One-Year Success Rate of Pulmonary Vein Isolation Using a Novel Irrigated Multipolar Mapping and Ablation Catheter With Reduced Power Settings

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Summary

The use of a novel irrigated multipolar ablation and mapping catheter for pulmonary vein isolation in patients with atrial fibrillation (AF) has demonstrated reasonable acute success rates and short procedure times, however, long-term outcome data are limited. The aim of this study was to analyze the long-term efficacy of this novel ablation system utilizing a reduced power setting for safety purposes.

A total of 89 patients with paroxysmal (63 of 89 patients; 71%) or persistent AF underwent PVI with a reduced power setting of maximum 20 Watts (W) unipolar radiofrequency energy and 30 seconds in duration. In cases of persistent AF, atrial substrate ablation was performed additionally. Follow-up was based on outpatient clinic visits at 3, 6, and 12 months and included 5-day Holter ECGs. All of the 347 identified pulmonary veins were successfully isolated. Mean procedure times in PVI and PVI plus substrate ablation were 102 ± 25 minutes and 126 ± 32 minutes, respectively, applying a mean total radiofrequency time of 14 ± 6 minutes and 19 ± 9 minutes. Mean fluoroscopy time was 17 ± 8 minutes and 18 ± 6 minutes, respectively. Follow-up was available for all 89 patients. At one-year follow-up, 44 (70%) patients with paroxysmal AF and 11 (42%) patients with persistent AF remained in stable sinus rhythm after a single-procedure and off antiarrhythmic drugs.

The use of a novel irrigated multipolar ablation catheter with a reduced power setting is safe and feasible, and demonstrates a one-year success rate of 70% in paroxysmal AF and 42% in persistent AF. (Int Heart J 2017; 58: 205-210)

Key words: Atrial fibrillation, Catheter ablation, Multielectrode ablation catheter, Clinical outcome

Pulmonary vein isolation (PVI) remains a cornerstone in catheter based therapy of drug refractory and symptomatic atrial fibrillation (AF).1 The standard approach consists of a point by point ablation using an irrigated single tip catheter guided by a 3-dimensional (3D) mapping system. An ablation strategy aims for a circumferential, contiguous lesion around ipsilateral pulmonary veins (PV) resulting in a bi-directional electrical block of PV proven by a circular mapping catheter inside the PV. Despite the introduction of several technological improvements, creation of durable and contiguous lesions remains a clinical challenge requiring advanced manual skills and profound experience. Several single shot devices have been established to aim at simplifying PVI by enabling faster and easier energy application either based on a cryogenic balloon or a multipolar ablation catheter concept lacking irrigation and 3D mapping ability.2,5 Recently, a novel irrigated decapolar mapping and ablation catheter (NMARQ) for PVI has been introduced, which takes advantage of a 3D mapping capability.6,8 Acute results and procedural properties showed favorable characteristics, but long-term data providing clinical results are still scarce.

Furthermore, concerns regarding the safety characteristics of this novel ablation tool have emerged, suggesting potentially higher rates of thermal esophageal lesions. Published data demonstrate a relationship between energy delivered into the tissue by means of altering maximum power and duration of ablation and the occurrence of esophageal injury.9,10 While reduced power settings are less likely to cause esophageal thermal damage and still provide reasonable acute efficacy in PVI, no data on long-term results regarding rhythm control are currently available.

Thus, the aim of this study was to investigate long-term efficacy of PVI using the NMARQ ablation system under a reduced power setting.
**METHODS**

**Patients:** Consecutive 89 consecutive patients were treated for symptomatic and drug refractory AF by catheter ablation. Sixty-three (71%) patients showed paroxysmal AF and 26 (29%) patients were diagnosed with persistent or long persistent AF with a mean duration of 35 ± 18 months. Mean age was 59 ± 9 years. Patient characteristics are presented in Table I. Informed consent was obtained from all patients, and the study protocol was approved by the institutional review board of the University Hospital Duesseldorf. Study and data management were solely investigator driven.

