



Original Article

Initial experience and treatment of atrial fibrillation using a novel irrigated multielectrode catheter: Results from a prospective two-center study



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ABSTRACT

Background: PV electrical isolation has become the cornerstone of catheter ablation for the treatment of atrial fibrillation (AF). Several strategies have been proposed to achieve this goal. The aim of this study was to assess the efficacy and safety of AF ablation using a new circular irrigated multielectrode ablation catheter designed to achieve single-delivery pulmonary vein (PV) isolation.

Methods: Thirty-five patients with drug refractory paroxysmal AF and normal ejection fraction from two centers were prospectively enrolled in this study. All patients underwent PV isolation with an nMARQ circular irrigated multielectrode ablation catheter guided by an electroanatomic mapping system. Magnetic resonance imaging was performed to exclude PV stenosis.

Results: PV isolation was achieved in 138 of 140 (98.57%) targeted veins. The mean procedure time was 79.5 min (SD 39.3 min). During a mean follow up of 16.8 ± 2.8 months, 27 of 35 (77.2%) patients were free of AF. No PV narrowing was observed. One case of pericardial effusion due to perforation of the left atrial free wall during catheter manipulation did occur.

Conclusions: PV isolation with a circular irrigated multielectrode ablation catheter is a feasible technique with a high acute success rate. The majority of patients remained asymptomatic during the midterm follow-up period. PV stenosis was not detected. While only a single serious adverse event occurred, this technique's safety profile should be tested in larger studies.

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1. Introduction

Catheter ablation has become a first line approach for the treatment of patients with symptomatic atrial fibrillation (AF) resistant to antiarrhythmic medication and circumferential pulmonary vein (PV) isolation is currently considered to be the technique of choice. Catheter ablation using irrigated single-tip catheters and three-dimensional (3-D) mapping systems with point-by-point delivery of multiple applications has been reported to be an effective approach for the treatment of paroxysmal and

persistent AF and is the most frequently used ablation procedure worldwide [1,2]. In the last decade, innovative technologies have been developed using so-called “single-shot” devices involving either balloon technology or circumferential multipolar ablation catheters. These new anatomically designed ablation tools allow for the delivery of different energy forms with the aim of creating linear lesions around PV ostia with only a few applications in order to achieve safer and simpler isolations [3–5].

Recently, a novel ablation system using an irrigated decapolar radiofrequency (RF) energy circular catheter (nMARQ, Biosense Webster, Diamond Bar, CA, USA) has been developed as an effective tool for circumferential PV isolation. However, the efficacy and safety of this new catheter has not yet been fully elucidated. Therefore, the aim of this study was to investigate the efficacy and safety of this novel tool. The primary end point was set as the acute isolation rate of targeted PVs and complications related to the procedure itself, as well as symptomatic AF recurrence during the follow-up period, were analyzed.

Abbreviations: PV, pulmonary vein; LSPV, left superior; LIPV, left inferior; RSPV, right superior; RIPV, right inferior; AF, atrial fibrillation; RF, radiofrequency; LA, left atrium; ACT, active clotting time; AAD, anti-arrhythmic drugs

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2. Material and methods

2.1. Patients

Patients with highly symptomatic and drug refractory paroxysmal AF and normal ejection fractions from two different centers (designated A and B) were prospectively and consecutively enrolled in this study. All patients presented with a history of at least one prolonged episode (greater than 30 min) per month within the previous 6 months and had been treated unsuccessfully with at least one antiarrhythmic drug (AAD) (class I or III). In all patients, AF was recorded using a 12-lead electrocardiogram (ECG) within the 6 month period prior to ablation. Exclusion criteria for this study included structural heart disease, congestive heart failure, left ventricular ejection fraction < 55%, left atrial (LA) dimensions > 50 mm measured in the parasternal long axis, LA thrombus, known as bleeding diathesis or anticoagulant intolerance, pregnancy, and severe comorbidity. Written and informed consent was obtained from all patients. A computed tomography (CT) or magnetic resonance image (MRI) was acquired and used to guide manipulation of the catheter. In all patients, a 3-D reconstruction of the LA was generated prior to performing the ablation procedure in order to reveal the anatomy of the PV.

