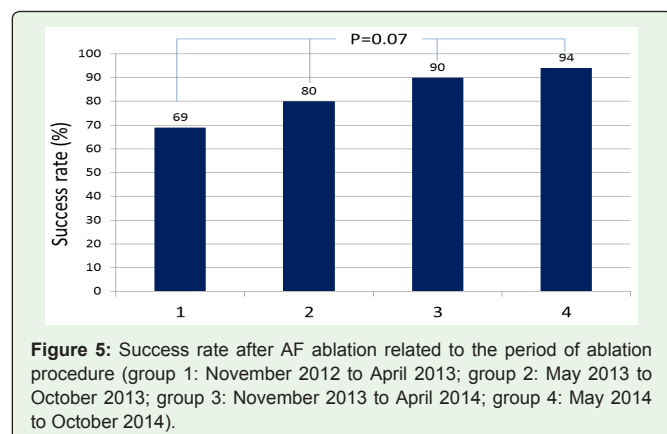
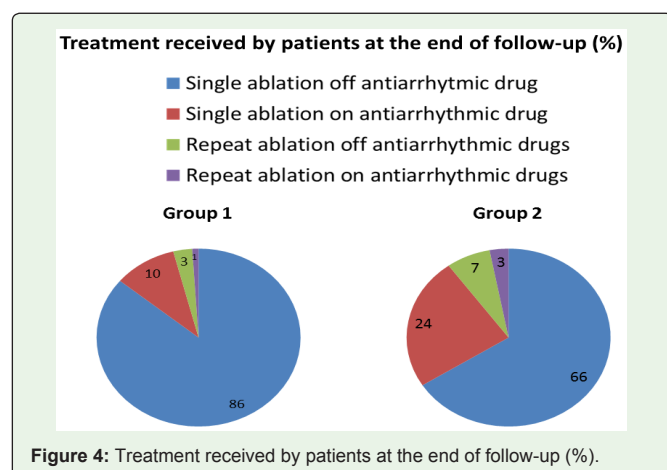
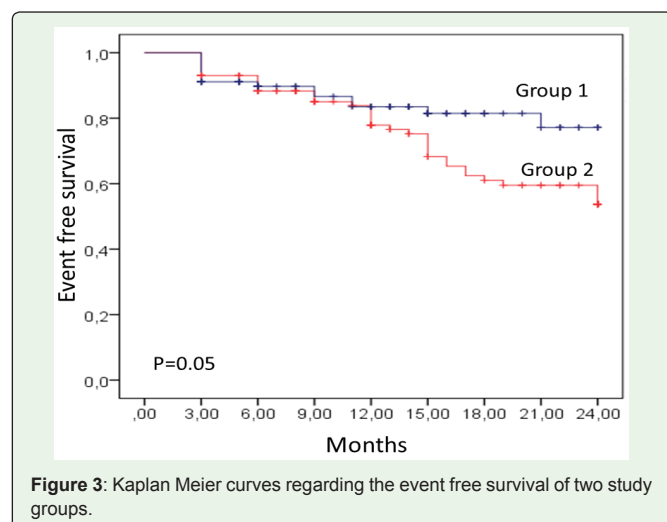
In patients with AF recurrences, 14 (31%) had repeated AF ablation (3 patients of group 1 and 11 patients of group 2), 11 (25%) underwent external direct current cardioversion (4 patients of group 1 and 7 patients of group 2) and the other patients were treated by optimizing antiarrhythmic therapy. At the end of follow-up all patients were in sinus rhythm (Figure 4). In patient undergoing repeat ablation procedure, 11 (78%) had reconnections located in

the ridge between the left PVs and left atrial appendage; the other 3 patients (22%) had reconnections in the right PVs.

Only one patient in group 2 had an asymptomatic cerebral lesion that disappeared at the control MRI performed 6 months after the ablation procedure. No further clinical adverse events were documented in other patients during clinical follow-up. No patients reported esophageal injury and no lesion was documented at esophagoscopy when performed.

Table 1: Clinical Characteristics of the 200 study patients.