**Multipolar mapping and ablation:** A novel open irrigated, decapolar mapping and ablation catheter (NMARQ, Biosense Webster Inc., Diamond Bar, CA, USA) utilizing a 3D mapping system was used for PVI as previously described. In brief, the catheter consists of 10 nitinol, 4 mm electrodes arranged on an adjustable circular array permitting irrigation (Figure 1). It can be deflected unidirectionally and all 10 electrodes are recognized by the CARTO system (Biosense Webster Inc.), which allows a 3D anatomic mapping of the left atrium (LA). Radiofrequency (RF) energy can be applied by a multichannel generator to all electrodes individually in a selectable unipolar or bipolar fashion. Energy levels can be varied from 1 to a maximum of 25 W in unipolar and to 15 W in bipolar mode with temperature limited to 45°C. Maximum duration of energy delivery is 60 seconds and can be stopped for each electrode separately at any time. During ablation a continuous irrigation with saline fluid is provided by a cooling pump (Cool Flow, Biosense Webster Inc.) with 60 mL/minute overall flushing rate.

**Ablation procedure:** All patients underwent ablation procedures during continuous oral anticoagulation by phenprocoumon and a target INR of 2 to 3. In the case of direct oral anticoagulation drugs (DOAC), the last dosage before the scheduled ablation day was withheld and restarted 3 hours after the ablation procedure. The ablation procedure was performed under deep sedation using midazolam, propofol, and piritramid using non-invasive monitoring of blood pressure and oxygen saturation. After placing a 4 pole diagnostic catheter into the right ventricular apex (Supreme CRD, St. Jude Medical/SJM, Minnetonka, MN, USA) and a 8 pole diagnostic catheter into the coronary sinus (Inquiry, St. Jude Medical), single transseptal puncture was performed using a long fixed sheath (Lamp45 8.5F, St. Jude Medical) and a Brockenborough needle (St. Jude Medical) under pressure and fluoroscopic control. A left atrial angiogram was performed under rapid RVA pacing (cycle length 300 ms) administering 20 mL of contrast in an anterior–posterior (AP) and left anterior oblique (LAO) view. Fluoroscopic data were transferred to the 3D mapping system (CARTO3, Biosense Webster Inc.) using image integration software (Univu, Biosense Webster Inc.). After exchanging the fixed long sheath by a steerable long sheath (8.5F Agilis NxT small curl, St. Jude Medical, Minnetonka, MN, USA / 8.5F Direx, Bard, Lowell, MA, USA) over a wire, the decapolar mapping and ablation catheter (NMARQ, Biosense Webster, Inc.) was advanced into the LA. After administration of heparin intravenously (80 IE per kilogram of weight) activated clotting time (ACT) was measured every 15 minutes targeting an ACT of > 300 seconds. Anatomical mapping of the LA and PVs was performed using the fast anatomical mapping function (FAM) of the CARTO system. Target zones for ablation around all PV ostia were determined under fluoroscopic control, guidance by the FAM, and interpretation of intra-cardiac mapping signals of the NMARQ catheter and visually marked by the snap shot function of the CARTO system. The catheter position was displayed in the electroanatomical

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>59 ± 9</td>
</tr>
<tr>
<td>Sex: male/female</td>
<td>59 (66%) / 30 (34%)</td>
</tr>
<tr>
<td>History of AF (months)</td>
<td>35 ± 22</td>
</tr>
<tr>
<td>Paroxysmal AF</td>
<td>63 (71%)</td>
</tr>
<tr>
<td>Persistent AF</td>
<td>26 (29%)</td>
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<tr>
<td>Prior antiarrhythmic drugs</td>
<td>1.6 (range 1 – 4)</td>
</tr>
<tr>
<td>EHRA I/II/III/IV</td>
<td>0/0/75/14</td>
</tr>
<tr>
<td>Left atrial size (mm)</td>
<td>42 ± 3</td>
</tr>
<tr>
<td>Hypertension</td>
<td>36 (44%)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>12 (13)</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>56 ± 3</td>
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Data are presented as the mean ± SD and as n (%). AF indicates atrial fibrillation; EHRA, European Heart Rhythm Association; and LVEF, left ventricular ejection fraction.