2.2. Ablation procedure

All patients were treated with oral anticoagulants at least 4 weeks prior to the ablation procedure. This treatment was subsequently withdrawn 3 days prior to ablation and replaced with subcutaneous heparin. Once the trans-septal puncture was performed, an unfractionated heparin bolus was administered. Intermittent bolus administration was initiated and doses were titrated to achieve an active clotting time (ACT) between 300 and 350 s. Measurements were routinely performed depending on the ACT. Following the procedure, low molecular weight heparin followed by oral anticoagulants were administered. LA thrombi had been previously excluded either by CT scan or transesophageal echocardiography.

The nMARQ catheter is an 8.4-F ablation and mapping decapolar irrigated RF system (Fig. 1). The catheter is composed of a circular array with an adjustable diameter between 20 and 35 mm

and 10 platinum-coated electrodes (3 mm) with 4 mm spacing. Each electrode is surrounded by 10 irrigation holes and can be recognized by the CARTO3 mapping system (Biosense Webster, Diamond Bar, USA), which allows for 3-D anatomic mapping of the LA. RF ablations are delivered in temperature-controlled mode for a maximum of 60 s. Energy delivery can be individually controlled for each combination of electrodes up to a maximum of 25 W in unipolar mode and 15 W in bipolar mode. Ablations are typically performed via all 10 electrodes and increase in temperature, drop in local impedance, and energy delivery are all continuously monitored using the novel nMARQ Multi-Channel RF System Ablation Generator (Biosense Webster, Diamond Bar, USA). With this generator, RF energy delivery for each electrode can be controlled separately. The system provides a visual display of electrodes in contact with tissue using so-called TissueConnect™ technology. Current and voltage from each electrode are constantly measured. When an electrode is in close contact with the endocardium, which has a 4-fold higher resistance when compared with blood, the spread of the current and voltage graph changes (phase change). Using a propriety algorithm, a contact threshold of 6 g was used to differentiate between contact and no-contact indications.

The ablation was generally conducted under conscious sedation except in cases where general anesthesia was required. Blood pressure and oxygenation were continuously monitored. Venous access was obtained via the femoral vein and a diagnostic catheter was positioned in the coronary sinus for stimulation of the LA. A trans-septal puncture was performed under fluoroscopic guidance by using a long 8-F guiding sheath (Biosense Webster Inc., California) and a Brockenbrough needle (BRK, St Jude Medical Inc.). A guidewire was introduced into the left superior PV via a fixed puncture sheath after retrieval of the needle. Under the protection of the guidewire, the sheath was introduced into the LA after which the nMARQ catheter was advanced. An electroanatomic map was obtained using the CARTO3 mapping system and fast anatomic mapping (FAM), defining the PV ostium and antral anatomy. The diameter of the circular array of the catheter was minimized and sequentially inserted into the veins in order to assess the PV electrogram. Once the catheter was inside the vein, the system was manipulated in order to enlarge the diameter of the antral region as defined by interpretation of a local electrogram and previously obtained electroanatomic mapping. Once