	Group 1 (n=100)	Group 2 (n=100)	P
Male sex, n (%)	75(75)	71(71)	0.52
Mean age (years)	55±10	57±8	0.18
Paroxysmal atrial fibrillation, n (%)	75(75)	78(78)	0.72
Persistent atrial fibrillation n (%)	25(25)	22(22)	0.72
Left atrial antero-posterior diameter	40±4	39±4	0.75
CHA ₂ DS ₂ -VASc, n (%)			0.74
0	13(13)	13(13)	
1	21(21)	25(25)	
2	43(43)	45(45)	
3	23(23)	17(17)	
HAS-BLED, n (%)			0.57
0	47(47)	51(51)	
1	42(42)	42(42)	
2	11(11)	7(7)	
Diabetes mellitus, n (%)	26(26)	25(25)	0.47
Hypertension, n (%)	59(59)	64(64)	0.26
Family history of coronary artery disease, n (%)	3(3)	2(2)	0.14
Hypercholesterolemia, n (%)	14(14)	12(12)	0.39
Hypertriglyceridemia, n (%)	2(2)	4(4)	0.47
Active smoking, n (%)	5(5)	4(4)	0.23
Body mass index (Kg/m ²)	26±4	26±3	0.91
Heart failure (EF<35%), n (%)	-	-	-
Coronary artery disease, n (%)	1(1)	1(1)	1
Previous ischemic stroke, n (%)	-	-	-
Transient ischemic attack, n (%)	1(1)	1(1)	1
Chronic renal failure, n (%)	-	-	-
Left ventricular ejection fraction, (mean ± SD)	59±6	58±7	0.98
Medical therapy, n (%)			
Angiotensin converting enzyme inhibitors, n (%)	22(22)	27(27)	0.42
Angiotensin II receptor blockers, n (%)	20(20)	28(28)	0.19
Beta blockers, n (%)	47(47)	46(46)	0.78
Antiaggregants, n (%)	9(9)	8(8)	0.80
Diuretics, n (%)	16(16)	12(12)	0.42
Calcium blockers, n (%)	11(11)	6(6)	0.21
Statins, n (%)	14(14)	9(9)	0.26
Flecainide, n (%)	24(24)	19(19)	0.39
Propafenone, n (%)	4(4)	9(9)	0.18
Amiodarone, n (%)	12(12)	9(9)	0.65
Sotalolol, n (%)	5(5)	9(9)	0.43
Warfarin, n (%)	100(100)	100(100)	1
Oral antidiabetics, n (%)	2(2)	5(5)	0.47



Finally, in group 1, dividing the patients with paroxysmal atrial fibrillation in 4 subgroups related to the period of ablation procedure (group 1: November 2012 to April 2013; group 2: May 2013 to October 2013; group 3: November 2013 to April 2014; group 4: May 2014 to October 2014), the patients of group 4 and 3 had a higher success rate compared to group 2 and 1 (94%, 90%, 80%, 69%, respectively, $p=0.07$) (Figure 5).

Discussion

Atrial fibrillation is the most prevalent cardiac arrhythmia affecting 1% to 2% of the general population [1-3]. AF is known to increase the mortality risk 1.5 to 2-fold and the risk for stroke 5-fold. Current international guidelines recommend catheter ablation in patients with symptomatic AF after failure of antiarrhythmic drugs [2,3]. Current expert consensus acknowledges the importance of PV targets in the strategy of AF ablation and recommends that when PVs are targeted, complete electrical isolation should be achieved [2,3]. PV isolation with single tip catheters is reported to achieve durable sinus rhythm without the need for antiarrhythmic drugs in 59% to 93% of patients with paroxysmal AF and in 20% to 61% of patients with persistent AF [2,3]. Arrhythmia recurrences in paroxysmal AF are mostly due to resumption of conduction at the PV-left atrium junction. Recently, novel circular multi-electrode catheters has been designed to reduce the conduction gaps among lesions in order to reduce the reconnection between PVs and left atrium tissue [4-11]. In particular, the nMARQ[™] catheter is a novel multipolar ablation catheter using irrigated radiofrequency technology and integration into the CARTO3 system. Deneke Tet al [4], despite a high incidence of silent cerebral lesion (33%) and thermal esophageal lesions (33%), reported an effective PVI in 98% of targeted PVs in a mean procedure time of 133 minutes, without other clinical procedure-associated complications. Furthermore, Shin DI et al [5] published data regarding a small population (25 pts) with a short follow-up time (4.1 months), not reporting procedure-related complications with a 100% successful isolation of the veins and 81% of patients in sinus rhythm at the follow up. Thirty-nine consecutive patients suffering from drug-refractory paroxysmal AF referred for PVI were included in the prospective study of Zellerhoff et al [8] with single and multiple procedure success rates during a mean FU of 140 ± 75 days of 66% and 77%, respectively. Scaglione M et al [7] documented in 25 patients with paroxysmal AF ablated with nMARQ[™] catheter a success rate of 68% after 6-month follow-up without procedural complications.