![Figure 1. NMARQ compared to circular mapping catheter. A: NMARQ catheter in comparison to a Lasso catheter (Biosense Webster Inc.) showing difference of electrode size and similar diameter at maximum expansion. B: NMARQ catheter in comparison to a Lasso catheter (Biosense Webster Inc.) showing difference of electrode spacing and minimum diameter at maximum contraction.](image-url)
map of the LA throughout the procedure and confirmed by intermittent fluoroscopy, ensuring optimal catheter placement and tissue contact prior to each energy application. Further information on wall contact was gained from an impedance based technology displaying all NMARQ electrodes with tissue contact in a color-coded manner (Tissue Connect, Biosense Webster). After high output pacing (10 V/2 ms) subsequently on all adjacent electrodes ensuring absence of phrenic nerve capture, 20 W of RF energy was applied simultaneously to all activated electrodes in a unipolar fashion with a maximum RF duration of 30 seconds (Figure 2). No power reduction algorithm (PRA) was used. The NMARQ catheter was then repositioned according to the 3D mapping and further RF energy was applied until PVI was achieved. Afterwards, NMARQ was placed into those PVs showing entrance block, additionally proving exit block by pacing from inside the PV (5 V/1 ms) without evoking atrial capture. This workflow was performed for all observed PVs. In the case of a common ostium, PVI was achieved by placing a contiguous lesion in the antral region of the ipsilateral PV. PVI was confirmed by repeating stimulation maneuvers after 20 minutes of waiting; no administration of adenosine or isoproterenol was used. In patients with persistent or long persistent AF, LA substrate ablation was pursued by mapping and ablation of complex fractionated atrial electrograms (CFAE), following the definition of Nademanee, et al employing the NMARQ catheter with unchanged energy settings. In the case of AF termination to sinus rhythm (SR), the ablation procedure was finished after proof of PVI. In cases of AF termination to atrial tachycardia (AT), activation mapping and ablation were performed by the NMARQ catheter followed by electrical cardioversion into SR if AT could not be terminated by ablation. If no AF termination could be achieved after PVI and complete CFAE ablation, patients were cardioverted electrically to SR. No lines were performed, and no touch up single tip ablation catheters were used. After PVI no voltage map was achieved. Furthermore, no

Figure 2. NMARQ ablation. NMARQ catheter (black arrow) position during RF-energy application (white arrow) at the right inferior pulmonary vein (RIPV) in a posterior-anterior (A) and right lateral (B) view. The NMARQ catheter overlaps the snap shot mark taken during fast anatomical mapping (black arrow). Final result after isolation of all pulmonary veins showing RF-energy application (red dots) in a posterior-anterior view (C).
luminal esophageal temperature (LET) monitoring was used.

Post-procedural management and follow-up: Patients were monitored in a setting of an intermediate care unit overnight. Cardiac magnetic resonance imaging (MRI) was performed in all patients within 24 hours and 3 months after the ablation procedure, and endoscopic examination of the esophagus was performed in discretion of the observer, depending of the amount of energy which had been delivered to the posterior wall of the LA. Post-procedural OAC was continued for at least 3 months and stopped when the CHADS2-VASc score was < 1. Class I antiarrhythmic drugs were allowed during the blanking period of 3 months and omitted subsequently. In cases given amiodarone, medication treatment was stopped immediately after catheter ablation. Proton pump inhibitors (PPI) were routinely administered for 4 weeks. All patients were seen for follow-up (FU) at 3, 6, and 12 months post ablation. Five-day Holter monitoring was performed at 6 and 12 months of FU. Clinical success was defined as freedom from AF symptoms, absence of any AT in Holter monitoring with duration of > 30 seconds, and being off antiarrhythmic drugs (class I and III) after a single procedure.

Statistical analysis: Continuous data are shown as the mean and standard deviation (SD). For global test statistics we used a significance level of 5%. All authors had full access to the data and read and agreed to the manuscript as written.

# RESULTS

Procedural results: All of the 347 targeted PV could be isolated with a mean of 7 ± 3 RF applications per vein and total burning time of 14 ± 6 minutes per patient (Table II). The amount of RF applications was largest for the isolation of LSPV and smallest in RIPV. Although anatomical differences in consideration of these different values have not been analyzed, we suggest a relationship of muscular thickness of the ridge between left sided PV and the left atrial appendage which is absent on the right sided PV. Early reconnection after 20 minutes of waiting could be observed in 15 of 347 (4%) PV. In cases of CFAE ablation, a mean of 5 ± 4 sites at the inferior, septal, roof, or posterior LA regions were targeted with a mean of 12 ± 7 RF applications and an additional total burning time of 5 ± 3 minutes. Total procedure and fluoroscopic time in patients with paroxysmal AF was 102 ± 15 minutes and 17 ± 8 minutes, respectively. In patients with persistent AF, the total procedure and fluoroscopic times were 126 ± 32 minutes and 18 ± 6 minutes, respectively (Table III). AF termination during ablation of persistent and long persistent AF (mean AF duration 12 months ± 8) was observed in 15 of 26 (58%) cases. Among these 15 patients, AF terminated directly to SR or into an AT in 4 (27%) and 11 (73%) patients, respectively. Four of 11 (36%) patients with resulting in an AT could be converted into SR after activation mapping and ablation, while 7 (64%) had to be converted electrically. No procedure related complications occurred.