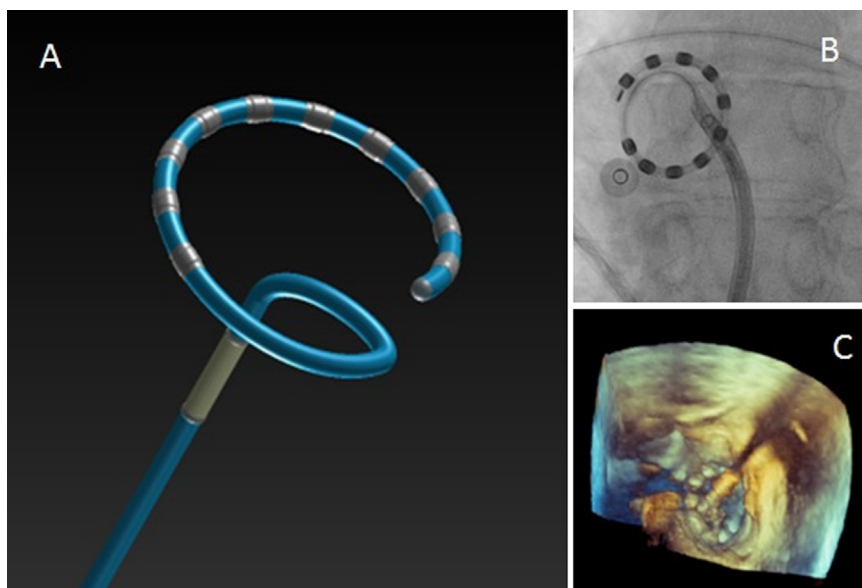


Fig. 1. (A) Ablation and mapping using the decapolar irrigated RF catheter (nMARQ™, Biosense Webster). (B) Fluoroscopy imaging of the catheter. (C) 3-D transesophageal echocardiogram showing the catheter during application.

satisfactory positioning of the nMARQ catheter in the PV antrum was achieved, ablation was performed and RF was simultaneously delivered from the 10 irrigated electrodes as previously described. Electrodes not in contact with the endocardium were deactivated beforehand. The electroanatomic map obtained with this system is presented in Fig. 2.

Catheter ablation was performed using the following settings: a catheter irrigation flow rate of 60 mL/min, a target temperature of 45 °C, and a maximal energy of 25 W (18 patients) or 20 W (17 patients) in unipolar mode, according to the manufacturer's recommendation. RF energy was applied at each ablation site for a maximum of 60 s. After each application, MARQ catheter was advanced into the PV and adjusted to the smallest diameter. PV isolation was assessed by registering any remaining electrical activity. If persistence of PV potentials was observed, the catheter was repositioned and a new application was performed using only those electrodes located in potential gaps and excluding those that did not display a signal. The nMARQ catheter permits the use of intracardiac electrograms during RF delivery and in certain cases, PV isolation can be assessed and monitored simultaneously (Fig. 3).

In all cases, phrenic nerve testing was performed during right superior (RS) and inferior (RI) PV ablation. At the moment of placement in the PV antrum, high-energy pacing (10 V, 2.0 ms) from all electrodes was performed, with the exception of phrenic nerve capture occurrence. PV isolation was validated using only the nMARQ Catheter by elimination of all PV potentials and

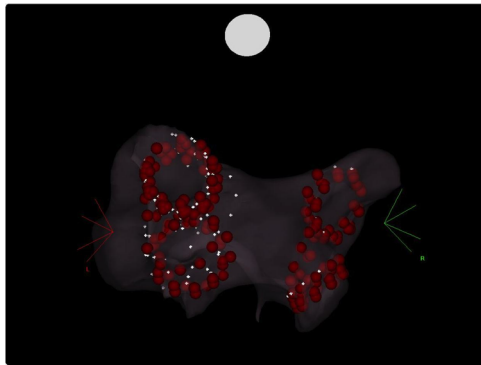


Fig. 2. Left atrial electroanatomic map obtained using the CARTO 3 mapping system using FAM and showing localization of ablation lesions.

demonstration of the exit block during pacing within the PV. PV isolation were reconfirmed either after a 20 min waiting period or by means of administration of an 18 mg adenosine bolus. If reconduction to the PV was confirmed, an additional application was performed until this was no longer the case.

2.3. Follow-up

Patient follow-ups were conducted in the outpatient clinic at least 3, 6 and 9 months post-procedure. Clinical evaluation and baseline ECGs were planned for all visits. Holter monitoring (for a minimum of 24 h) was planned for patients at the 6 and 9 month follow-ups. Patients with a clinical suspicion of relapse underwent additional Holter monitoring and an external event-recording system was used where necessary. All documented AF episodes of > 30 s were considered to be a recurrence. In the first 19 patients enrolled from center A, an MRI was performed 3 months after ablation in order to exclude PV stenosis. After the procedure, patients were continued on the anti-arrhythmic drug (AAD) they were taking in the 3 month period before the ablation was performed.

3. Results

3.1. Baseline characteristics

Thirty-five consecutive patients with highly symptomatic paroxysmal AF and without structural heart disease were enrolled in this study between May 2013 and February 2014. Twenty-seven patients were enrolled from center A and 8 patients were enrolled from center B. Baseline characteristics are presented in Table 1. Three patients had a history of unsuccessful AF ablation with the use of other techniques.