Recently, Vurma et al [15] published data regarding 327 patients with paroxysmal and persistent AF ablated with NMARQ catheter showing that this tool is highly effective for treatment of this arrhythmia but with 0.6 % of life-threatening oesophageal fistulas. This data is in contrast with our previous data reporting no esophageal damage with NMARQ catheter using sulfate barium to localize the esophagus and delivering on posterior wall bipolar energy and unipolar energy with max 15-18 W [9].

In our study, we compared the nMARQ[™] catheter with standard single point approach for the ablation of AF reporting data regarding the success rate after a long term follow-up.

In particular, we reported in the group of patients ablated with nMARQ[™] catheter a lower procedure time, fluoroscopy time and radiation exposure compared to standard focal technology with Thermocool catheters. Previous studies, in fact, reported a significant correlation between the reduction of procedural time and the lower percentage of complications [16,17] and, moreover, the reduction of the fluoroscopy time and the radiation dose plays an important role lowering the risk of radiation-related diseases [17].

Moreover, our data confirm a good profile of efficacy for the new multipolar irrigated radiofrequency ablation catheter. The AF recurrences, in fact, were lower for the nMARQ[™] group (13%)

compared to single tip catheters (32%). In patients with paroxysmal AF, a statistically significant reduction of recurrences was found in the nMARQ[™] group compared to Thermocool one. Furthermore, in the subgroup of persistent AF, despite a low number of patients, we also reported a reduction in AF recurrences in the nMARQ[™] group compared to Thermocool one. Our procedure success rate was higher compared to other published studies; these data, probably, depend on operator experience with this new technology.

Of interest, the patients ablated in the first semester have a higher AF recurrence rate at long-term FU than those ablated in the last semester (from 31% to 6%), likely reflective of a significant learning curve effect.

Furthermore, in our study population, 31% of patients with AF recurrences had repeat ablation. In these patients the most frequent area of reconnection was the ridge between the left PVs, mainly the carina between the two veins, and the left atrial appendage. This anatomical location is a challenging point due to the confluence of 3 anatomic fibers (atrial myocardium, PVs and appendage) generating a high thickness. In this area the physician should utilize high unipolar RF energy to perform a deep lesion to reduce the risk of a future reconnection [18]. In our center, to get a transmural lesion in this challenging area, we usually deliver RF on the anterior portion of the LSPV and on the posterior portion of left atrial appendage (we named this approach “toast lesion”).

Finally, the complication rates in our study were low. One patient in Thermocool group had an asymptomatic cerebral lesion that disappeared 6 months after the ablation procedure. No other major clinical complications were documented in our study population. In particular, regarding the nMARQ[™] group, using bipolar energy or unipolar energy with max 18 W on the posterior wall, no patients had clinical symptoms of esophageal damage [9].

Conclusions

The use of thenMARQ[™] ablation catheter for PVI is feasible and safe, resulting in acute isolation of all targeted PVs. Compared to the standard single tip approach, we found a significant higher success rate in the nMARQ[™] group at long term FU.

Study limitations

The main study limitation is the lack of a randomized design and the few number of patients with persistent AF.

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