Clinical results: FU data were collected at a 12-month time point after a single procedure and off antiarrhythmic drugs. Forty-four of 63 (70%) patients with paroxysmal AF and 11 of 26 (42%) patients with persistent AF showed no recurrence of AF. Patients, in which persistent AF terminated during the ablation procedure into SR, were free of recurrence in 6 of 8 cases, while the success rate was 5 of 18 (28%) when AT or AF had to be converted electrically during the procedure. Utilizing cardiac MRI, no acute or late occurrence of PV stenosis (> 50% reduction of PV diameter) or PV narrowing (< 50% reduction of PV diameter) could be detected. Endoscopic examination of the esophagus was performed in 23 of 89 (26%) patients showing 1 (4%) thermal induced lesion of the esophageal mucosa. After treatment with PPI and control endoscopy after 10 days, the detected lesion had healed completely without further clinical implications.

## DISCUSSION

Long-term efficacy: We present one-year follow-up data for PVI after using the NMARQ ablation system in patients with paroxysmal and persistent AF, and observed success rates of 70% and 42%, respectively, after a single procedure. These results are in concordance with published data from other groups using the same multipolar ablation catheter. Mahida, et al demonstrated a one-year success rate of 65% in patients with both paroxysmal and persistent AF with a total number of 85 patients from a multicenter registry. Furthermore Stabile, et al published data of an Italian multicenter registry with success rates in paroxysmal and persistent AF of 73% and 70%, respectively, after a mean FU time of 13.9 months in a total of 180 patients. In contrast to both studies, we introduced a reduced power setting with a maximum of 20 W and 30 seconds, while in both studies standard energy was applied with a maximum of 25 W and duration of 60 seconds. However, the mean total burning time of 14 ± 6 minutes for PVI appears to be comparable to the Italian multicenter registry that demonstrated a mean total burning time of 13 ± 5 minutes. Therefore, comparable long-term efficacy can be assumed for reduced and standard power settings using the NMARQ ablation system.

Our data also suggest a similar long-term efficacy compared to other ablation strategies for AF. One year success rates of 72 to 88% in point by point ablation of paroxysmal AF us-

<table>
<thead>
<tr>
<th>Table II. Acute Ablation Results</th>
<th>RSPV</th>
<th>RIPV</th>
<th>LSPV</th>
<th>LIPV</th>
<th>LCPV</th>
</tr>
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<tbody>
<tr>
<td>No. of PVs, n</td>
<td>89</td>
<td>89</td>
<td>80</td>
<td>80</td>
<td>9</td>
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<tr>
<td>Isolated PVs</td>
<td>89/89</td>
<td>89/89</td>
<td>80/80</td>
<td>80/80</td>
<td>9/9</td>
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<tr>
<td>No. of RF-applications</td>
<td>5 ± 3</td>
<td>6 ± 3</td>
<td>9 ± 6</td>
<td>7 ± 4</td>
<td>12 ± 8</td>
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Data are presented as the mean ± SD. RSPV indicates right superior pulmonary vein; RIPV, right inferior pulmonary vein; LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein; and LCPV, left common pulmonary vein.

<table>
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<tr>
<th>Table III. Procedural Data</th>
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<tr>
<td>Procedure time (minutes)</td>
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<tr>
<td>Fluoroscopy time (minutes)</td>
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<tr>
<td>Total burning time (minutes)</td>
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<tr>
<td>Complications</td>
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Data are presented as the mean ± SD. PVI indicates pulmonary vein isolation; and CFAE, complex fractionated atrial electrogram.
ing force measurement have been published, while cryothermal ablation utilizing a second generation balloon based ablation catheter showed recurrence free survival of 80 to 82% after one year. Multipolar ablation using a pulmonary vein ablation catheter (PVAC) achieved lower success rates (54 to 60%) after one year FU. 

Safety: In our study no procedure related complications occurred. Furthermore, no acute or late PV stenosis could be detected by cardiac MRI after ablation procedure despite an ostial ablation approach. PV stenosis a range of 1 to 3% has been described for all ablation techniques including single tip and balloon based catheter technology. Compared to the PVAC as a multipolar, circular, non-irrigated ablation catheter and ostial ablation approach, published PV stenosis rates are higher for PVAC with observed PV narrowing between 50 to 70% and > 70% in 9% and 3%, respectively. This could be explained by better avoidance of energy application inside the PV due to usage of a 3D mapping system allowing a clear distinction of the PV lumen, ostium, and antrum during ablation.