3.2. Ablation procedure

During 35 procedures, 140 veins were targeted, including 1 left common PV and a right middle vein. Complete PV isolation was achieved in 138 targeted cases (98.57%). During the course of the ablation procedure, dissociated PV potentials were observed in 35% of patients. After successful isolation, LA-to-PV conduction was restored in 15 of 140 (11%) veins. Further RF applications eliminated LA–PV conduction in all cases. Nevertheless, we were

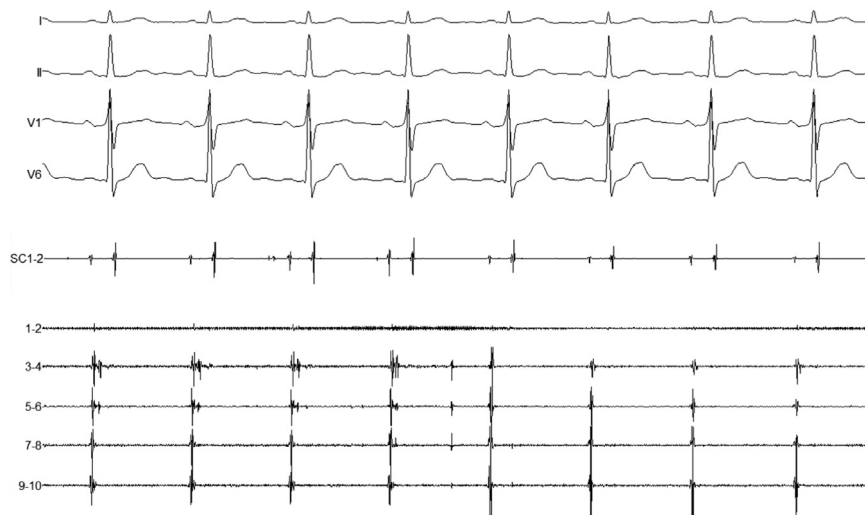


Fig. 3. Loss of PV potential (indicated by arrow) during RF application in the LIPV demonstrating isolation of the vein.

Table 1
Baseline patient characteristics.

Age, years	57.3 ± 8.6
Male:female	28:7
LVEF (%)	62.6 ± 5.8; rank 55–77
LA size (mm)	41.2 ± 3.1; rank 34–48
History of hypertension	9
Coronary artery disease	1
CHADS2 Score	0.4 SD 0.7
CHADS2 Score = > 2	3
<i>PV diameter obtained by CT scan (mm)</i>	
LSPV	19.7 ± 2.5
LSPV	18.4 ± 3.1
RSPV	18.4 ± 4.7
RIPV	18.2 ± 3.1
Left common PV	27.6
Right middle PV	17.4

LVEF, left ventricular ejection fraction; LA, left atrium; PV, pulmonary vein; LSPV, left superior; LIPV, left inferior; RSPV, right superior; RIPV, right inferior.

Table 2
Procedure times.

Total procedure time (min)	79.5 ± 39.3
Fluoroscopy time (min)	31.6 ± 8.2
Applications per patient (mean)	9.2 ± 1.8
Total radiofrequency time (min)	7.9 ± 1.9

after ablation (two applications of one min each were delivered without complications). The distal pole of the catheter was enclosed by the left atrial appendage (LAA) (Fig. 4) with subsequent cardiac tamponade requiring pericardicentesis and cardiac surgery. During surgery, a laceration of the LAA was found and repaired. The patient was discharged 5 days post-procedure without any significant complications. No PV stenosis was encountered in the 19 patients in whom an MRI was performed.

4. Discussion

The main finding of the present study was that complete PV isolation was obtained in 94% of patients with paroxysmal AF and in 98% of treated veins using a novel multielectrode 3-D mapping system and an irrigated RF catheter. This study further found that PV isolation using an nMARQ catheter results in freedom from symptomatic AF in the majority of patients at midterm follow-up. PV stenosis was not observed. This study further demonstrated a benign safety profile, although one major adverse event did occur.

PV isolation is currently the cornerstone for treatment of patients with paroxysmal AF [6]. An extended technique is circumferential PV isolation using point-by-point ablation around the PV ostium. However, that is a technically challenging and time-consuming procedure. In order to overcome the inherent limitations of conventional PV isolation ablation, new technologies have been developed with the main objective of simplifying and shortening the procedure itself.

4.1. Acute efficacy

In the present study, the procedural endpoint of PV isolation was achieved in 98% of targeted veins. The acute success rate was similar or even superior to that obtained using standard RF ablation with the point-by-point approach [7]. In addition, these results are similar to those obtained with so-called “one-shoot” technologies, such as non-irrigated PV ablation catheter (AC) and cryoablation, with acute PV isolation rates of up to 98–99% [8–10]. Shin et al. recently reported initial results for PV isolation using the nMARQ catheter in 25 consecutive patients. In that study, 100% of targeted PVs could be isolated exclusively with the use of this catheter [11]. Using the same catheter, Deneke et al. reported successful isolation in 160 of 163 (98%) targeted PVs [12]. Finally, in a recent report by Zellerhoff et al., 98% of PVs were acutely isolated using the nMARQ catheter in 39 consecutive patients with paroxysmal AF [13]. Hence, our acute success rate compares similarly with the results presented by other investigators using different techniques, including previous investigations of acute efficacy with the nMARQ catheter.

4.2. Procedure

In the present study, mean procedure time using the nMARQ catheter was 79.5 ± 39.3 min and mean fluoroscopy time was 31.6 ± 8.2 min. This is in accordance with previous reports on the nMARQ ablation system, where the mean procedure duration ranged from 86 ± 29 to 133 ± 41 min and fluoroscopy time ranged from 20 ± 6 to 23 ± 9 min [11–13].

unable to completely isolate the RIPV in one patient and the left inferior (LI) PV in a second patient. However, all targeted PVs were completely isolated in 33 of the 35 (94.2%) patients. The mean duration of the ablation procedure (from first insertion to withdrawal) was 79.5 min (SD: 39.3 min), fluoroscopy time averaged 31.6 min (SD: 8.2 min), and total ablation time was 7.9 min (SD: 1.9 min). Results are summarized and presented in Table 2. The median number of applications per vein was 2.3, left superior (LS) PV 2.39 (SD: 0.9), LIPV 2.2 (0.8), RSPV 2.57 (1.2), and RIPV 2.1 (1.06). The PV RF data is presented in Table 3.

3.3. Follow-up

All patients were followed-up with for a minimum period of 1 year and the mean follow-up period was 16.8 ± 2.8 months. Recurrence of AF was documented in 8 patients (22.8%), of whom 3 underwent a repeat procedure. Three of these 8 patients were asymptomatic and AF episodes were detected during Holter monitoring. The remaining 2 patients with recurrence rejected a new procedure as they had experienced a clear reduction of arrhythmia-related symptoms after ablation. One patient developed left atrial flutter on the fourth day post-procedure. Electric cardioversion was performed and no further recurrence was observed during the follow-up period. Recurrence of AF was verified using ECG tracings in all patients who reported arrhythmia-related symptoms.

Complete PV isolation was not achieved in 2 patients (LIPV in 1 patient and RIPV in the second). The first patient recovered well and was still asymptomatic at the time of final follow-up. The second patient suffered AF recurrence and underwent a second ablation. During the repeat procedure, RIPV isolation was performed using point-by-point ablation and reconnection of the LIPV was observed and closed by focal RF ablation that re-isolated the PV. Recovered conduction was detected in the RS and LIPVs, and the LS and LIPVs, respectively of 2 patients who had undergone an initially successful PV isolation procedure. A new ablation procedure using the point-by-point approach was successfully performed in these patients.

At the end of the follow-up period, 29 of 35 (82.8%) patients were no longer on antiarrhythmic medication.

3.4. Adverse events

Neither thromboembolic events nor phrenic nerve palsies occurred during the procedure or the follow-up period. A 76-year-old woman experienced cardiac tamponade during LSPV isolation

Table 3
Pulmonary vein radiofrequency data.