No atria-esophageal fistula occurred. In one of 23 examined patients, an esophageal lesion after extensive CFAE ablation at the posterior wall of the LA could be detected by endoscopy one day after ablation procedure, which resolved completely under PPI medication within 10 days. We must state that no LET was used during ablation due to published data suggesting a possible contribution of LET to esophageal damage by passive heating during RF energy application. Emphasizing our reduced power settings with a maximum of 20 W and 30 seconds of duration, our data are in accordance with recently published data by Rillig, et al, who observed that esophageal lesions are dependent on the level of applied power. Using 20 W (unipolar mode) for 60 seconds compared to 15 W and 30 seconds in a small group of patients (6 versus 15), a comparison of both groups showed a thermal esophageal lesion in 50% and 6.7%, respectively. In this context no clinical data referring to long-term success rates are given. Recently, Deneke, et al reported a reduction of thermal esophageal lesions from 45% using standard energy settings in combination with LET down to 0% with reduced power of 20 W for 60 seconds and LET avoidance. Overall, a 12-month success rate of 66% in a total of 145 patients was observed, changing the course by using different energy settings for the LA posterior wall. Due to incomplete patient FU treated with standard or reduced energy settings, one-year success rates could not be evaluated finally with regard to different energy settings. Our data suggest that clinical results were favorable combined with a low rate of esophageal damage using a maximum power of 20 W for 30 seconds.

No transient ischemic attacks (TIA) or stroke could be detected after catheter ablation. No data can be given related to asymptomatic cerebral embolization (ACE) because no cerebral MRI was performed.

Procedural characteristics: PVI in paroxysmal AF could be achieved with a total procedure time of 102 ± 15 minutes, demonstrating shorter procedure times compared to point-by-point ablation strategies. Furthermore, fluoroscopic times (17 ± 8 minutes) were shorter compared to cryothermal ablation and similar to procedural characteristics of single tip ablation. Combining short procedure and fluoroscopic times, the NMARQ ablation system provides an improvement of existing ablation techniques.

In cases of persistent AF, PVI plus LA substrate ablation could be performed with a total procedure and fluoroscopic time of 126 ± 32 minutes and 18 ± 6 minutes utilizing multipolar mapping and ablation. Therefore, procedure times in patients with persistent AF were shorter compared to published data using a single tip approach. However, the termination rate of AF to an AT or SR was 58%, and therefore, lower in comparison to single tip technology enabling AF termination in 84 to 87%.

Furthermore, in cases of AT, multipolar mapping and ablation of the LA showed disadvantages in achieving an accurate local activation mapping (LAT) due to a lack of homogeneous tissue contact of all 10 mapping electrodes. Also, the creation of linear lesions, especially aiming for a mitral isthmus line in cases of perimtrial macro-reentry-tachycardia, was limited due to suboptimal adjustment of the circular catheter design to anatomical needs or a lack of epicardial ablation opportunities in the coronary sinus. In conclusion, these aspects might explain the low rate of AT termination (36%) compared to the single tip approach.

Study limitations: Our study does not provide a direct comparison between reduced and standard power settings as all ablations were performed with a maximum power of 20 W for 30 seconds. Therefore, suggestions regarding the comparability of standard power settings have to be taken with caution. No continuous AF monitoring by using an implantable event recording device was performed, thus, the rate of AF recurrence might be underestimated. Furthermore, safety issues addressing the occurrence of ACE or asymptomatic esophageal lesions cannot be analyzed comprehensively as no cerebral MRI scans were performed and endoscopic validation of possible esophageal lesions was conducted in only 23 of 89 (26%) cases. Finally, no adenosine was given to uncover dormant conduction sites after the waiting time of 20 minutes, and thus, a possible improvement of demonstrated success rates remains unclear.

Conclusions: Employing a novel irrigated multipolar ablation catheter with reduced power settings, we obtained one-year success rates in patients with paroxysmal and persistent AF of 70% and 42%, respectively. In cases of persistent AF termination, the rate during ablation was 58%, which could be achieved in a brief additional mapping and ablation time. Termination of AT by using the NMARQ system was rare due to limited mapping and ablation abilities.

Disclosure

No conflicts of interest to declare.

References