	Number of applications (mean \pm SD)	Total radiofrequency time in seconds (mean \pm SD)	Applications with all electrodes (%)	Applications with 8–4 pairs of electrodes (%)	Applications with less than 4 pairs of electrodes (%)
LSPV	2.39 \pm 0.9	132.5 \pm 52.6	83.3	16.7	0
LIPV	2.2 \pm 0.8	109.8 \pm 45.6	94.7	5.3	0
RSPV	2.57 \pm 1.2	128.4 \pm 55.9	86.4	9.1	4.5
RIPV	2.1 \pm 1.1	105.8 \pm 55.7	80.7	11.5	7.7

PV, pulmonary vein; LSPV, left superior; LIPV, left inferior; RSPV, right superior; RIPV, right inferior.

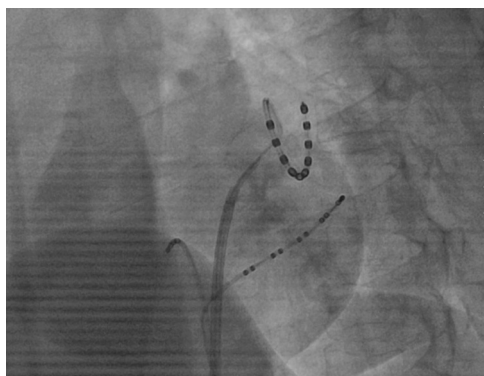


Fig. 4. Fluoroscopy imaging showing catheter position when cardiac tamponade occurs (LAO).

The nMARQ ablation system compares favorably to existing ablation systems, with significantly shorter procedure and fluoroscopy times. Using point-by-point conventional ablation, a wide range of procedural and fluoroscopy times have been reported, from Hocini et al.'s 156 \pm 85 min procedure time and 50 \pm 17 min fluoroscopy time, to the 256 \pm 72 min procedure time and 72 \pm 26 min fluoroscopy time reported by Karch et al. [14,15]. This wide variation may be attributable to the complexity of the technique, which requires considerable skill and training and is highly operator-dependent [16]. Procedure and fluoroscopy duration times using the cryoballoon are similar or slightly shorter than those recorded using RF ablation. Neumann et al. reported a median total procedure time of 170 min and a median fluoroscopy time of 40 min [17]. By contrast, in the recently published STOP AF trial, the mean procedure duration was 371 min while fluoroscopy exposure averaged 63 min, possibly due to the inclusion of patients dating from the outset of the operator's experience with cryoballoon technology [18]. PV isolation using PVAC technology in paroxysmal AF reports shorter procedure and fluoroscopy times. Wiczorek et al. reported mean procedure and fluoroscopy times of 125 \pm 28 min and 21 \pm 13 min, respectively [19], differing only slightly from the times reported by Boersma et al. [20].

4.3. Outcome data

Follow-up data showed freedom from AF in 77.2% of patients during the mean follow up period of 16.8 \pm 2.8 months. Similar results have been obtained by other investigators, with reports ranging from 56% to 92% of patients, depending on the ablation strategy used and the intensity of the follow-up. These results are very similar to those achieved with RF ablation using point-by-point PV isolation [21]. When compared with cryoballoon PV isolation, a recently published large representative cohort study of patients with paroxysmal AF showed a 61.6% freedom from AF recurrence at 1 year [22]. Using a duty-cycled multielectrode RF ablation catheter, Boersma et al. described an 83% freedom from AF without AAD during the follow-up period of 6 months [20]. Similar results were reported by Wiczorek et al. using the same

catheter and freedom from AF without AAD was observed in 79% of patients [19]. The results of the preset study are superior to those reported in a recent study using the nMARQ catheter, where 80.9% freedom from AF was reported after 3 months of follow-ups, even when similar acute PV isolation rates were taken into account [11]. This difference may be attributable to the fact that in the present study, ADD was administered to all patients during the first 3 months. Thus, this early experience suggests that PV isolation using the nMARQ catheter is effective for the maintenance of sinus rhythm during the first year post-procedure in patients with paroxysmal AF.

4.4. Complications

The only peri-procedural complication observed was a pericardial tamponade caused by LAA perforation during electrode manipulation. It must be taken into account that the nMARQ catheter is more challenging to maneuver when compared with other systems, as a result of the rigid catheter shaft and the lack of an "over-the-wire" system. Therefore, increased caution is required during manipulation in order to avoid LA damage. No other short-term complications were reported; including groin problems, stroke, gastrointestinal complaints, PV stenosis, or phrenic nerve damage.

Phrenic nerve injury is a serious complication of AF ablation. Indeed, it accounts for the most frequently observed complications using balloon ablation catheters, irrespective of the energy source [23]. This complication is usually related to its application in the RS or RI PVs, as the phrenic nerve may run behind the right atrium. Using cryoballoon ablation, the risk could be minimized by monitoring diaphragmatic contraction during right phrenic nerve pacing through the superior vena cava [24]. However, while persistent phrenic nerve palsies are rare with the use of a cryoballoon, incidence appears to be approximately twice that reported with conventional RF ablation [25]. In our experience of performing high-output pacing through the nMARQ poles to rule out phrenic nerve capture and previous to right PVs RF application, no phrenic nerve damage was observed.

PV stenosis is another well-recognized complication of AF ablation. In a recent literature review, significant PV stenosis was reported in 0.5% of patients [26]. When using cryoablation, the incidence of PV stenosis resulting in symptoms or requiring intervention is just 0.17% [10]. In this study, PV stenosis was not observed at the 3-month follow-up in any patients in whom an MRI was performed. This result is similar to that obtained in a previous study using the nMARQ catheter [11]. However, in that study, an MRI was performed 24–48 h after the procedure and development of late stenosis could therefore not be excluded.

4.5. Study limitations

This study had several limitations. The main limitation was the relatively small sample size. However, this represents our initial experience using the nMARQ catheter in two different hospitals, and the data collected on clinical outcomes are in accordance with

other small series studies conducted with this catheter, as well as studies utilizing other RF ablation techniques. The short follow-up in the present study was a further limitation as it is known that the efficacy of catheter ablation declines over time. Therefore, future studies with extended follow-up periods and larger sample sizes are required.

Evaluation of the safety profile of then MARQ catheter is further limited by the small sample size. Demonstration of the absence of PV stenosis during the follow-up period was limited to 19 of 35 patients and should therefore be assessed in greater detail, although these data are consistent with the results of previous small series studies conducted using the same device, which does suggest a low incidence of PV stenosis with this catheter.

As routine esophagoscopies were not performed, the possible development of thermal esophageal lesions as described in a previous study cannot be excluded from the present data set [12].

In the present study, no clinically significant neurologic symptoms were observed. However, there have recently been concerns regarding the incidence of silent cerebral lesions during the AF ablation procedure. Unfortunately, routine CT scans were not performed in accordance with the protocol used here. There is limited data available pertaining to the use of the new nMARQ ablation device. Recent reports have suggested a high rate of microembolization when using this new catheter [12,27,28], although earlier experience with focal Irrigated RF ablation demonstrated a lower incidence of microemboli when compared with multipolar non-irrigated catheter RF ablation [29]. Further investigations with the nMARQ system are needed regarding embolization rates and potential responsible mechanisms, in order to individualize and optimize ablation parameters and improve the safety of this technology.

Our study represents an initial, small and non-randomized experience with a midterm follow up period. The long-term efficacy of this system is currently being addressed by ongoing clinical trials (EVOLUTION and reMARQable) and the results are expected in time.

5. Conclusions

The results of this two-center prospective study suggest that electrical isolation of PVs using an irrigated multielectrode mapping and ablation system is an effective initial approach for patients presenting with paroxysmal AF, comparable to other available PV isolation technologies. With the use of this catheter, electrical isolation of the PVs can be obtained in the majority of patients. Sinus rhythm was maintained in the larger part over the mid-term follow-up period. This is a simple procedure, leading to fluoroscopy and procedural times that appear to be shorter than those associated with other AF ablation techniques. PV stenosis was not observed and the procedure appears to be safe, despite the occurrence of a single clinically relevant complication in one patient. Further studies should aim to evaluate the long-term efficacy and safety of this technique in order to clarify safety concerns regarding the incidence of esophageal damage and silent cerebral lesions.

Conflict of interest

All authors declare no conflict of interest related to this study.

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